

LIST OF ABBREVIATIONS AND ACRONYMS

ARV	Antiretroviral
AZT	Azidothymidine
COMESA	Common Market for East and Southern Africa
EC	European Communities
EU	European Union
ECOWAS	Economic Community of West African States
GATT	General Agreement on Tariffs and Trade
DDI	Didanosine
IPAB	Intellectual Property Appeal Board (Thailand)
IP	Intellectual Property
IPRs	Intellectual Property Rights
IPO	Intellectual Property Office (Thailand)
NGO	Non-Governmental Organisation
SADC	Southern African Development Community
HIV/AIDS	Human Immuno virus/Acquired Immunodeficiency Syndrome
SARPAM	Southern African Programme for Access to Medicines and Diagnostics
TRIPS	Trade-related Aspects of Intellectual Property Rights
U.N	United Nations
US	United States of America
WTO	World Trade Organisation

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CHAPTER ONE

INTRODUCTION

1. Background to the Study

In March 2004, the World Health Organisation¹ estimated that one third of the world's population lacked access to essential drugs.² Further, the WHO estimated that over 50% of the people in Africa and Asia had no access to very basic and essential drugs.³ On a closely related note, five years later, when a comparison was made between access to essential drugs in the public and private sectors, the results painted a further negative picture.⁴ In 2011, UNCTAD reported that nearly two billion of the world's population, many of whom live in Least Developed Countries (LDCs), lacked access to essential medicines.⁵ By 2013, the situation in respect of access to medicines had improved marginally and the total number of people without access to medicines was estimated to be between 1.3 and 2.1 billion people.⁶ Access to essential medicines is important for developing countries particularly those in sub-Saharan Africa as they are vulnerable to deaths caused by preventable diseases.⁷

¹ The World Health Organisation (hereafter WHO), an arm of the United Nations, was established on 7 April 1948; a day that has now come to be celebrated across the globe as World Health Day. The WHO constitution came into force on this date, thus giving the global health organisation its legal existence. Broadly speaking, the mandate of the WHO straddles *inter alia*, providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends (see WHO website at <http://www.who.int/about/en/>, last visited 04/04/2009).

² See WHO, 'Equitable Access to Essential Medicines: a Framework for Collective Action' in *WHO Policy Perspectives on Medicines* (2004) 1 available at http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf (last visited 01/11/2013). The actual number was estimated to be between 1.2 and 1.3 billion. At the time of writing, these were the most recent statistics on the subject.

³ Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness (WHO above at 1).

⁴ According the United Nations report dated 4 September 2008, titled 'Delivering on the Global Partnerships for Achieving the Millennium Development Goals', available <http://who.int/medicines/mdg/en/> (04/03/2009), in the public sector, generic medicines are only available in 34.9% of facilities, and on average cost 250% more than the international reference price. In the private sector, those same medicines are available in 63.2% of facilities, but cost on average about 650% more than the international reference price.

⁵ UNCTAD *Investment in Pharmaceutical Production in Least Developed Countries: A Guide for Policy Makers and Investment Promotion Agencies* (2011).

⁶ WHO "Essential Medicines and Health Products Information Portal: A World Health Organization Resource" at <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html> (last visited 13/12/2013).

⁷ Examples that easily come to mind are malaria, cholera, Ebola and avian flu among other diseases that are easily curable in an environment where drugs are accessible and available. One other nagging health problem is the issue of HIV/AIDS and access to antiretroviral and other immunity -boosting treatment. With specific reference to access to medicines in the context of HI/AIDS, see generally Mushayavanhu D, 'The realisation of access to HIV and AIDS – related medicines in Southern African countries: Possibilities and actual realisation of international law

Access to essential medicines and vaccines depends on specific factors such as rational selection and use, sustainable financing, reliable supply systems and affordable prices.⁸ In the context of this study, access to medicines also depends on the availability and efficacy of legal instruments at the municipal,⁹ regional¹⁰ and international levels.¹¹

Access to medicines, a concept with no clear definition, is generally considered as a collection of different dimensions¹² such as accessibility,¹³ affordability,¹⁴ acceptability,¹⁵ and availability.¹⁶ 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.¹⁷ This is not good news for access to medicines, since drug prices in the absence of price regulations create ‘affordability barriers’.¹⁸

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 the developing countries.¹⁹ For

obligations’ in Viljoen F and Precious S (eds) *Human Rights Under Threat: Four Perspectives on HIV, AIDS and the law in Southern Africa* (2007) 127 -169. In this study, essential drugs and essential medicines are used interchangeably and should be regarded as carrying the same meaning.

⁸ WHO above at 2 – 5.

⁹ In the context of South Africa, legislation such as the Patents Act 57 of 1978 as amended and the Medicines and Related Substances Control Act 101 of 1965 easily come to mind. In Zimbabwe, the relevant municipal instruments would be the Patent Act (Chapter 26:03) of 1972 and the Declaration Period of Emergency (HIV/AIDS) Notice, 2002.

¹⁰ 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.

¹¹ Examples are the Paris Convention, the Patent Cooperation Treaty and the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS).

¹² Tetteh EK “Providing Affordable Essential medicines to African Households: The Missing Policies and Institutions for Price Containment” (2008) 66 Social Science and Medicine at 570.

¹³ Referring to health services coverage.

¹⁴ This relates to prices and volumes of consumption.

¹⁵ This refers to quality, safety and efficacy.

¹⁶ This refers to drug production, procurement and distribution.

¹⁷ Tetteh above at 570.

¹⁸ Ibid.

¹⁹ 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 and Another* 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

example, to safeguard Zimbabweans' right to health, the Patents Act²⁰ was amended²¹ in order to "enable the state or a person authorised by the Minister in terms of section 34 of the Act" to make or use any patented drug used in the treatment of persons suffering from HIV/AIDS-related conditions or import any generic drug to treat HIV/AIDS.²² While the right to health has traditionally been regarded as a civil and political right,²³ it has, nevertheless, been increasingly applied broadly and has been extended in some instances to cases involving access to medicines.²⁴ The right to health is one among a range of socio economic rights for which states accept an obligation at international law.²⁵

The right to life is part of the International Covenant on Civil and Political Rights²⁶ while the right to health is part of the International Covenant on Economic, Social and Cultural Rights.²⁷ It may be argued that the separation of the two is artificial and misleading because the right to life not only depends on the realisation of the right to health but also on other composite rights such as the right to food and nutrition.

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 O 'Environmental Governance and Accountability of Non-state Actors in Africa: A rights –based Approach' (2007) 32 *South African Yearbook of International Law* 261 at 279. For a general overview of the right to health and in its democratic context, see Hassim A, Heywood M, and Berger J (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 G (ed) *A Compilation of Essential Documents on the Right to Health* (2000).

²⁰ Chapter 26:03 of 1972.

²¹ This was done by the then Justice Minister, the Honourable Patrick Chinamasa, in terms of sections 34 and 35 of the Patent Act and thus General Notice 240 of 2002 was introduced as an emergency measure for six months.

²² See paras 2 (a) – (b) of the Declaration of Period of Emergency (HIV/AIDS) Notice, 2002.

²³ 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.

²⁴ Mushayavanhu above at 135. For example, in the case of *Odir Miranda v El Salvador* cited by the author 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.

²⁵ See in this regard Evans T, 'A Human Right to Health?' (2002) 23 *Third World Quarterly* 197.

²⁶ Per article 6 of the International Covenant on Civil and Political Rights.

²⁷ Per article 12 of the International Covenant on Economic, Social and Cultural Rights.

Although the Southern African Development Community (SADC)²⁸ Protocol on Health²⁹ does not expressly refer to the right to health, the importance of access to essential medicines for the SADC region is highlighted.³⁰

The constitutive Act of the African Union³¹ 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.

Notably, lack of access to essential medicines will negatively influence the achievement of millennium development goals by countries in sub-Saharan Africa.³²

²⁸ Current member states of the SADC are Angola, Malawi, Namibia, Mauritius, Botswana, Lesotho, South Africa, Seychelles, Democratic Republic of Congo, Tanzania, Swaziland, Zambia and Zimbabwe. Each member state has a responsibility to coordinate a sector or sectors on behalf of others. Angola coordinates energy, Botswana livestock production and animal disease control, Lesotho environment and land management, Malawi forestry and wildlife, Mauritius tourism, Mozambique transport and communications, Namibia marine fisheries and resources, South Africa finance and investment, Swaziland human resources development, Tanzania industry and trade, Zambia mining and Zimbabwe food, agriculture and natural resources. For detailed discussion of the SADC institutional history and its gradual evolution into a free trade area, see Osode PC, "The Southern African Development Community in Legal Historical Perspective" (2003) 28 *Journal for Juridical Science* 1; SADC Secretariat, *The Official SADC trade Industry and Investment Review* (1997) 5-9, Chipeta C and Mandaza I "The future of the SADC" (1998) 11 *Southern African Political and Economic Monthly* 35; Kamidza R "Is SADC ready For Free Trade?" (2000) 14 *Southern African Political and Economic Monthly* 23; Moyo S, O' Keefe P and Sill M, *The Southern African Environment* (1993) 28 -36; Jenkins C, Leape J and Thomas L (eds) *Gaining from Trade in Southern Africa: Complementary Policies to Underpin the SADC free Trade Area* (2000) 1-20; and Thomas RH "The World Trade Organisation and Southern African Trade Relations" (1999) 3 *Law, Democracy and Development* 105 at 105-106.

²⁹ The Protocol on Health was approved by the SADC Heads of State in August 1999 and entered into force in August 2004. The full text of the Protocol is available at <http://www.sadc.int/index/browse/page/152> (last visited 12/06/2012)

³⁰ See generally Article 29 of the Protocol dealing with pharmaceuticals.

³¹ 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 C and Killander M (eds) *Compendium of Key Human Rights Documents of the African Union* (2007) 4 – 12.

³² Of paramount importance in this context are goals 4, 5 and 6 that canvass child health, maternal health and combating HIV/AIDS respectively. Very specifically, millennium development goal number 8 (global partnership) target 4 directly talks to the issue of access to medicines by enjoining members of the United Nations, in cooperation with pharmaceutical companies, to provide access to affordable essential drugs in developing countries. For a full list and description of the millennium development goals, see the United Nations site at <http://www.un.org/millenniumgoals/> (last visited 04/03/2009). The WHO reports that some developing countries have made progress in achieving health-related millennium development goals but progress has been slow in sub-Saharan Africa. The notable progress recorded is in the reductions of HIV/AIDS infections [<http://www.who.int/mediacentre/factsheets/fs290/en/index.html>] (last visited 02/03/2009).

In order to facilitate access to essential drugs and medicines, the European parliament passed a resolution on the World Trade Organisation³³ Trade Related Aspects of Intellectual Property Rights (hereafter TRIPS Agreement) and Access to Medicines on 12 July 2007.³⁴ The resolution enjoins the European Union and its membership to take active and deliberate steps in assisting developing countries increase their manufacturing capacity of essential drugs by providing expertise and funding. On a related note, in October 2007, the African Union, under the auspices of the United Nations, adopted an African Union Pharmaceutical Manufacturing Plan for Africa,³⁵ which seeks to facilitate more production of generic versions of essential drugs through the facilitation of a working relationship between the Union, partners and local manufactures of domestic drugs. The plan further seeks to assist African countries to make use of the flexibilities afforded to them by the TRIPS agreement and the Doha Declaration on TRIPS and Public Health.³⁶

The two developments in the preceding paragraph show the importance and urgency of accessing medicines by the developing countries.

On 14 November 2001, the WTO adopted a Declaration on the TRIPS Agreement and Public Health.³⁷ The declaration recognises the gravity of public health problems afflicting many

³³ Hereafter WTO. Established on 1 January 1995, the World Trade Organisation provides a forum for implementing the multilateral trading system, negotiating new trade agreements and resolving trade disputes. The concept of a WTO dates back to 1919 when the United States president Woodrow Wilson proposed a 'World Trade Board' as part of the Covenant of the League of Nations. The 'Board' dropped out in a later draft, but the idea did not die. A United Nations Conference approved an international Trade Organisation (ITO) in 1948 but the organization never eventuated due to opposition in the US Congress. The agreement establishing the World Trade Organization, which was signed in Marrakesh, Morocco in 1994, incorporates the original General Agreement on Tariffs and Trade (hereafter GATT), which continues to apply to issues not covered by the more specific agreements negotiated during the Uruguay round. The trade rules of this organization are constantly negotiated and broadened to cover a number of issues that were not included or anticipated during the signing of the initial agreement. Each negotiation, which focuses on specific aspects of international trade such as tariffs or subsidies is called a round and usually assumes its name from the place in which it is negotiated. Examples are Geneva (1947); Annecy (1948); Torquay (1950); Geneva (1956); Dillon (1960-1961); Kennedy (1964-1967); Tokyo (1973-1979) and Uruguay (19986-1994) rounds. The current Round, which has been characterised as the longest and most contentious, is the Doha Round. Some authorities have referred to it as the 'Development Round' due to its thrust towards developmental issues in international trade law.

³⁴ Available at http://www.un.org/esa/policy/mdggap/mdggap_matrix_drugs.html (last visited 02/02/2009).

³⁵ The full text is available at [http://www.pambazuka.org/action/alerts/images/uploads/Pharmaceutical_Plan-CAMH_MIN.8\(III\).pdf](http://www.pambazuka.org/action/alerts/images/uploads/Pharmaceutical_Plan-CAMH_MIN.8(III).pdf) (last visited 05/06/2009).

³⁶ See note 28 below.

³⁷ The full text of the declaration is available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited 04/12/2008). It is

developing and least-developed countries and identifies HIV/AIDS, tuberculosis and malaria as some of the most prominent afflictions.³⁸ Further, the declaration acknowledges the importance of intellectual property protection in the development of medicines while at the same time bemoaning its effects on prices.³⁹ Of paramount importance is the fact that the declaration unequivocally affirms WTO members' rights to take measures to protect public health by making use of the flexibilities⁴⁰ in the TRIPS agreement that allow each member state to determine what amounts to a public health threat and thus act accordingly.⁴¹ One major instrument which can be used to take advantage of the flexibilities in TRIPS would be a compulsory licence. Compulsory licensing occurs when a government allows someone else to produce the patented product or process without the consent of the patent owner.⁴² It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property.

The declaration suggests that the TRIPS agreement should be interpreted and implemented in a manner that is supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.⁴³ The declaration creates a regime that is sympathetic to the cause of least-developed WTO member states because it exempts them from sections 5 and 7 of the TRIPS agreement until 1 January 2016 with a proviso for further extension of the grace period.

While the above information was received with mixed enthusiasm from developing countries, especially those in sub-Saharan Africa, the implementation thereof has been slow if not

crucial to point out that the declaration sets WTO members the task of agreeing on an appropriate mechanism to address the problem of access to medicines by developing and least-developed WTO members. According to Mathews D, 'Is History Repeating Itself? The Outcomes of Negotiations on access to medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation' (2004) 1 *Law, Social Justice and Global Development* 2 – 16 at 2, an agreement on such a mechanism was finally reached on 30 August 2003.

³⁸ Declaration on the TRIPS agreement and Public Health, paragraph 1.

³⁹ Ibid para 3.

⁴⁰ Some of the flexibilities are outlined in paragraph 5 of the Declaration. They include members' autonomy in granting compulsory licences, the freedom to determine the grounds for the granting of the licence, flexibility in the determination of what constitutes a national emergency, and that each member is free to establish its own regime for the exhaustion of intellectual property rights without challenge.

⁴¹ Declaration on the TRIPS agreement and Public Health para 4.

⁴² See WTO, "Compulsory Licensing of Pharmaceuticals and TRIPS" at http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited 13/08/2012)

⁴³ Ibid.

insignificant. The SADC position is guided by the SADC Pharmaceutical Business Plan,⁴⁴ which outlines the TRIPS flexibilities and spells out a concrete plan to take full advantage of the flexibilities from 2007 -2013 and beyond.⁴⁵

Developing countries remain in desperate need for access to essential medicines that are patented in developed countries. In the SADC region, the need to access essential medicines and drugs, especially generic drugs, is made dire by the high disease burden, attributable mainly to HIV/AIDS, tuberculosis and malaria. With such a dilemma still unresolved, questions about improving the efficacy of TRIPS flexibilities for developing countries arise. With specific reference to the SADC region, the following questions are relevant and were answered in this study:

1. How do we ensure that developing countries in general and SADC members in particular make full use of the TRIPS flexibilities without falling foul of the basic tenets of intellectual property law?
2. What is the relationship between the TRIPS Agreement, access to medicines and human rights?
3. To what extent have the TRIPS flexibilities been incorporated in the SADC members' domestic legislations to advance the cause of access to medicines?
4. What legal and policy interventions are necessary to ensure that developing countries and SADC members utilise the flexibilities in their favour?
5. Looking at comparative jurisprudence on litigating access to medicines from other developing country jurisdictions, what lessons can the SADC region learn in the context of pharmaceutical patents?

⁴⁴ Available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf (last visited 13/08/12).

⁴⁵ See operational paragraph 4.1.8 of the SADC Pharmaceutical Business Plan.

6. Is it possible to come up with SADC tailored solutions and recommendations for access to medicines, premised on the right to life, human dignity and health, which will attempt to balance the rights of developing countries to access essential medicines against pharmaceutical patentees' rights to commercially exploit products of their intellectual endeavour?

2. Statement of the Problem

Despite the adoption of the Declaration on the TRIPS Agreement and Public Health and the ultimate Decision of the WTO General Council of 30 August 2003,⁴⁶ patent protection of pharmaceutical products still prevents poor countries from having access to essential medicines.⁴⁷

Without doubt, developing countries are faced with health problems emanating from the lack of access to essential drugs and vaccines occasioned by inadequate manufacturing capacities and the exorbitant costs of importing drugs. The cost of patent-protected medicines has long been out of reach for many developing countries, partly because of the agreement by their governments to abide by the minimum intellectual property guarantees as a condition of membership in the WTO.

The problem was partially solved by the adoption of the Declaration on the TRIPS Agreement and Public Health,⁴⁸ and the subsequent WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.⁴⁹ The latter actualises the instruction of the Ministerial conference to the Council for TRIPS, contained in paragraph 6 of the 2001 Decision, whereby WTO members with little or insufficient manufacturing capacity in the pharmaceutical sector must be assisted to make effective use of compulsory licences under the TRIPS agreement.

⁴⁶ The WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (06/03/2009).

⁴⁷ See WTO, *Understanding the WTO* (2007) at 44.

⁴⁸ Declaration on the TRIPS agreement and Public Health, paragraph 1.

⁴⁹ See Decision of the General Council of 30 August 2003, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#asterisk (04/12/2008).

Despite the above two positive developments, developing countries still have not improved their lot with respect to accessing essential medicines and their intellectual property laws have not been amended accordingly to accommodate the flexibilities. Two impediments are identifiable here. Firstly, there is a lack of pharmaceutical manufacturing capacity occasioned by a strict intellectual property regime. Secondly, there is the question of high costs of essential drugs,⁵⁰ also occasioned by the continued unjustified adherence to an inflexible intellectual property regime.

It is fair at this stage to posit that in order to improve access to essential medicines by developing countries, there is a need to actualise the flexibilities introduced by the amendments to the TRIPS agreement. This will require a paradigm shift in legal policy by amending existing intellectual property laws in the member states and, a reinterpretation of the relevant WTO provisions, which have been the subject of litigation in disputes involving pharmaceuticals and access to medicines.

Reviewing WTO and other jurisprudence in this context will entail a critical appraisal of past jurisprudential practice and a development of a contextual and more progressive interpretation that looks beyond the parameters of the Vienna Convention.⁵¹

Broadly speaking, there are three approaches to treaty interpretation namely, the textual,⁵² the teleological⁵³ and the intention of the parties.⁵⁴ It is our submission that revisiting the above

⁵⁰ This problem manifested itself in South Africa in the following cases: *New Clicks South Africa (Pty) Ltd v Tshabalala Msimang N.O and Another and Pharmaceutical Society of South Africa and 6 others v Minister of Health and another* (4128/04; 4329/04) and *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* 2006 (8) BCLR 872 (CC). The disputes in the above cases arose because the government of South Africa, in a bid to make sure that drugs were affordable to the poor, had asked the Pricing Committee, an administrative arm of the health ministry charged with determining prices of medicines and related products, to come up with a viable pricing structure. New Clicks, a pharmaceutical company and the Pharmaceutical society of South Africa challenged the pricing proposal on the basis that it was unviable and would drive them out of business.

⁵¹ The Vienna Convention on the Law of Treaties, (1969) ILM 679, hereafter Vienna Convention, was signed on 23 May 1969 in Vienna, Austria and entered into force on 27 January 1980. According to Dugard J, *International Law: A South African Perspective* 3rd Ed (2005) at 406, the Vienna Convention is viewed as a definitive statement on the law of treaties by both signatories and non-signatories. For an overview of the subject of treaties and other international agreements, see McNair A.D *The Law of Treaties* (1961), Elias T.O *The Modern Law of Treaties* (1974), Sinclair I *The Vienna Convention on the Law of Treaties* (1984), Slomanson W.R *Fundamental Perspectives on International Law* (2000) 323 – 360, Evans M. D (ed) *Blackstone's International Law Documents* 7th Ed (2006) 129 – 147, Amerasinghe C.F *Principles of the International Law of International Organisations* (2005) 24 – 61, Rosene S *Developments in the Law of Treaties 1945-1986* (1989), Klabbbers J *The Concept of Treaty in International Law* (1996) and Aust A *Modern Treaty Law and Practice* (2000).

interpretive approaches in a context that takes into account the peculiar circumstances of the individual WTO members in sub-Saharan Africa may yield positive results for access to medicines.

The TRIPS Agreement does not and should not prevent measures to protect public health; it should be interpreted⁵⁵ and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.⁵⁶

There is, therefore, a need to ensure that there is adequate supply of essential medicines to poor countries while at the same time maintaining the patent system's role in providing incentives for research and development into new medicines.⁵⁷ Flexibilities, such as compulsory licensing and parallel importation, are built into the TRIPS agreement notwithstanding the fact that some governments in developing countries are unsure as to how these would be interpreted, and how far their right to use them would be respected.⁵⁸

An investigation into the causes of such intransigence and a critical appraisal of the current jurisprudential practice is called for in order to improve developing countries' access to essential medicines. In a bid to unravel the jurisprudential problems, there is a need for a critical appraisal

⁵² Dugard above at 417. The textual approach provided for in Article 31 gives effect to the literal or grammatical meaning of the words and is widely favoured by formalists and positivists.

⁵³ Ibid. This methodology emphasises the object and purpose of a treaty in the interpretive process.

⁵⁴ Article 32 of the Vienna Convention. This approach attempts to give effect to the intention or presumed intention of the parties, which the judge infers from the text and the preparatory works (*travaux préparatoires*) or the historical record of the treaty.

⁵⁵ Interpretive problems associated with the TRIPS agreement are likely to occur less frequently if the proposed World Intellectual property Organisation's substantive Patent Law Treaty is adopted. For a full discussion and some enlightening arguments against the adoption of the treaty from the point of view of developing countries, see Reichman J.H and Dreyfuss R.C, 'Harmonisation without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty' (2007) 57 *Duke Law Journal* 86-130.

⁵⁶ Mathews 5. This is further supported by article 66 of the TRIPS agreement, which makes specific mention of the unique and precarious position of least-developed WTO members that may require some limited exceptions to the strict application of intellectual property rights. The article points out that the countries' economic, financial and administrative constraints necessitate some form of flexibility in order to allow them to develop a sound technological base for intellectual property innovation. It was for this reason that article 16 gave least-developing WTO members a 10 year grace period before they could be subject to the major provisions of TRIPS.

⁵⁷ Ibid.

⁵⁸ To date, only Rwanda has notified the WTO of its intention to use the WTO notification process to import HIV/AIDS medication from Canada [see CRS Report for Congress entitled 'The WTO, Intellectual Property Rights and the Access to Medicines Controversy', 5 November 2007, available at <http://www.usembassy.it/pdf/other/RL33750.pdf> (last visited 03/03/2009)].

of the interpretive cannons employed by the WTO panels and the Appellate Body with the view of making future treaty interpretation sympathetic to the access cause to medicines.

This study analysed the relevant TRIPS provisions (flexibilities) and attempted to explain why developing countries in general and the SADC region in particular have been reluctant to take full advantage of the specific provisions. Ultimately, selected intellectual property legislation in SADC member states was analysed and the potential for the inclusion of flexibilities afforded by the TRIPS Agreement was explored against the backdrop of a rights-based approach.⁵⁹

In the final analysis, this study came up with recommendations, premised on the rights-based approach which, if adopted at the regional level, will solve the problem of lack of access to essential medicines and drugs, including generics.

Regrettably, there is a paucity of comparative literature on the human rights approach to the use of TRIPS flexibilities from the SADC and the developing countries' perspective. Only scant attention has been given to the potential of regional trading bloc and the developing countries' solutions to the access to medicines problem. Few studies have in fact examined in-depth the extent of incorporation and use of TRIPS flexibilities in the SADC region beyond lamenting the fact that the flexibilities are currently not being taken advantage of by the SADC member states. This study, therefore, proffers home-grown solutions to the SADC access to medicines problem through the aid of jurisprudence from other developing countries. This is the gap which this study sought to fill.

⁵⁹ For scholarly references to the concept of a rights –based approach, see Olowu above at 261-282 and Olowu O, 'Conceptualizing a Rights-based approach to poverty alleviation in Africa: The platform for Social Security (2003) 43 *Indian Journal of International Law* 67, UNAIDS Global Reference Group on HIV/AIDS and human Rights, 'What Constitutes a Rights – based approach? Definitions, Methods, and Practices' issue paper, 23-24 August 2004. Mary Robinson, the former United Nations High Commissioner for Human Rights, suggested an adoption of the rights – based approach when she cited the example of intellectual property rules that have led to the exclusion of many people from access to medicines. At a panel discussion titled 'Towards Development: Human Rights and the WTO Agenda', held in Cancun, Mexico on the 12 of September 2003, she succinctly spelt out how such an approach could yield positive results for the access to medicines debate. The full text of her submissions to the panel discussion is available at www.eginitiative.org/documents/wtocancun.html (last visited 03/03/2009).

3. Preliminary Literature Review

Essentially, the battle for access to medicines revolves around the right to issue compulsory licences and to manufacture and export generic versions of well-known branded drugs.⁶⁰ Intellectual property policy continues to be shaped by asymmetrical power relations, which reduce the amount of leeway that poorer states have in devising regulatory approaches that are most suitable for their individual needs and stages of development.⁶¹ This problem has long been recognised by developed countries. For example, as early as the late 1990s the United States and the European Union revealed some willingness to assist the least developed countries in Africa to access drugs to ameliorate the effect of the HIV/AIDS pandemic. However, this was not robustly followed up.⁶² There has been a mismatch between the willingness to assist and the actual granting of assistance and this has had a negative effect on alleviating the dire need for essential medicines in Africa.

Most writings on the subject of lack of access to medicines in the context of sub-Saharan Africa have tended to be obsessed with themes discussed immediately below.

Firstly, the recurrent call by developing countries has been that they should be allowed to market, import, export and produce generic drug versions that are ‘essential’ not only for ‘national emergencies’.⁶³

Secondly, there have also been increasing calls for the striking of a balance between the rights of developing countries to access medicines and the rights of pharmaceutical companies to continue with medical innovations while gaining market-related returns for their intellectual property.⁶⁴

⁶⁰ Sell SK “TRIPS-Plus Free Trade Agreements and Access to Medicines” (2007) 28 *Liverpool Law Review* 41.

⁶¹ Ibid.

⁶² Hoekman BM and Kostecki MM *The Political Economy of the World Trading System: the WTO and Beyond* (2001) at 298. The authors report that the United States government issued an executive order in May 2000 to help make HIV/AIDS-related drugs and medical technologies more affordable and accessible in sub-Saharan African countries.

⁶³ This could be achieved by making use of compulsory licences by developing and least-developed WTO members, in terms of article 31 of the TRIPS agreement.

⁶⁴ See generally, Hanefeld J “Patent Rights v Patient Rights: Intellectual Property, Pharmaceutical Companies and Access to Treatment for People Living with HIV/AIDS in Sub-Saharan Africa” (2002) 72 *Feminist Review* 84-92. See further, Lanaszka A “The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries” (2003) 24 *International Political Science Review* 181 who argues that TRIPS emphasises a property rights approach which favours private ‘owners’ of the inventions. This can restrict access on the basis of commercial considerations. Hanefeld argues further that the result is higher prices for pharmaceuticals and other

This is closely tied to the insistence that pressure should be brought to bear on pharmaceutical companies with the view of reducing prices.⁶⁵

The third and last theme has been premised on calls to strengthen public health provisions of TRIPS by putting greater emphasis on public health for developing countries.⁶⁶ It should also be acknowledged that pharmaceutical companies need to recoup their investment into the development of medicine/ the intellectual property right.⁶⁷

One suggested solution to the problem of access to medicines for developing countries has been the call for change in the pharmaceutical drug policies in the developing countries.⁶⁸ Such calls unfortunately have been conspicuous by their silence on changing the developed countries' pharmaceutical policy in sympathy with their developing and least-developed counterparts. It is submitted that an interrogation of policy (WTO and pharmaceutical in developed countries) lies at the heart of solving the access to medicines enigma for developing countries.

This study examined whether in adjudicating disputes relating to accessing medicines, more emphasis should not be put on WTO policy and TRIPS' objectives so that the interpretive result may become acceptable to all.⁶⁹

Very few studies have focussed on the problem of access to medicines from a human rights perspective let alone the SADC perspective. The very first attempt to analyse the problem through the lens of the rights-based approach was in 2003.⁷⁰ With specific reference to the

health care inventions. This can prevent low-income consumers in developing countries from obtaining life-saving medication and equipment. On a related costs and expenses note, see Rai AK, "The Ends of Intellectual Property: Health as a Case Study" (2007) 70 *Law and Contemporary Problems* 125 at 125.

⁶⁵ According to Ostergard RL "The Measurement of Intellectual Property Protection" (2000) 31 *Journal of International Business Studies* 349 at 350, pharmaceutical companies are a good example of an industry that is sensitive to intellectual property regulation hence the call to reduce prices is likely to be met with resistance.

⁶⁶ This is partly addressed by the 2001 Declaration on the TRIPS Agreement and Public Health, referred to at note 16 above.

⁶⁷ See specifically on this point Rawlins MD "Cutting the Cost of Drug Development?" (2004) 3 *Nature Reviews* 360 -363 who cites recent studies showing that the average cost of discovering and developing a new drug is now in excess of US \$800 million

⁶⁸ Lanaszka above at 182.

⁶⁹ See specifically Articles 7, 8 and 27 of the TRIPS Agreement.

⁷⁰ At a panel discussion entitled 'Towards Development: Human Rights and the WTO agenda', scheduled during the WTO'S fifth Ministerial held in Cancun, Mexico in 2003, Mary Robinson, the former UN High Commissioner for

problem of access to medicines, Mary Robinson emphasised that human rights include the right to adequate food, safe water, education and health.⁷¹ She described her version of the rights-based approach to trade policy as values-led and likely to increase participation by those affected by trade policy (such as those unable to access essential medicines).⁷² Further, she submitted that such an approach will result in a trade policy that is not only transparent but also accountable and responsive to the needs of the people it purports to serve.⁷³ In the end, such a policy will be more sustainable and more legitimate.⁷⁴

The main strength of the rights-based approach is that it is based on agreed legal standards agreed to by governments.⁷⁵ Since all WTO members are parties to at least one of the six principal human rights treaties, they have voluntarily undertaken to enforce trade rules and to respect and fulfil human rights.⁷⁶ The rights-based approach is important in determining the benefits of the rights holder and identifying the obligations of the duty bearer.⁷⁷

The present study is, therefore, different from other studies done before it because it applied the rights-based approach to the problem of lack of access to medicines and use of TRIPS flexibilities in the SADC region. This has never been done before in the context of a regional trading block like SADC. More importantly, this study offered a rare opportunity for an exploration of the problem of access to medicines from an African and more importantly SADC perspective. This has never been attempted before as most studies have focused on the problem from the perspective of developing countries in general. Therefore, the use of a rights-based approach in a SADC context, adds to the uniqueness of this study. Such an approach will add to the alternative expertise sought to improve the legal regime in individual SADC member states.⁷⁸

Human Rights and other prominent speakers attempted to infuse the human rights agenda into international trade law rules. The discussion offered a unique forum to bring people together to examine international trade rules and practice from a human rights perspective.

⁷¹ Robinson 2.

⁷² Ibid.

⁷³ Ibid.

⁷⁴ Ibid.

⁷⁵ Robinson 2.

⁷⁶ Ibid.

⁷⁷ Olowu above at 281.

⁷⁸ This will go a long way towards strengthening the provisions of the SADC Health Policy Framework, SADC Protocol on Health and the Regional Indicative Strategic Development Plan (RISDP).

4. Assumptions Underlying the Study

This study was based on the following assumptions: Firstly, despite advances in medical and pharmaceutical technology, the problem of lack of access to medicines for citizens in poor countries continues. Secondly, there is a conflict between the intellectual property rights of manufacturers of essential medicines in developed countries and the rights of those in dire need of medicines and drugs in the developing and least developed countries (LDCs). Thirdly, to solve the problem of lack of access to medicines, the views of developing and least developed WTO member states must be afforded a sympathetic hearing. Finally, while the TRIPS Agreement makes provision for flexibilities which developing and least developing WTO members can take advantage of, the African Union (AU) and SADC member states have not taken advantage of the flexibilities due to the lack of understanding of the Agreement, lack of interpretive legal certainty, and for other reasons such as poverty and TRIPS-plus pressures.⁷⁹

5. Aims and Objectives of the Study

5.1 Aims

This study pursued three aims. The first one was to analyse WTO legal instruments and ascertain their adequacy in balancing the right to health and right to intellectual property in the context of pharmaceutical patents. The second aim closely related to the first one was to show through an examination of international human rights legal documents and other instruments that there is a conflict between intellectual property rights and the right to health in the context of access to essential medicines in general and for the SADC region in particular. The third one, through an analysis of selected SADC members' intellectual property legislation, comparative law and a rights-based approach, proposed viable solutions to the SADC access to medicines problem.

5.2 Objectives

To achieve the above aims, this study pursued the following specific objectives:

- (a) It outlined the basic tenets of WTO and IP law through exploring the theories of intellectual property and legal historical origins;

⁷⁹ Channual A *Are Affordable Pharmaceuticals within reach for Developing Countries? – Clarifying the access situation of today and projecting beyond the Paragraph 6-Agreement* (2004) Dissertation submitted in partial fulfillment of the Requirements for the LLM degree at the University of Lund, at 34.

- (b) It outlined and discussed the tenets of the rights-based approach and explained how it can be applied to the problem of access to medicines as a human right in order to humanise it;
- (c) It critically analysed specific regional instruments and SADC Policy documents relating to access to medicines and established the extent of incorporation of TRIPS flexibilities in SADC member states' legislation;
- (d) It analysed selected SADC members' intellectual property policies and legislation and exposed how each country used some of the flexibilities to improve access to medicines for its citizens;
- (e) It extracted thematic lessons for other SADC members' from the practice of select SADC members and other developing countries, namely India, Thailand and Kenya; and
- (f) It proposed solutions to SADC access problems to medicines through making recommendations and suggesting areas for further research.

6. Research Methodology

This study, which was largely desktop and library-based, relied on primary and secondary sources including legislation, treaties, WTO Ministerial Decisions, law reports and academic studies on the subject of access to medicines from a wide range of jurisdictions. The study was supplemented by both formal and informal face to face interactions and email exchanges with members of civil society, academics, public health consultants, legal practitioners, judges and officers affiliated with the secretariats of the SADC, COMESA, African Union (AU) and the WTO.

The most prevalent research method, which was employed in this study, was the desk-top literature study coupled with the historical method and comparative perspective. The researcher subscribes to the views of human rights activists who argue that trade rules should be subjected to human rights norms and standards. The reasons for such a subscription are discerned from the

commentary and analysis engaged in throughout the study. The comparative method was employed in the last two chapters.

The forms of literature that were perused are outlined below.

6.1 Legislation and Treaties:

Treaties and conventions on international human rights law and the right to health, SADC protocols, WTO provisions including the TRIPS agreement and the relevant Ministerial decisions were examined. Intellectual property laws of most SADC countries were referred to, with particular emphasis on the laws of South Africa, Botswana and Zimbabwe. The analysis of the intellectual property laws of the last mentioned countries formed the bedrock of the thematic lessons for other SADC members in the effective use of TRIPS flexibilities.

6.2 WTO Disputes and Decisions

Decisions of the selected WTO Panels and the Appellate Body dealing with access to medicines and pharmaceuticals were referred to and cursorily analysed. Where interpretive gaps not furthering the cause of access to medicines were manifest, these were highlighted and contextualised in relation to the aims and objectives of the study.

6.3 Textbooks and Journals

This study referred to both old and recent textbooks and journal articles on the topic drawn from fields as diverse as law, economics and to some extent, political science. However, the bulk of the literature consulted in this specific context related to the TRIPS Agreement and access to medicines from the legal perspective. However, the paucity of literature on the access to medicines debate in the context of the SADC was a major challenge. This study, therefore, relied on primary sources of SADC law such as treaties and protocols, and secondary sources such as policy documents and declarations.

6.4 Case law

The study made extensive reference to case law from within the SADC region and other developing countries such as India, Thailand and Kenya. In the SADC region, case law from South Africa, a country that has made tremendous inroads in litigating the right to health in the

municipal context, was liberally used in this study to show that public interest litigation can in actual fact yield positive results towards accessing medicines.

6.5 Internet Resources

The global village which we inhabit has largely been made habitable by the presence of the internet connectivity. This study was no exception and drew quite liberally from current information on the internet. The internet was used to source information from electronic journals and other scholarly articles online. Websites of international and regional organisations such the United Nations, World Health Organisation, Southern African Development Community, World Trade Organisation, African Union and many others proved to be invaluable sources of current and up to date information.

7. Mode of Citation

The mode of citation of authorities in this study is a slight adaptation of the house style of the journal, *Law, Democracy and Development*, (LDD) published by the University of the Western Cape in South Africa.⁸⁰ Thus, the citations in footnotes and bibliography of works cited largely mirror the LDD house style.

8. Justification and Limitations of the Study

8.1 Preliminary Remarks

The problem of access to medicines from the perspective of both the developed and the developing countries has been discussed *ad nauseam*. However, the problem remains unresolved and continues to evolve with new judicial and treaty-making activity. Notably, much of what has been written has tended to focus on the conventional ‘north v south’ approach, ignoring regional trading blocs and the human rights dimension. Therefore, a rigorous and unbiased analysis specific to a regional trading bloc such as SADC, premised on the rights-based approach, can enrich the debate and consequently proffer alternative solutions to the problem.

8.2 Justification of the Study

This study was primarily motivated by the general gap in the current law whereby TRIPS flexibilities are provided for with the intended beneficiaries making very limited use thereof. I have been fascinated by the emotional fervour with which students and legal academics have

⁸⁰ The house style is available at <http://www.ddd.org.za/2013-05-29-13-44-23/guidelines-for-authors.html> (last visited 13/12/2013).

tended to handle the subject of access to medicines whenever they get the opportunity for debate. This has always provoked the question, “what will happen if we suspend emotions and confront access to medicines objectively?” This then led me to think of a research project that would explore the problem from a SADC perspective and come up with a legal model solution premised on human rights.

From a teaching-learning point of view, I sincerely hope that the findings in this study will go a long way towards adding new knowledge to the access to medicines database and open up new academic and intellectual horizons.

The findings in this study are likely to attract the interests of governments and trade policy makers in the SADC region. Very little has been written on the subject of access to medicines in the SADC region and implications for free trade, especially in the context of SADC having acquired free trade area status. It is, therefore, hoped that this study is to some extent an attempt at alleviating the paucity of literature on the subject and lays the foundation for further research in the specific subject field.

Hopefully, the findings in this study, especially the proposed recommendations, will shape future jurisprudence relating to access to medicines in general and in the SADC region in particular. The findings on this aspect of the study may also be a useful tool for shaping the SADC trade dispute settlement system in intellectual property-related disputes in the access to medicines context.

It needs to be noted, therefore, that this subject deserves to be studied, not only for its own sake but also for the insights into the rights-based approach towards accessing medicines. Such a study can provide the SADC region and the international community at large a partial solution to the nagging issue of access to medicines. Because poor citizens of developing and least-developing countries continue to die from preventable diseases due to lack of medicines, making the medicines accessible will not only actualise the rights to health and life but will also ensure a better life for all the global citizens and the achievement of the relevant millennium development goals.

8.3 Limitations

The study has inherent limitations necessitated by the scope, geographical spread and financial resources. Firstly, in terms of scope, the study is confined to the rights-based approach as it relates to the issue of access to medicines in the context of selected SADC member states. It would have been desirable to cast the net wider and cover the whole of Africa or the SADC region but this was not attempted due to the limited time and resources at the disposal of the researcher.

The WTO disputes that were referred to in this study are limited to the theme of access to medicines under the TRIPS Agreement and do not extend to other WTO agreements. This theme may also arise in the context of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) or the Agreement on Technical Barriers to Trade (TBT). In this study, however, the focus was only on the TRIPS Agreement.

The proposed recommendations for SADC would have been more valuable if they were based on a number of free trade areas compared to each other. On the contrary, the focus was only on the SADC region due to limitations in scope as indicated earlier on. The fact that the SADC will become part of the envisaged Tripartite Free Trade Area (Tripartite FTA) did not raise immediate concerns which would have led to a reformulation of the objectives of this study.⁸¹ The information ascertained from the findings of this study will in all likelihood feed into improving the technical documents and strategies already developed in anticipation of the creation of the Tripartite FTA.⁸² An analysis of the provisions of the Tripartite FTA and its possible legal ramifications for the access to medicines debate was surely beyond the scope of this study.

Due to the geographical spread of the SADC member countries and the paucity of information on the individual countries' legislation relevant to international trade and access to medicines,

⁸¹ For a comprehensive note on the origins, negotiations and current state of the envisaged Tripartite FTA, see "COMESA-EAC-SADC Tripartite: Greater Harmonisation and Cooperation" available at http://www.comesa-eac-sadc-tripartite.org/intervention/focal_areas/tripartite_fta (last visited 14/08/2012).

⁸² For scholarly critiques and analysis of the Tripartite FTA, see generally Hartzenburg T. et al *The Tripartite Free Trade Area: Towards a New African Integration Paradigm?* (2012) 1 - 138.

the research had to rely on readily available information.⁸³ Hence, there was an obvious bias towards SADC member states whose intellectual property laws were readily accessible in the English language.

9. Ethical Issues

Despite the fact that this study involved interactions with human subjects through face to face discussions and email exchanges, the interactions do not raise serious ethical issues since most of the exchanges were collegial and informal. For these reasons, the study is ethical and thus complied with the basics of ethical research.

10. Organisation of the Rest of the Study

The rest of the study, organised in six other chapters, focuses on the following pertinent issues. Chapter two contextualises the study by providing the background on the law of patents, exploring the theories of intellectual property, giving an expository account of the salient TRIPS provisions relevant to the topic and narrating how the discussions in relation to access to medicines evolved to what they have become today.

In chapter three, access to medicines is discussed from the human rights perspective and the concept of a rights-based approach is introduced. The goal of the study was to propose recommendations based on a rights –based approach in the SADC context. Therefore, it is appropriate to lay the groundwork early by discussing pertinent human rights issues in this chapter.

Chapter four focuses generally on the WTO TRIPS flexibilities which SADC members can use before briefly contextualising the flexibilities to the laws of specific countries. The chapter prepares the reader mentally for the detailed technical discussions to be embarked upon from chapter five onwards.

⁸³ Most of the information is contained in old and outdated textbooks and newspaper articles. Generally, the newspaper has never been a reliable source of law. Very few SADC member countries government departments have an Internet presence. With the exception of South Africa, most SADC government websites contain scanty information such as postal and physical addresses and such information is seldom updated. To partly deal with the above problem, this study heavily relied on the website www.wipolex.com and other internet sources for current information on SADC members' intellectual property legislation.

Chapter Five is a continuation of Chapter Four and becomes more specific. The chapter is dedicated to the practical application of the TRIPS flexibilities in individual SADC countries IP legislation, focussing on Botswana, South Africa and Zimbabwe. From the selected SADC members, the chapter distils thematic lessons for the whole region.

In Chapter Six, case law in the jurisdictions of three developing countries in which TRIPS flexibilities were litigated, namely India, Thailand and Kenya is comparatively discussed and contextualised to the SADC region. The chapter is in the form of case commentaries on the selected disputes which were critiqued. Having narrated and critiqued the cases, thematic lessons for SADC are then extracted and highlighted in anticipation of the recommendations in Chapter Seven.

Chapters Seven of the study comprises the summary, conclusions, recommendations and areas for further research. The chapter concludes the study by making recommendations specifically calling for local production of pharmaceuticals, the issuing of a regional compulsory licence in terms of Article 31 *bis* of TRIPS, the use of south-south collaborations, the use of pooled procurement and the adaptation of intellectual property laws of individual countries to TRIPS flexibilities and specific situations in the region and individual countries. The chapter also recommends the use of the rights-based approach and the adaptation of the rewards theory to accommodate both the interests of pharmaceutical companies and consumers in dire need of affordable essential drugs.

CHAPTER TWO

ACCESS TO MEDICINES: CONCEPTS, THEORIES AND LEGAL HISTORICAL FOUNDATIONS

2. Introduction

This chapter focuses on the access to medicines debate from a conceptual and theoretical point of view. Such an approach is appropriate to contextualise the study and explain the specific meanings of peculiar terms as they are used in the study. This chapter focusses on the basic principles of intellectual property law with specific reference to the law of patents since this study deals with the conflict between patent rights and the right to access medicines. Patents are defined and the scope of their rights delimited in order to locate the access to medicines problem in its correct habitat. The main international agreements dealing with patents in general and access to medicines in particular are also dealt with to clearly spell out the currently applicable legal regime. This is achieved through discussing the pertinent WTO provisions and aspects of the legal regime under the World Intellectual Property Organisation (WIPO). After discussing the basic patent law principles, an exposition of the theories and rationales for intellectual property follows. The theoretical exposition is important because some theories of intellectual property actually give prominence to the rights of the holders of pharmaceutical patents almost to the total exclusion of patients' rights. This will not bode well for access to medicines in the SADC region as aptly alluded to in a different but related context.¹ The theoretical exposition, therefore, affords the reader the opportunity to view the access to medicines problem from different theoretical standpoints and make an informed evaluation.

After the theoretical and legal background, this chapter gives an expository account of the international legal historical regime applicable to patents and access to medicines. The main focus is on the applicable international conventions, the GATT/WTO state of play and aspects of the regime under the WIPO.

¹ See Phiri D.S "Economic Partnership Agreements and Intellectual Property Protection: Challenges for the Southern African Development Community Region" (1999) 48 *South African Institute of International Affairs Occasional Paper* at 5.

After the exposition of the law, the chapter focuses on the evolution of the access to medicines debate through engaging in an analysis of the major medically significant epochs/case studies. The main case study covers the anthrax scare cases in the United States of America and parts of Europe after the September 11 2001 attacks without discussing the debacle around the amendment of the South African Medicines Act². The case studies mentioned in this section of the chapter clearly show that despite this study's focus on access to medicines from the SADC perspective, historically, the problem of access to medicines has surely not been confined to the developing and least-developed countries. SADC related case studies, mainly around the HIV/AIDS epidemic and access to medicines in that context, are discussed in chapter five below.

This chapter is, therefore, aimed at introducing the reader to the theoretical and conceptual frameworks underpinning the access to medicines debate in order to assist the reader become familiarized with the basic terminology used in the law of patents in that specific context. Further, the chapter serves as a contextual bridge that leads the reader to an understanding of the full scope of the study through exposing the reader to the terminology, theories, major influential historical occurrences and the applicable WTO and international law provisions.

2.1 Intellectual Property Law: Basic Concepts and Distinctions

It is important in a study of this nature to explain concepts and lay the necessary conceptual and technical groundwork. Intellectual property is implicated in many fields of public interest and concern. In the context of this study, the high cost of prescription drugs, many of which are protected by patent law, is seriously implicated.³ The need for such a backgrounder is premised on the reality that access to medicines raises intellectual property law questions, specifically the issue of pharmaceutical patents and the rights inherent therein.⁴ At the centre of the alleged conflict between the TRIPS Agreement and access to medicines is the often touted claim that patents on pharmaceuticals raise prices, thereby reducing accessibility of the drugs.⁵ Therefore, a thorough background on patent law, particularly its international aspects, is an indispensable inclusion in an analysis of the alleged conflict.

² The Amendment was brought by the Medicines and Related Substances Control Amendment Act 90 of 1997. See a discussion of the South African access case in chapter five below.

³ Mueller JM *An Introduction to Patent Law* (2006) at 3.

⁴ Saddiqi A "Patents and Pharmaceutical Drugs" (2005) *Sanford Undergraduate Research Journal* 1 at 1.

⁵ Hestermeyer H *Human Rights and the WTO: The case of Patents and Access to Medicines* (2007) at 18.

For the purposes of the TRIPS Agreement, the areas that constitute intellectual property include copyright and related rights,⁶ trademarks,⁷ geographical indications,⁸ industrial designs,⁹ *patents* (my emphasis),¹⁰ layout designs (topographies) of integrated circuits¹¹ and undisclosed information.¹²

The TRIPS Agreement does not provide the notion of intellectual property.¹³ Instead, it specifies which of the covered rights are, specifically dealt with in sections 1-7 of Part II of the Agreement.¹⁴ The definition of ‘intellectual property’ may be found in the Convention Establishing the World Intellectual Property Organisation (1967),¹⁵ but this definition includes subject matter that is in the public domain (scientific discoveries) as well as matters that are not deemed, under many national systems as subject to property rights.¹⁶ Correa has argued that

⁶ The specific rights are canvassed in Articles 9 – 14 of the TRIPS Agreement. Copyright, which was described by the South African Supreme Court of Appeal in *Gallo Africa Ltd v Sting Music (Pty) Ltd* 2010 (6) SA 329 (SCA), para 19, as a corporeal immovable, protects the material expression of ideas apart from the physical embodiment of the work of the work in which they are expressed (per Klopper et al *Law of Intellectual Property in South Africa* (2011) at 145). Works eligible for copyright protection may be conveniently grouped into literary works, sound recordings, artistic works, programme-carrying signals, musical works, cinematograph films, broadcasts, published editions and computer programmes (s1 of the South African Copyright Act 98 of 1978).

⁷ See Article 15 of the TRIPS Agreement. A trademark may be a word, device, symbol or other sign or any combination of these used by a trader in relation to his goods or services to identify and distinguish them from similar goods or services of others (Klopper et al at 71).

⁸ Article 22 of the TRIPS Agreement. In terms of the relevant provision of TRIPS, geographical indications are indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin (per Article 22.1 of TRIPS).

⁹ Article 25 of the TRIPS Agreement.

¹⁰ See para 2.1.2 below. According to Burrell TD *Burrell's South African Patent and Design Law* (1999) at 450, designs are registered in respect of designs applied to articles having features which appeal to or are judged solely by the eye (aesthetic design) or to articles having features which are necessitated by the functions which the article to which the design is applied, is to perform (functional design).

¹¹ These are addressed in Articles 35 -38 of TRIPS.

¹² Article 1.2 of the TRIPS Agreement. Specifically, the relevant article provides that the term ‘intellectual property’ refers to all categories of intellectual property that are the subject of Sections 1 through 7 of part II.

¹³ It does not refer either to ‘industrial property’, the expression used in the Paris Convention in relation to patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source, or applications of origin and the repression of unfair competition (article 12 of Paris Convention).

¹⁴ Correa CM *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2007) at 31.

¹⁵ Article 2 (viii) of the Convention states that ‘intellectual property’ shall include the rights relating to: literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

¹⁶ Correa above at 31. In Article 1.1 of the TRIPS Agreement, the term ‘intellectual property’ refers to all categories of intellectual property that are the subject of sections 1 through 7 of part II namely computer programmes and

Article 1.2 of the TRIPS Agreement is poorly worded.¹⁷ The specific examples of the alleged poor wording cited are, firstly, the reference of the article to section 1-7 as covering intellectual property while in actual fact the relevant sections do not contain clear cut categories of intellectual property.¹⁸

Secondly, the author argues that it is unclear whether the categories refer to the subject matter or to the rights conferred.¹⁹ If one were to adopt an interpretation that suggests that the categories refer to rights conferred, then the implication is that any rights not covered by the TRIPS Agreement that are conferred at the national level would be subject to the provisions of the Agreement.²⁰ It is the present writer's considered view that WTO members will base their intellectual property laws on the TRIPS Agreement within the delimitation in Article 1.2 section 1-7, and any municipal peculiarities would naturally be included while taking into account the hallmarks spelt out in article 1.2.

The interpretation of Article 1.2 of TRIPS in the context of the coverage of the Agreement was raised in the Panel case of *United States – Section 211 Omnibus Appropriations Act of 1998*²¹ in relation to trade names, which are not specifically mentioned in the Agreement, but are referred to in the Paris Convention.²² The Panel purported to interpret 'intellectual property' and 'intellectual property rights' as delimited in Article 1.2 of TRIPS and concluded that the definition was exhaustive.²³ The implication emanating from this form of interpretation was that there were no obligations under those articles in relation to the categories of intellectual property which are not set forth in article 1.2, such as trade names.²⁴ On appeal, the Panel's findings were

compilations of data, rental rights, sound recordings, trademarks, geographical indicators, industrial designs, patents, layout designs and undisclosed information.

¹⁷ Ibid.

¹⁸ Correa cites section 5 of part II which refers to the protection of plant varieties under an 'effective sui generis regime' but does not elaborate the standards thereto. He doubts if this category should be considered a category of intellectual property (at page 31).

¹⁹ Correa above at 32.

²⁰ Ibid.

²¹ WT/DS176/R, 6 August 2001.

²² Article 1(2) of the Paris Convention.

²³ Panel report at para 8.26.

²⁴ Panel report at para 8.26. Apparently, the Panel sought to justify its interpretation by basing it on Article 31 of the Vienna Convention on the Law of Treaties (1969), which provides that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

reversed by the Appellate Body which reasoned that the Panel's interpretation ignored the plain words of Article 1.2; which deal not only with the categories of intellectual property indicated in each section title, but with other subjects as well.²⁵ The Appellate Body further held that the Panel's interpretation of Article 1.2 could not be reconciled with the plain words of Article 2.1.²⁶

2.1.2 A Short Primer on the Law of Patents

Patent law is domestic law; hence there is an astonishing variety of national patent laws peculiar to each country.²⁷ This section gives a general outline of patent law without aligning it to a particular jurisdiction. Where there are obvious jurisdictional differences, they are briefly highlighted to reassure the reader that the writer is aware of the peculiarities.

A patent can be granted for 20 years to an inventor, or the first person to file for a patent,²⁸ for products that are new,²⁹ involve an inventive step³⁰ and are capable of industrial application,³¹ by disclosing the invention to the patents office in a way that a person skilled in the art will be able to carry out the invention.³² For access to medicines, the requirements for patentability are important in preventing a proliferation of ever green patents that may stifle the growth of the generic drug industry.³³ The importance of novelty as a requirement for patentability can be traced back to the 16th century in England as exemplified by the leading case of *Darcy v Allen*.³⁴

²⁵United States – Section 211 Omnibus Appropriation Act of 1998, Appellate Body Report, WT/DS176/AB/R, 2 January 2002, paras 54-55.

²⁶Ibid para 336.

²⁷Hestermeyer above at 19.

²⁸ Whether patents should be granted to the first to file, or the first person to invent is one of the raging patent law debates. The United States used to grant patents to the first person to invent (Hestermeyer at 19). However, this position has since changed with effect from 16 March 2013 when United States Code Title 35 – Patents was amended by the new section 35 U.S.C. 102(a)(1) of the same code (source: United States Patents and Trademark Office, available at <http://www.uspto.gov/patents/law/index.jsp> (last visited 05/07/2013). The new law now provides for a “first-inventor-to file” doctrine implying that the priority date for a patent application will now be the date on which the application for a patent was filed with the relevant office. This position is now similar to the one obtaining in South Africa (see section 31 of the South African Patents Act 57 of 1978).

²⁹ New patents are those that have the attribute of being ‘non-obvious’ such as was aptly explained in the case of *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd* 1995 BP 199 (A) 212-221. The issue of obviousness will generally be determined by the Court as held in the cases of *Gentiruco AG v Firestone South Africa (Pty) Ltd* 1971 BP 58 (A) at 92 and *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AEI Explosives and Chemicals Ltd* 1998 BIP 271 (SCA) 281C-D.

³⁰ The US Patents Act requires the invention to be non-obvious.

³¹ The South African Patents Act requires that the invention must be capable of being used or applied in trade, industry and agriculture (s 25 of Act 57 of 1978).

³² See generally section 25 of the South African Patents Act 57 of 1978.

³³ Problems associated with ever greening are discussed further in chapters five and six below.

³⁴(1603) 72 Eng. Rep 830; 74 Eng. Rep 1131; 77 Eng. Rep 1260. The products at stake were playing cards.

In this case, it was held that patent monopolies were only to be granted where the product was previously unknown in England. It was further held that the patent monopolies posed the danger of the patentee demanding unreasonably high prices for the product.³⁵ The Statute of Monopolies,³⁶ widely regarded as the first statutory expression of English Patent law, lasted 200 years after establishing the rudiments of patentability which continue to inform intellectual property laws of the world to date.³⁷

In South Africa, the term of a patent granted under the current Patents Act of 1978 is 20 years from the date on which the complete specification is lodged at the Patents Office, subject to the payment of the prescribed renewal fees.³⁸ The term of patent granted under South Africa's repealed Patents Act³⁹ of 1952 was 16 years from the date on which the complete specification was lodged at the Patents Office,⁴⁰ but an extension of that term was possible on application to the Commissioner of Patents⁴¹ on the ground of inadequate remuneration and/or war loss during the normal term.

The typical application for a patent consists of a description of the invention (specification) and of language claiming precisely the technology that was invented and that will be the subject of the patent rights – the claims.⁴² The claims are for the purposes of defining the patentee's rights and not for instructing the public; the latter function being that of the body of the specification.⁴³

³⁵ *Darcy v Allen* at 831.

³⁶ English Statute of Monopolies of 1623, 21 Jac. 1 c. 3. The full text of the legislation as originally passed is available at http://www.ipmall.info/hosted_resources/lipa/patents/English_Statute1623.pdf (last visited 07/03/2012).

³⁷ The Venetian Enactment of March 19, 1474 which appeared years before the English Statute of Monopolies established the foundation for the world's first patent system (Mueller 8).

³⁸ Burrell TD *Burrell's South African Patents and Design Law*, 3rd Ed (1999) 3. This is specifically provided for in section 46 of the Patents Act 57 of 1978.

³⁹ Act 37 of 1952.

⁴⁰ Repealed Patents Act 37 of 1952 s 28.

⁴¹ Patents Act 57 of 1978 s 45.

⁴² Klopper H et al *Law of Intellectual Property in South Africa* (2011) at 293.

⁴³ See the following South African cases *Moroney v West Rand Engineering Works (Pty) Ltd* 1970 BP 452 (T); *Letraset Ltd v Helios Ltd* 1972 BP 243 (A); *Deutsche Gesellschaft Fur Schadlings bekampfung MB v Coopers (South Africa) (Pty) Ltd* 1973 BP 447 (CP) and *Selas Corporation of America v The Electric Furnace Company* 1982 BP 442 (A).

The claim or claims must relate to a single invention, must be clear and must be fairly based on the matter disclosed in the specification.⁴⁴

Patent offices are, generally, national institutions.⁴⁵ They usually examine whether the requirements for patentability under their national laws are fulfilled,⁴⁶ grant the patent if that is the case, and publish the patent application.⁴⁷

Product patents confer the right to prevent third parties not having the patentee's consent from making, using, offering for sale, selling, or importing for these purposes the patented product.⁴⁸ Similarly, process patents confer the right to prevent third parties not having the patentee's consent from using the process and using, offering for sale, selling, or importing for these purposes a product obtained directly by the patented process.⁴⁹ Patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.⁵⁰ Anyone engaging in one of the proscribed activities with respect to product and process patents in the manner claimed in the patent faces damages and injunctive relief.⁵¹

Process patents⁵² may be granted for a patentable process.⁵³ Such patents similarly confer the right to prevent third parties not having the patentee's consent from using the process and using,

⁴⁴ Section 32(4) of the South African Patents Act 57 of 1978. In terms of section 10 (4) South Africa's repealed patents Act 37 of 1952, in addition to being 'clear', the claims were additionally required to be 'succinct', despite the obvious tautology.

⁴⁵ There are currently three major regional patent offices that grant patents that are treated like national patents of the member states after they have been granted: the European Patent Office (EPO), the African Regional Industrial Property Organisation (ARIPO), and the *Organisation Africaine de la Propriete Intellectuelle* (OAPI).

⁴⁶ Not all countries provide for such examination. Some, like South Africa, have registration systems that only examine the formal compliance of the application with the requirements for patentability; with the process of objecting to the patentability of the invention opening after the patent has been published in the Patents Journal. The examination system is common in the US, Germany and the European system.

⁴⁷ Commonly, the application is usually published a certain time after filing, whether by that time the patent has been granted or not.

⁴⁸ Hestermeyer above at 19.

⁴⁹ Ibid.

⁵⁰ Article 27.1 of the TRIPS Agreement.

⁵¹ Hestermeyer above at 20.

⁵² Burrell above at 38-39.

⁵³ There previously used to exist in the United States of America, a misguided notion, fuelled by the dictum in the often cited case of *Cochrane v Deener* 94 US 780, 788, 24 L ed 139 (1877) cited in Burrell at 36 and 39, that in order for a process to be patentable, it must act on a substance.

offering for sale, selling or importing for these processes a product obtained directly by the patented process.⁵⁴

Product patents are more desirable for the patentee than process patents, because product patents grant the patentee market exclusivity for the product, whereas the owner of a process patent faces competition from others producing the same product by a different process.⁵⁵

Infringement of product patents⁵⁶ would be easier to prove than the process⁵⁷ ones because the patentee can see and point out the infringing product which is produced without his authorization.⁵⁸ The corollary of the above reasoning is that an inventor of a product will easily identify the same or similar products that adopted the main integers of the original invention without the inventor's prior authorization. The burden would, therefore, be on the inventor to prove that the impugned product infringes on his existing patent. However, in process patent suits, the courts shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.⁵⁹ The burden of proof in these specific circumstances will, therefore, be reversed.⁶⁰

Some countries impose local working requirements as a condition precedent to the granting of a patent.⁶¹ This requirement compels the inventor to manufacture the product or use the process

⁵⁴ Article 27.1 of TRIPS.

⁵⁵ It is also easier to prove the infringement of a product patent, as anyone selling the product without license from the patentee is clearly infringing. Many countries resolve this difficulty for process patent holders by reversing the burden of proof; so that the defendant will have to prove that it is using a different process (see Article 34 of the TRIPS Agreement). However, the strong possibility remains that patentees might be reluctant to commence a lawsuit, because they are uncertain whether the defendant makes use of the patented process.

⁵⁶ In terms of Article 28.1 (a) of TRIPS, where the subject matter of a patent is a product, the patent owner shall have the right to prevent others from the acts of making, using, offering for sale, selling or importing the product.

⁵⁷ Article 28.1 (b) of TRIPS provides that where the subject matter of a patent is a process, the patent owner must be conferred the exclusive rights to prevent others from the act of using the process, and from the acts of: using, offering for sale, selling or importing the product obtained directly by the process.

⁵⁸ Article 34 of TRIPS read together with Article 28 of same.

⁵⁹ Article 34.1 of TRIPS.

⁶⁰ See Articles 1.2 and 1.3 of TRIPS read together with the two antecedent conditions listed in Article 1 (a) and (b) of TRIPS.

⁶¹ See generally Halewood M "Mandatory Working and Compulsory Patent Licensing" (1997) 35 (2) *Osgoodehall Law Journal* 244 -284 at 245 and the countries cited at footnote 3. The author convincingly argues that such mandatory requirements are TRIPS compliant.

within the country that grants the patent.⁶² The local working requirement as a concept allied to the process of granting patents has its origins in French law.⁶³ The commercial exploitation of certain inventions may be prevented by WTO Members in order to protect public order or morality, protect human, animal or plant life or health or to avoid serious prejudice to the environment; provided such exclusion is not made merely because the exploitation is prohibited by municipal law.⁶⁴

The General Agreement on Tariffs and Trade of 1947 (now GATT 1994) makes express reference to intellectual property rights by providing that trade restrictions may be imposed if they are necessary to secure compliance with laws and regulations which are not inconsistent with the GATT.⁶⁵ Such laws include those relating to the protection of patents, trademarks, copyrights and deceptive practices.⁶⁶ A similar provision, couched in almost identical language, is found in the SADC Protocol on Trade,⁶⁷ which provides that members may adopt and enforce measures that are necessary to *protect intellectual property rights, or to prevent deceptive trade practices* (emphasis added).⁶⁸

Despite patents giving the inventor a 20 year monopoly over the invention, it is, however, possible to use a patent without the authorization of the right holder.⁶⁹ This is achieved through the issuance of what are called compulsory licenses.⁷⁰ Compulsory licenses are very important in this study,⁷¹ and may generally be used sparingly and only in situations where there are no other alternative ways of improving access to medicines. Where the patentee wishes to gain

⁶² See on a related note, Champ P and Attaran A “Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute” (2002) 27 *Yale Journal of International Law* at 365.

⁶³ Specifically the French Patents Act of 1791 and supplemented by a Regulation dated 25 May 1791, obliging the patentee to work his invention in France within two years of the patent grant, failing which the patent could be revoked.

⁶⁴ Article 27.2 of TRIPS.

⁶⁵ Article XXIV (d).

⁶⁶ Ibid.

⁶⁷ SADC Protocol on Trade, original text signed in Maseru, Lesotho, August 1996, available at <http://www.sadcstan.co.za/Secure/downloads/protocol.pdf> (last visited 09/07/2013).

⁶⁸ Per Article 9 (d) of the SADC Protocol on Trade.

⁶⁹ See Article 31 of TRIPS.

⁷⁰ See the conditions for the grant of such licenses as categorized in paras (a) – (l) of the TRIPS Agreement. In South Africa, compulsory licenses are regulated by the provisions of sections 55 and 56 of the Patents Act 57 of 1978.

⁷¹ See chapter five below.

commercial advantage by allowing others to use his invention with permission, then voluntary licenses may be granted to those who seek them.⁷²

2.2 Theories and Rationales for Intellectual Property

2.2.1 Preliminary Remarks

Theories of intellectual property generally seek to establish and justify the basis for the protection of intellectual property rights. Broadly speaking, the theories fall into four specific categories. The first category is utilitarian and it specifically posits that when law makers legislate in the field of intellectual property, the end result ought to be the maximisation of social welfare. There is, therefore, a need to strike a balance between encouraging invention or innovations and ensuring that social welfare is not relegated to backburner status. The second category is the natural rights theory which is premised on the use by the inventor of goods that are unowned or 'held in common'; hence he has a natural property right to the fruits of his endeavour. The premise of the third approach, derived from the writings of Kant and Hegel, is that private property rights are crucial to the satisfaction of fundamental needs; hence policymakers should strive to create and allocate entitlements to resources in a fashion that best enables people to fulfil those needs. The last of the four approaches derives from the premise that property rights in general and intellectual property rights in particular, can and should be shaped so as to foster the achievement of a just and attractive culture.

Proponents of the fourth approach draw their inspiration from political and legal theorists such as Jefferson,⁷³ the old Marx,⁷⁴ legal realists,⁷⁵ and the various proponents of classical republicanism (both new and old).⁷⁶

⁷² Article 28.2 of TRIPS.

⁷³ The views of Thomas Jefferson, a former United States president and leading intellectual property legal scholar of his time are aptly captured in Mutsuura J.H *Jefferson vs. The Patent Rolls: A Populist Vision of Intellectual Property Rights* (2008) at 154.

⁷⁴ See generally Harris M *Works of Frederick Engels 1884 – The Origin of the Family, Private Property and the State* (2010) available at <http://www.marxists.org/archive/marx/works/1884/origin-family/index.htm> (last visited 09/07/2013).

⁷⁵ According to the Free Legal Dictionary, available at <http://legal-dictionary.thefreedictionary.com/Legal+Realism> (last visited 9/07/2013), legal realism, which originated in the United States in the 1880s and flourished in the 1920s and 1930s, sought to challenge the orthodox view that law is an autonomous system of rules and principles that courts can logically apply in an objective fashion to reach a determinate and apolitical judicial decision. The most famous brand of legal realism is American realism, which was founded by Oliver Wendell Holmes (1841-1935). Other famous American realists are Jerome Frank, the most radical of them all and Karl Llewellyn, who views the function of law in society as the performance of certain 'law jobs' which result in social control and cohesion. On

Because theories seek to justify why intellectual property rights are protected and enforced, some authorities have characterized them as rationales for intellectual property rather than theories.⁷⁷ In this study, therefore, no deliberate attempt was made to distinguish between a theory and a rationale hence the expressions were used interchangeably, the one substituting the other in the specific context.

2.2.2 *The Public Goods Theory*

In terms of this theory, in order to encourage innovation and avoid underproduction of new inventions, inventors must be given adequate incentives. If incentives are not given, then a ‘market failure’ will result and create a public goods problem. Intellectual property rules are, therefore, introduced to exclude free riders.⁷⁸ Free riders will be those people who desire to enjoy the benefit of the good without paying for it.⁷⁹ If free riding is allowed, it will likely lead to underproduction.⁸⁰ Therefore, if the right relates to a patent, the government conveys to an inventor a time-limited property right in the invention.⁸¹ The right implies the prevention of others (including the free riders) from making, selling, offering to sell, importing or even using the patented invention in the patent-granting country during the patent term.⁸²

However, it should be noted that exceptions to the general rule abide in free market economies and their variants.⁸³ Imitation of a competitor’s product is allowed as long as the competition is not deemed to be legally unfair.⁸⁴ In terms of this theory, intellectual property rights must be

the subject of legal realism and intellectual property, see specifically Cohen F “Transcendental Nonsense and the Functional Approach” (1935) 35 *Colombia Law Review* at 814 -817.

⁷⁶ Classical Republicanism is modelled after the Roman Republic, where the government provides its citizens with liberty under government and stresses the common good, or what is best for the society as a whole (see Bellamy R *Political Constitutionalism: A Republican Defence of the Constitutionality of Democracy* (2007) at 67.

⁷⁷ See in this specific regard Mueller at 3 – 40.

⁷⁸ Hettinger E.C “Justifying Intellectual Property” (1989) 13 *Philosophy and Public Affairs* 31 – 52 at 32.

⁷⁹ Mueller above at 7.

⁸⁰ Lemley M.A “Property, Intellectual Property, and Free Riding” (2005) 83 *Texas Law Review* at 1031. See further on a related note, discussing the subject from the perspective of copyright infringement, Demuijnck G “Is P2P Sharing of MP3 Files an Objectionable Form of Free Riding?” in Gosseries A, Marciano A and Strowel (eds) *Intellectual Property and Theories of Justice* (2008) at 141-159.

⁸¹ The time limit for patents is generally 20 years, see the ‘primer’ in para 2.1 above and Article 33 of the TRIPS Agreement.

⁸² See Article 28.1 of TRIPS.

⁸³ For example, voluntary and compulsory licenses may be granted, in violation of the specified rights but as an exception to the general rules (TRIPS Agreement Arts. 30-31).

⁸⁴ Mueller above at 7.

understood to be carefully limited exceptions to the general rule of free and open competition through imitation.⁸⁵

2.2.3 Natural Rights Theory

This theory has been characterized as a deontological justification which has been heavily influenced by intellectual property laws of continental Europe.⁸⁶ The main proponent of the theory is John Locke, who developed ‘a labour theory of property’.⁸⁷ Locke argued that every man has a natural right to the fruits of his work, thus rooting patent law in natural law.⁸⁸ Locke believed that God gave people the earth in common, and that all people have property interests in their own bodies and labour. When a person’s labour is mixed with the objects found in the common, this becomes the mixer’s property, and anyone who takes away the property will be guilty of theft.⁸⁹ The labourer must also hold a natural property right in the resource itself because, as Locke believed, exclusive ownership was immediately necessary for production. This submission was criticised by Jean-Jacques Rousseau,⁹⁰ who convincingly argued that the natural right argument does not extend to resources that one did not create. Both philosophers hold that the relation between labour and ownership pertains only to property that was unowned before such labour took place.⁹¹

The person mixing his labour with common goods must not appropriate all common goods; this is because private ownership depends on leaving some for others. The theory further has a ‘no waste’ condition which implies that one must not take more than what they require. This theory has found wide and easy application in copyright law and not the law of patents.

⁸⁵ Mueller above at 7.

⁸⁶ Morrissey M *An Alternative to Intellectual Property Theories of Locke and Utilitarian Economics* (2012) MA Thesis, Louisiana State University 1-52 at 2.

⁸⁷ See in this specific regard Hettinger EC “Justifying Intellectual Property” (1989) 18 *Philosophy and Public Affairs* 31 and Hughes J “The Philosophy of Intellectual Property” (1988) 77 *Georgetown Law Journal* 287.

⁸⁸ See Locke J. “An Essay Concerning the True Original Extent and End of Civil Government” in Hutchins RM (ed) *Great Books of the Western World* (1952) 25 -30.

⁸⁹ This sounds like a veiled reference to patent infringement.

⁹⁰ Rousseau Jean-Jacques, *The Social Contract or Principles of Political Right* (1762) Book I translated in 1782 by Cole G.D.H available at <http://www.constitution.org/jjr/socon.htm> (last visited 09/07/2013).

⁹¹ Epstein R “The Utilitarian Foundations of Natural Law” (1989) 12 *Harvard Journal of Law and Public Policy* 713 at 733-34

2.2.3.1 Criticism of the Theory

This theory has been criticized on the following grounds. Firstly, the theory seems to provide for perpetual property rights with no passage into the public domain. This theory is not easily applicable to patent law because inventors have to endure administrative procedures instead of having automatic rights to the invention as simplistically suggested.⁹² Other occurrences that interfere with the inventor's exclusive enjoyment of the patent are loss of rights due to parallel inventors once patent is granted to another person and the time limitation on the life of the patent. This theory, however, does have an appeal in human rights law and will in all likelihood be readily embraced by human rights activists.⁹³

The theory does not address the question of balancing proprietary rights against the enhancement of the public domain. Further, the theory does not grapple with the allocation of efforts by multiple inventors. This criticism is premised on the axiom that the invention process is generally cumulative due to the work of an inventor building on the work of earlier inventors.⁹⁴

2.2.4 Theory on the Reward for Services Rendered

One of the major proponents of this theory was Adam Smith.⁹⁵ This theory and the natural rights one discussed above is premised on fairness and fundamental justice to inventors. In terms of the theory, once an inventor has invented something, a reward in the form of the recognition and protection of intellectual property rights is necessary. The theory posits that inventors render a useful service to society and in return, society must reward them for it. Therefore, the inventor has a right to receive a reward while society has a moral duty to give the reward for services of the inventor in proportion to their (services of the inventor) usefulness to society.⁹⁶

2.2.4.1 Criticism of the Theory

The theory has been criticized on a number of grounds. Firstly, the theory does not make it clear whether the reward is for the use of the invention or the inventor's effort. Secondly, assuming that the reward is for the effort of the inventor; how does one justify such a reward in cases of accidental inventions as opposed to conscious effort and hard work? Thirdly, the price the

⁹² Hestermeyer above at 30.

⁹³ Ibid.

⁹⁴ Hestermeyer above at 27.

⁹⁵ Smith A *An Enquiry Into the Nature and Causes of the Wealth of Nations*, Vol III, 11th Ed (1805) 41.

⁹⁶ This may be the main reason why utility is a major requirement for patentability of an invention in most jurisdictions with intellectual property laws.

inventor gets for the invention may not be a measure of the invention's usefulness to society.⁹⁷ The price may be influenced by the fact that the inventor is the only source of the product (monopoly) or the presence or absence of competition.⁹⁸ Sometimes inventions may be created before their time and be regarded as not that useful at the time of their inception but may later turn out to be useful and even time saving.⁹⁹

For such inventions, therefore, at the time when they are invented, the 'reward' society pays for them will not be reflective of the inventions' intrinsic value; hence this theory is flawed in this specific regard. Further and on a related note, some inventions may be overvalued by the market place well beyond their intrinsic value to society. Fourthly and finally, it is common cause that most inventions do not take place in a vacuum but draw heavily on the work of others. If this truism is accepted, the morality of the 'reward' is, therefore, cast in serious doubt. The reward offered to the inventor for the invention is rarely proportional to the social value of the invention.

2.2.5 The Prospect Theory

According to the prospect theory, patents provide the patentee with the necessary legal security to investigate market opportunities and search for venture capital. Patents allow for further research and prevent duplication of similar efforts by others.¹⁰⁰ Patents lay a foundation for future inventions and interested parties will know who to turn to for licenses. The patent itself is an incentive to the inventor to make further investments to maximize the value of the patent.¹⁰¹

2.2.5.1 Criticism of the Theory

Like the other theories discussed and critiqued above, this theory has also not been spared of criticism. One of the major criticisms laid against it has been that it does not appreciate the possibility of researchers working on the same research (in some form of competition) but contributing useful ideas. This surely cannot be considered a waste of resources. In some areas in which technology changes almost daily and such change is desired, such as in software research and biotechnology, a non-proprietary 'innovation commons' is desired, unhindered by the

⁹⁷ Shavell S and van Ypersele T "Rewards Versus Intellectual Property Rights" (1999) *National Bureau of Economic Research Working Paper* 1-35 at 3.

⁹⁸ Shavell and van Ypersele above 4.

⁹⁹ Ibid.

¹⁰⁰ Hestermeyer above at 33.

¹⁰¹ Kitch EW "The Nature and Function of the Patent System" (1977) 20 *Journal of Law and Economics* 260 at 275.

presence of patent rights. According to Hestermeyer,¹⁰² allowing patents to dictate the pace of research would lead to a situation similar to that which befell would-be plane makers after the Wright brothers, the first inventors of the modern airplane used their patent on a feature of airplanes that was no longer in use to impede the efforts of other inventors such as Curtis to improve planes. So frustrating was the action of the Wright brothers that a representative of Curtis had to remark that, ‘a man has to have ten years in law school before he has had a chance of becoming an aviator’.¹⁰³

2.2.6 Exchange for Secrets Theory

This theory posits that had it not been for the incentive to disclose that the patent system provides most innovations and inventions would remain a secret. The patent system, therefore, is a quid pro quo for inventing. The inventor is then conveyed a time-limited right to exclude others from exploiting his invention in exchange for disclosing how to make and use the invention by all once the patent expires. This sounds too simplistic and does not accord with reality.

2.2.6.1 Criticism of the Theory

The most notable criticism levelled against this theory has been the fact that it does not take into account the ‘ripeness of time’ concept in innovation. If inventors working independently do not disclose an invention to the public, in due course, one of them surely will. The reason for the disclosure may be due to the ‘incentive’ alluded to in the tenets of the theory but surely other reasons may spur the disclosure. For instance, an inventor may disclose the invention motivated by the desire to be famous, or the time may be ripe for the invention to be disclosed because the market is ready for it.

It can, therefore, not be confidently stated that the patent system is needed to guarantee the disclosure of inventions that would otherwise be kept secret. Surely, other reasons for disclosure as outlined above may exist. The patent system is, therefore, a sufficient economic incentive to overcome the attractions of trade secrecy, thus facilitating the disclosure of new inventions in exchange for a time-limited right to exclude others.

¹⁰² Hestermeyer above at 34.

¹⁰³ Hestermeyer above at 35 citing Schulman S *Unlocking the Sky: Glen Hammond Curtis and the Race to Invent the Airplane* (2002) at 57.

2.2.7 *Contractual Theory*

This theory became popular in the English and American courts and some of its features prevail to this day. The contractual theory is based on Rousseau's concept of a social contract in terms of which citizens are supposed to undertake to serve the State and the State to protect the citizens.¹⁰⁴ When the theory is applied to intellectual property, it is argued that:

- (a) a creator of a new mental product must undertake to disclose its creation to the community at large and he is then;
- (b) deemed to have ceded all rights in respect of the creation to the State; in return for which;
- (c) the State undertakes to allow the creator a sole right to exploit it for his sole benefit, for a limited period; and
- (d) at the end of the period, the creator loses such rights and the State becomes the sole owner.

2.2.7.1 *Criticism of the Theory*

The contract theory is prone to the following points of criticism: Firstly, it has been convincingly argued that no such contract (express/implied) exists in reality and citizens are unlikely to acknowledge its existence. Secondly, public disclosure takes place in terms of statutes governing such rights, for the purpose of informing the public of the latest developments in 'the art', facilitating new inventions and not to effect a cession. Thirdly, it has been argued that there is no cession to the State or reversion to the creator; the rights are created by formal compliance with statutes and they fall away in terms of the relevant statutory provisions, after which any member of the public may exercise them.

2.2.8 *Theory of Immaterial Property Rights*

The originator of this theory, Josef Kohler, explained for the first time in 1875, that the object of patents or copyright should be sought in the product of the author or inventor's mind rather than his personality.¹⁰⁵ Kohler agrees with Gierke¹⁰⁶ that, as long as a creation only exists as an idea

¹⁰⁴ Jean Jacques Rousseau's widely acclaimed work, *The Social Contract or Principles of Political Right* (1762) is liberally cited in various fields of knowledge, the most common of which is teacher education. Other famous works by Rousseau include *The New Eloise* (1761) and *Emile* (1762).

¹⁰⁵ See generally Kawohl F 'Commentary on Josef Kohler's The Author's Right (1880)' in Bentley L. and Kretschmer M (eds) *Primary Sources on Copyright (1450-1900)* (2008) available at http://copy.law.cam.ac.uk/cam/tools/request/showRecord?id=commentary_d_1880 (last visited 19/07/2013).

¹⁰⁶ Otto Von Gierke explains the nature and legal objects of intellectual property rights, through his theory of personality rights. According to Gierke, creations are inseparable components of the creator's (inventor or writer's) personality and the rights emanating from such creations fall in the category of personality rights, similar to the right

in its creator/inventor's mind it belongs to (and the creator's activity does not extend beyond) the domain of his personality.¹⁰⁷ Therefore, it is essentially a personality right, since thoughts cannot be the objects of rights on their own, the underlying right being a personality right.¹⁰⁸ The theory resonates with Gierke's reference to the vague concept of 'mental product'. Further, it should be mentioned that not all the products of the mind are necessarily worthy of protection. For example, it is not the idea how to play a game that is patentable, but the apparatus used to play it.¹⁰⁹ Copyright for instance, only exists on an idea if it is reduced to a document or book form.¹¹⁰

Only after the idea assumes an individual character or is materially expressed in an outwardly perceptible form,¹¹¹ can it assume an individual and independent character, acquire an economic value and be stolen.¹¹²

2.2.8.1 Criticism of the Theory

The main criticism against this theory is that it fails to explain the relationship, the similarities or distinctions between accepted objects of intellectual property *inter se*, for example, between goodwill (which is a product of business tactics rather than a mental product) and a trade mark. The two are in a sense linked to each other. A link also exists between an invention and a design, or between copyright and other intellectual property rights. Traditionally, only the well-known four categories of subjective rights were recognised, that is, real rights, personal rights, personality rights and intellectual property rights.¹¹³ Legal objects such as creditworthiness, earning capacity, goodwill and others were acknowledged to have elements of both intellectual

to one's good reputation that is never separable from the inventor's personality. This premise is unconvincing in that it fails to acknowledge that such rights, once the underlying idea is materially expressed, can exist separately from their creator.

¹⁰⁷ Kawohl note 104 above 2.

¹⁰⁸ Ibid.

¹⁰⁹ Section 1(2) (c) of the United Kingdom Patents Act 1977 as amended, available at <http://www.legislation.gov.uk/ukpga/1977/37> (last visited 19/07/2013). A similar provision is provided for in Article 52(2) c) of the European Patent Convention, available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/\\$FILE/EPC_14th_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf) (last visited 19/07/2013).

¹¹⁰ Kopel S *Guide to Business Law* (2009) at 420.

¹¹¹ Documented, reduced to material form etc. i.e. transformed from the sphere of the personality to the sphere of communication.

¹¹² See Generally *Haupt t/a Soft Copy v Brewers Marketing Intelligence (Pty) Ltd and Others* 2006 (4) SA 458 (SCA).

¹¹³ See Kruger H and Skelton A (eds) *The Law of Persons in South Africa* (2010) 12-19 and Boezaart T *Law of Persons* 5th Ed (2010) 2.

property (they have economic value) and personality (they do not really exist separately from the person concerned).

Neethling and others¹¹⁴ argue that another category must be recognised, namely personal immaterial property rights, which unlike personality rights have economic value and do not automatically, come into existence with a person's birth. The holder must first build up a professional or business reputation and these rights can have an economic value but they cannot like personality rights, be transferred/bequeathed to others, or be attached.

Contrary to Neethling's argument, other authorities argue that these are only aspects of a person's personality, but Neethling and his colleagues unswervingly argue that these rights can be infringed, without necessarily infringing the holder's personality, for example, on the destruction of a lawyer's library, or a person's computer containing essential information.

2.3 Theories of Intellectual Property and Access to Medicines: A very Brief Contextual and Preliminary Evaluation¹¹⁵

From the discussion of the theories or rationales above, an impression is created that utilitarian theories aim at the maximization of social welfare. This implies that there is a need to strike a balance between encouraging invention or innovation and ensuring that social welfare is not compromised. The approach is likely to be attractive to access activists, Non-Governmental Organisations (NGOs) and governments in the developing countries which are grappling with access issues.

On the other hand, the natural rights theory which is premised on the use by an inventor of goods that are unowned or 'held in common', gives the inventor a natural property right to the fruits of his endeavour. This argument is likely to appeal to big pharmaceutical companies obsessed with profit maximization when they sell their patented drugs. Access arguments, like the proposals to introduce parallel imports and compulsory licences on equity grounds, are less likely to convince pharmaceutical companies with 'natural rights' to the drugs to sell to the poor at affordable

¹¹⁴ Neethling J, Potgieter JM and Visser PJ *Law of Personality* (2005) at 5.

¹¹⁵ My evaluation and contextualization of the theories against the research objectives is brief here because it pre-empts my proposed possible solutions, forming the bedrock of the thesis in Chapter Seven below. This evaluation therefore continues in its proper context in Chapter Seven

prices. There will, therefore, be a need to weigh the pharmaceutical companies' rights to their intellectual property and the poor consumers' rights to affordable essential medicines.

The third group of theories, derived from the writings of Kant and Hegel, emphasize that private property rights are crucial to the satisfaction of fundamental needs; hence policymakers should strive to create and allocate entitlements to resources in a manner that best enables people to fulfil those needs. This theoretical approach may be used to justify the continued existence of patents on essential medicines on the basis that banning patents would be an anathema to social welfare. A counter argument, based on the same theoretical approach can be raised on behalf of those lacking access to essential medicines namely, that the state must ensure an equitable allocation of resources taking into account the citizens' ability to pay.¹¹⁶

The last of the four approaches is rooted on the premise that property rights in general and intellectual property rights in particular, can and should be shaped so as to foster the achievement of a just and attractive culture. Proponents of the fourth approach draw their inspiration from political and legal theorists such as Jefferson, the old Marx, legal realists, and the various proponents of classical republicanism. The approach is also relevant to access to medicines from the perspectives of both access activists and pharmaceutical companies. A 'just and attractive culture' may be achieved through allowing pharmaceutical companies to recoup their Research and Development (R&D) costs by charging market related costs for patented medicines.¹¹⁷ This recoupment does somewhat amount to a reward to the pharmaceutical company for engaging in the research that culminates in the production of the patented drug.¹¹⁸ On a simplistic analytical level, allowing for such rewards will lead to justice for the pharmaceutical companies.

On the other hand, viewed from the perspective of those in dire need of access to medicines, such a form of 'justice' will, in all likelihood, amount to a travesty of justice.¹¹⁹ Rather than just reward the development of a new drug through the granting of patents, it has been argued that the development of a new drug ought to be rewarded in proportion to its impact on the global disease

¹¹⁶ See generally Dietsch P "Patents on Drugs – The Wrong Prescription?" in Gosseries A, Marciano A and Strowell A (eds) *Intellectual Property and Theories of Justice* (2008) at 230-245.

¹¹⁷ Pogge TW "Human Rights and Global Health: A Research Programme" (2005) 36 *Metaphilosophy* at 182-209.

¹¹⁸ Shiffrin SV "The Incentives Argument for Intellectual Property Protection" in Gosseries A, Marciano A and Strowell A (eds) *Intellectual Property and Theories of Justice* 94-105.

¹¹⁹ Pogge above at 182 argues that the imposition of the TRIPS in its current form is a human rights violation in light of the avoidable mortality it causes due to expensive patented essential medicines which remain hardly accessible to the poor.

burden, and not through monopoly rents.¹²⁰ Such a version of the rewards theory would lower the prices of drugs and stimulate pharmaceutical research into currently neglected diseases affecting the poor,¹²¹ including those in the SADC region. Despite possible implementation challenges that are likely to accompany the employment of such an approach, if carefully thought through, the ‘new’ rewards approach is likely to lead to positive access results.

From the brief discussion above, it is evident that I subscribe to the Lockean perspective wherein human beings take what nature provides and mix it with their own labour so that it becomes their property.¹²² This perspective will work well when blended with incentives and rewards to create some form of social contract. Once human beings have mixed what nature provides with their own labour, patents may then be granted to protect the effort in the form of rewards/incentives. For equitable results, such rewards/incentives must be viewed from both a pharmaceutical industry¹²³ and access to medicines perspective. This will, therefore, call for a blended theory¹²⁴ or theories that take into account the reality presented by TRIPS flexibilities and the situation obtaining in the SADC region, wherein more than half of the membership consists of poor Least Developing Countries (LDCs).

It is axiomatic that the above discussion does somewhat point to the need for an exploration of other theories that can be blended for the developing world and SADC in particular. A hybrid model that includes some of the relevant elements of selected discussed theories can be suggested for this purpose.¹²⁵ SADC Member States may also pursue policies that facilitate intra-regional access to medicines. This may take the form of a regional common binding legal or policy agreement, based on any of the prominent TRIPS flexibilities.¹²⁶ Compulsory licenses are hereby suggested as a common regional access vehicle, and their importance is discussed in chapters four, five, six and seven below.

¹²⁰ Pogge above at 182.

¹²¹ Ibid.

¹²² Morrissey M *An Alternative to Intellectual Property Theories of Locke and Utilitarian Economics* (2012) MA Thesis submitted to Louisiana State University at 1-52.

¹²³ See very specifically in the context of pharmaceutical patents Belleflamme P “How Efficient is the Patent System? A General Appraisal and Application to the Pharmaceutical Sector” ” in Gosseries A, Marciano A and Stowell A (eds) *Intellectual Property and Theories of Justice* at 201-224.

¹²⁴ This blended theory is the thesis of this study and is suggested as a solution to the SADC access problem. The hybrid theory, discussed in detail in Chapter Seven below borrows from the tenets of distributive justice, John Rawls’ Theory of Justice and Locke’s theory of rewards.

¹²⁵ See Chapter Seven below.

¹²⁶ This recommendation and others related to are discussed and critiqued in Chapter Seven.

2.4 International Patent Law in the Context of Patents and Access to Medicines

2.4.1 Preliminary Remarks

At the international level, patents are regulated by the rules encapsulated in international conventions such as the Paris Convention and the general WTO rules under the GATT 1994 and the TRIPS Agreement. The aim of this section of the study is to explore the applicable international legal regime applicable to the study in the context of access to medicines by identifying the salient provisions of the WTO and TRIPS directly relevant hereto. Before delving into the specifics of international patent law in the context of access to medicines, it is appropriate to first render a historical account of the patentability of pharmaceutical products. This is important because this study deals with access to patentable pharmaceutical products in the context of the TRIPS Agreement. An account of the historical patentability of pharmaceutical products will, therefore, be very appropriate at this stage to further contextualize the study, after the theoretical exploration and critique rendered in the preceding discussion above.

2.4.2 Historical Patentability of Pharmaceutical Products

Although many developed countries and some ex-colonies had patents on medicines by the 1960s, a large number of developing countries in Europe and many developing countries did not provide patents for pharmaceutical products. Many countries did not start providing for pharmaceutical patents voluntarily until the 1980s and involuntarily after the passage of the TRIPS Agreement.

The first statutes defined explicitly what was eligible for patentability.¹²⁷ The Patent of Monopolies¹²⁸ allowed patents for ‘the sole working or making of any matter of new manufacture’.¹²⁹ This was interpreted by the courts to include patents on ‘substances formed by chemical and other processes’.¹³⁰ Meanwhile, the United States Patent Act¹³¹ had allowed patents

¹²⁷ In this study, the English Statute of Monopolies and the United States Patent Act of 1790 are regarded as one of the key first statutes.

¹²⁸ Passed on 25 May 1624.

¹²⁹ Section VI of the Statute of Monopolies.

¹³⁰ See *Boulton v Bull*, Court of Pleas and Exchequer Chamber, 1795 126 Eng. Rep 651, 660. Later, the term ‘other process’ was extended to cover the processes themselves.

¹³¹ The US Patent Act of 1790 was the first patent statute passed by the federal government of the United States. It was enacted on April 10, 1790, about one year after the constitution was ratified and a new government was organized. Before then, each State had its own peculiar patent laws [source Devaiah V ‘A History of Patent Law at <http://www.sarai.net/research/knowledge-culture/critical-public-legal-resources/historyofpatentlaw.pdf> (last visited 18/03/2012)].

for the invention of ‘any useful art, machine, manufacture, or composition of matter, or any new and useful improvement...’¹³² The modern United States patent law¹³³ allows patents on ‘any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.’¹³⁴ The whole section which is relevant in this instance is reproduced below:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.¹³⁵

The composition of matter mentioned in the above cited provision of the legislation, therefore, will cover pharmaceuticals.

The fear of public health effects of patents on pharmaceuticals led some countries to adopt a cautionary approach to pharmaceutical patents. The French Patent Act¹³⁶ for example, excluded ‘*[L]es compositions pharmaceutiques ou remèdes de toute espèce*’, (my emphasis) that is, pharmaceutical compositions or medicines of all kinds from protection.¹³⁷ The Act banned patents on pharmaceutical products and their pharmaceutical composition but not the process of fabrication of a pharmaceutical substance.¹³⁸ The ban remained until 1959 when an ordinance was passed providing that patents would be granted for pharmaceutical products with the possibility of issuing compulsory licences in the case of insufficient quantities and abnormally high prices. To date, methods of surgical or therapeutic treatment and diagnostic methods are still not patentable under French law due to their alleged lack of industrial application.¹³⁹ The reluctance to grant pharmaceutical patents and chemical ones was not only confined to England, the US and France. Many industrialised countries maintained this form of ban until specific periods in their history.¹⁴⁰ The other approach to pharmaceutical patents and public health,

¹³²Section 1 of the US Patents Act 1790.

¹³³Title 35 of the United States Code.

¹³⁴ 35 U.S.C § 101.

¹³⁵35 U.S.C § 101.

¹³⁶ French Patent Act, adopted on 5 July 1844.

¹³⁷ See Kropholler J and Zweigert K *Sources of International Uniform Law* (1973) at 718.

¹³⁸ This obviously did not auger well for patent protection, thus leaving the product vulnerable to illegal reproduction with impunity.

¹³⁹ See Article L 611-616 and Article 611-610 para 1 of *Code de la Propriété industrielle* (1996) 34.

¹⁴⁰ According to Koshy S “The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective” (1995) 1 *Journal of Science & Technology Law* 4, Germany maintained the ban until 1968, Japan until 1976, Switzerland until 1977, Italy until 1978, and Spain, Portugal and Norway until 1992.

adopted by some countries such as the United Kingdom and Canada was to grant compulsory licenses¹⁴¹ in pharmaceutical products until the early 1990s.¹⁴²

It is, therefore, inevitable that given the initial resistance to the patentability of pharmaceuticals as outlined in the preceding paragraphs, adherence to an international harmonized legal system was necessary. This harmonization, despite its inherent limitations did come in the form of TRIPS in 1994. This had been preceded by the Paris Convention and the GATT of 1947. It is now appropriate, therefore, to turn our discussion to the international legal regulatory regime applicable to pharmaceutical patents under the most important international instruments.

2.4.3 International Intellectual Property Law before TRIPS

2.4.3.1 Preliminary Issues

An increase in international trade in cross border trade necessitated patent protection in other countries and national patent laws of the 18th and 19th centuries were very disparate.¹⁴³ Some laws did not allow patent protection of foreign products while others prevented patents on already patented products, on the basis that there was no novelty.¹⁴⁴ The problem was further compounded by the different laws, languages, stringent time frames and other impediments unique to the international context with the publication of a patent specification in one country destroying novelty.¹⁴⁵

2.4.3.2 The Paris Convention

At the international level, intellectual property used to be regulated by a small number of treaties, chief among which was the Paris Convention.¹⁴⁶ The adoption of this Convention was preceded by the international conference on patent rights in 1873, in Vienna, Austria. Initially, the US inventors contemplated not attending the conference because they feared that the conference would result in the loss of protection and copying of their inventions. At the conference, the US

¹⁴¹ See chapters five and six below.

¹⁴² Koshy S “The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective” (1995) 1 *Journal of Science & Technology Law* 4 11.

¹⁴³ Hestermeyer above at 34.

¹⁴⁴ Hestermeyer above at 34. This was despite the fact that patent law by its very nature is territorial and registration in one jurisdiction, in the absence of a corresponding Patent Cooperation Treaty (PCT) application, does not necessarily prevent registration in another jurisdiction.

¹⁴⁵ Ibid.

¹⁴⁶ The Paris Convention for the Protection of Industrial Property was adopted in 1883.

stance was to conceive patents as property rights¹⁴⁷ than instruments of public policy. By 1 January 1995 when the TRIPS came into being under the auspices of the WTO, the Paris convention had already been ratified by 129 states.¹⁴⁸ Developing countries were reluctant to sign the Paris Convention.¹⁴⁹ This was partly due to the fear that innovation and creativity in developing countries would be arrested by the liberalisation of intellectual property in the absence of technical assistance being afforded to the developing countries.¹⁵⁰

Correa and Yusuf report that despite embracing TRIPS norms in 1990 through the proposal submitted to the TRIPS' Council by a group of 14 developing countries, concerns about the availability, scope and use of intellectual property lingered on.¹⁵¹ In the context of this study, these concerns were partially addressed later through the Doha Declaration on the TRIPS agreement and public health¹⁵² and the WTO General Council decision amending the TRIPS Agreement.¹⁵³ These important legal developments are discussed in their proper context in chapter four below.

The Paris Convention sets up a union for the Protection of Industrial Property with a secretariat to carry out administrative tasks for the Union.¹⁵⁴ The convention, which recognizes and applies the obligation of national treatment, did improve cross-border patenting. It simplifies the patent application process by allowing a patentee who filed a first patent application in a member state a 12 month priority period to file in other states.¹⁵⁵ The convention has substantive rules on compulsory licensing¹⁵⁶ and revocation.¹⁵⁷ Under the convention, the forfeiture of a patent is

¹⁴⁷ This is a natural law approach as discussed under 'theories of intellectual property' above.

¹⁴⁸ At the time of writing, the convention boasted ofmembers.

¹⁴⁹ Mathews D *Globalising Intellectual Property Rights: the TRIPS Agreement* (2002) at 10.

¹⁵⁰ Correa CM and Yusuf A.A (eds) *Intellectual Property and International Trade: The TRIPS Agreement* (2008) at 36.

¹⁵¹ Correa and Yusuf above at 9.

¹⁵² Doha Declaration on the TRIPS agreement and public health, adopted on 14 November 200, WT/MIN(01)/DEC/2 20 November at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited 09/07/2013).

¹⁵³ The WTO GENERAL COUNCIL decision amending the TRIPS Agreement WT/L/641 8 of December 2005, available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (last visited 09/07/2013).

¹⁵⁴ This task is today carried out by the WIPO, a specialized agency of the United Nations set up in 1970, which administers 23 other intellectual property conventions.

¹⁵⁵ Namely, member states.

¹⁵⁶ This aspect is quite relevant to this study, which in essence deals with the use of compulsory licenses to improve access to medicines in the SADC region.

¹⁵⁷ Article 5A (2).

possible if a compulsory license would not be sufficient¹⁵⁸ and may not be the consequence of mere importation by the patentee of the patented product into the country of the patent grant. The 1970 Patent Cooperation Treaty facilitates obtaining normal patents from national and regional patent offices under their laws.¹⁵⁹

2.4.3.3 *The GATT/WTO*

Intellectual property was basically considered in the GATT context as an ‘acceptable obstacle’ to free trade at least until the Tokyo round.¹⁶⁰ Most intellectual property protection negotiations in this round hovered around counterfeits.¹⁶¹ During the WTO Uruguay Round of negotiations,¹⁶² industrialised countries did not want to undermine the WIPO, with the United States particularly regarding negotiation on trade-related intellectual property as a condition precedent to the launching of the Uruguay Round.¹⁶³ This was motivated by the United States’ desire to find a market for its burgeoning patents and innovation industry then. On the other hand, developing countries were vehemently opposed to the inclusion of intellectual property issues in the negotiations, due to the apprehension that they would later amount to a protectionist tool and an obstacle to free trade.¹⁶⁴ Despite the resistance from the developing countries, in the Uruguay Round, intellectual property was included as an express item for negotiation.¹⁶⁵ Towards the end of the Round, intellectual property ranked together with agriculture as the issues that could make or break the round.¹⁶⁶

Under GATT, intellectual property was a permissible impediment to trade.¹⁶⁷ A few exceptions such as Articles III,¹⁶⁸ XXII and XXIII,¹⁶⁹ IX, XX (d),¹⁷⁰ XII: 3 (c), XVIII: 10 and IX are worth

¹⁵⁸ Article 4.

¹⁵⁹ It is now possible to file a single international application and regional organisations such ARIPO and OAPI, which are also able to grant bundles of national patents, are complimentary in this specific regard.

¹⁶⁰ Gervais 7. The round lasted from 1973 -1979.

¹⁶¹ For examples, the draft of the Agreement on Measures to Discourage the Importation of Counterfeit Goods was circulated in 1979 and 1974 while the Decision on Trade in Counterfeit Goods was contained in the Ministerial Declaration of 29 November 1982.

¹⁶² The Uruguay Round covered the period 1986-1994.

¹⁶³ See foreword by Anel L, then chairman of the negotiating group on trade –related aspects of intellectual property Rights, including trade in services, in Gervais D *The Trips Agreement: Drafting History and Analysis* (2003) at vii-viii.

¹⁶⁴ Ibid.

¹⁶⁵ See GATT Ministerial Declaration on the Uruguay Round of Ministerial Trade Negotiations (1986) 25 ILM 1623 of 20 September 1986, reproduced in full by Hestermeyer above at 44.

¹⁶⁶ Gervais at viii.

¹⁶⁷ This was generally provided for in Article XXIV (d) of GATT 1947.

noting in this regard. *The United States – Imports of Certain Automotive Spring Assemblies*¹⁷¹ dispute is widely regarded as the first patent infringement case in the GATT history.¹⁷² In another GATT dispute involving the US government,¹⁷³ the Panel made it clear that in light of article XX (d), the substantive patent law of a contracting party could probably not be challenged under GATT, but contracting parties were enjoined to enforce their patent laws in a manner that was not inconsistent with GATT provisions. Therefore, in terms of the *US – Section 337 of the Tariff Act of 1930*,¹⁷⁴ contracting parties are allowed to adopt protectionist policies which may restrict international trade in goods in order to protect intellectual property. Contracting parties' individual, national and intellectual property laws would, therefore, grant the right to block the entry of infringing goods into the customs territory in order to protect intellectual property rights.

It is, therefore, possible for developed countries to retaliate for GATT or General Agreement on Trade in Services (GATS) violations by suspending obligations under the TRIPS Agreement or any other similar agreement. Indeed, there are instances when developed countries resorted to unilateral pressure when multilateral negotiations failed.¹⁷⁵ The implications for fair and just trade in this context are dire as countries with the political and economic wherewithal bully the weaker ones into submission.

Unilateralism of this nature would in all likelihood lead to negative access to medicines results as the South African Medicines Act example, narrated briefly below showed.

¹⁶⁸ National treatment.

¹⁶⁹ Dispute settlement.

¹⁷⁰ Protection of human health.

¹⁷¹ Report of the Panel adopted on 26 May 1983 (L/5333 - 30S/107), available at <http://www.worldtradelaw.net/reports/gattpanels/usspringassemblies.pdf> (last visited 18/04/2012)

¹⁷² Gervais above at 5.

¹⁷³ *United States - Section 337 of the tariff act of 1930*. Report by the Panel adopted on 7 November 1989. (L/6439 - 36S/345), available at http://www.wto.org/english/tratop_e/dispu_e/87tar337.pdf (last visited 18/04/2012).

¹⁷⁴ Ibid.

¹⁷⁵ An example cited by Hestermeyer at 45 is the withdrawal of trade benefits under the generalized system of preferences by countries such as the US when there was a perceived failure to grant intellectual property protection.

The 1968 Stockholm conference adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organisation (WIPO) in 1970.¹⁷⁶ The history of TRIPS, discussed below, starts with GATT¹⁷⁷ through to the Uruguay Round that gave birth to the WTO.

2.4.4 International Intellectual Property Law under TRIPS

2.4.4.1 Preliminary Remarks

The preamble to the TRIPS Agreement¹⁷⁸ expressly spells out the objectives negotiating parties sought to achieve during the negotiations, which are said to have been one of the most difficult both politically and economically.¹⁷⁹ The preamble spells out six important issues/objectives.¹⁸⁰

Firstly, the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods is recognized.¹⁸¹ Secondly, intellectual property rights are recognized as private rights.¹⁸² Thirdly, the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives are recognized.¹⁸³ Fourthly and very importantly for this study, the agreement recognizes the special needs of the least-developed country members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and technological base.¹⁸⁴ Fifthly, the importance of avoiding and reducing tensions is given prominence by committing to the resolution of trade-related intellectual property issues through multilateral procedures, thus limiting the impact of unilateralism and its accompanying pejoratives and other unintended ills.¹⁸⁵ Finally, the preamble spells out clearly

¹⁷⁶ Gervais at 3. WIPO administers the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works and the Rome Convention on the Rights of Performers, Broadcasters and products of phonographs (also known as neighbouring rights) jointly with UNESCO and the International Labour Office (Gervais at 9).

¹⁷⁷ Gervais at 5. GATT signatories were called 'contracting parties' and not 'members' when referred to individually. However, when they acted together as a constituent body, they were referred to as 'CONTRACTING PARTIES' (in capital letters).

¹⁷⁸ The full text of the TRIPS Agreement is reproduced as Annex 1 in Taubman A, Wager H and Watal J A *Handbook on the WTO TRIPS Agreement* (2012) 247-288.

¹⁷⁹ Correa (2007) 1 citing Hoekman B and Kostecki M *The Political Economy of the World Trading System: the WTO and Beyond* (2001) 283.

¹⁸⁰ Taubman, Wager and Watal above at 248-249.

¹⁸¹ TRIPS preamble paragraph 8.

¹⁸² TRIPS preamble para 9.

¹⁸³ Ibid para 10.

¹⁸⁴ Ibid para 11.

¹⁸⁵ Ibid para 12.

the objective to establish a mutually supportive relationship between the WTO and WIPO as well as other relevant international organisations.¹⁸⁶

While the above stated objectives generally reflect plural views, it has been argued that substantially they are protectionist and in line with the United States' and developed countries' protectionist stance on intellectual property generally.¹⁸⁷ This study subscribes to this view and opines that in its context, had the TRIPS not been heavily influenced by the entrenched developed countries' views on intellectual property,¹⁸⁸ the access to medicines problem could be less acute today.

The example that clearly shows that developed countries and the United States' views prevailed is the fact that during the negotiations, pharmaceutical patents were discussed and their inclusion on the IP list was strongly resisted by the developing countries on public health grounds.¹⁸⁹ This argument, despite its logical and reality based appeal, was rejected and the developed countries' views, and principally the views of the United States prevailed, hence the access to medicines mess we have to date.¹⁹⁰ It is heartening, however, to write that the position is not as gloomy as one would imagine since the developing countries found their voices during the negotiation of the Agreement on TRIPS and Public Health by establishing a coalition and had it maintained throughout the negotiating process thus preventing being outmanoeuvred by the EU-US block.¹⁹¹

The basic assumption for the negotiation of the TRIPS is encapsulated in the preamble's *chapeau*.¹⁹² The wording of the *chapeau* is entirely drawn from the Punta Del Este Ministerial

¹⁸⁶ TRIPS Agreement para 13.

¹⁸⁷ Correa above at 1.

¹⁸⁸ Hereafter IP.

¹⁸⁹ See generally Abbot F.M "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" (2002) 5 *Journal of International Economic Law* at 469.

¹⁹⁰ Relief had to however come during the negotiations of the Agreement on TRIPS and public health when developing countries established a coalition motivated by common developmental interests and asserted their view, which subsequently carried the day, that the TRIPS must be interpreted in such a manner as to promote public health objectives as reported by Abbot above note 169 and Gathii JT "The Doha Declaration on Trips and Public Health Under the Vienna Convention of the Law of Treaties" (2002) 15 *Harvard Journal of Law and Technology*, available at SSRN: <http://ssrn.com/abstract=315371> or <http://dx.doi.org/10.2139/ssrn.315371> (last visited 10/07/13).

¹⁹¹ Abbot above at 469.

¹⁹² The wording of the entire Chapeau was entirely drawn from the paragraph in the Punta del Este Ministerial Declaration that launched the Uruguay Round (Correa at 1).

Declaration that launched the Uruguay round.¹⁹³ The *chapeau* puts a lot of emphasis on ‘effective’ and ‘adequate’ IP protection. On this very point of adequate and effective protection of IP, Correa submits that the national standards of IP protection consistent with the TRIPS obligations are to be considered ‘effective’ and ‘adequate’.¹⁹⁴ If this submission is pursued to its logical conclusion, then ‘TRIPS-plus’ IP protection may, therefore, be justified on this basis as effective or adequate as may be the case in some regional integration arrangements (RIAs).¹⁹⁵

In summary, the TRIPS Agreement was negotiated to address problems of unauthorised copying, unauthorised imports for domestic sale, disincentives created by inadequate protection (from the perspective of investors and inventors), the use of IP to discourage imports in favour of local production and disparities in the protection of IP in different jurisdictions.¹⁹⁶ It lays down mandatory minimum standards of IP protection and enforcement, based on pre-existing international conventions.¹⁹⁷ The TRIPS establishes positive regulatory objectives for the members.¹⁹⁸

2.4.4.2 Nature and Scope of Obligations under TRIPS

The TRIPS enjoins members to give effect to the provisions of the Agreement.¹⁹⁹ Such a statement is a restatement of the vital *pacta sunt servanda* principle of international law which is based on the doctrine of good faith.²⁰⁰ Despite all this, Article 1.1 does not specify how such

¹⁹³ Correa above at 1. The paragraph listed the reduction of distortions and impediments to international trade, the need to promote effective and adequate protection of intellectual property rights and ensuring that measures and procedures to enforce intellectual property do not themselves become barriers to legitimate trade as some of its key obsessions.

¹⁹⁴ Correa above at 2.

¹⁹⁵ Regional integration arrangements, in the form of free trade areas, customs unions and other interim arrangements which may later culminate in free trade areas or customs unions are permitted in terms of Article XXIV of GATT 1994 as an exception to the general rule against the prohibition of discrimination. The SADC is a customs union. On the subject of the SADC customs union and questions around its compatibility with WTO tenets, see generally Saurombe A “The Southern African Development Community Trade Legal Instruments Compliance with Certain criteria of GATT Article XXIV” (2011) 14 *Potchefstroom Electronic Law Journal/Potchefstroom Elektroniese Regstydskrif* available at <http://dx.doi.org/10.4314/pelj.v14i4.10> (last visited 18/04/2012).

¹⁹⁶ Van Den Bossche P *The Law and Policy of the World Trade Organisation: Text, Cases and Materials* (2008) at 748. See further, Drahos P “Developing Countries and International Intellectual Property Standard-Setting” (2002) 5 *Journal of Intellectual Property* at 765 -789 and Gervais D *The TRIPS Agreement: Drafting History and Analysis* (2003) at 8.

¹⁹⁷ Van Den Bossche above at 742.

¹⁹⁸ Ibid.

¹⁹⁹ Per Article 1.1 of TRIPS.

²⁰⁰ The legal and other principles underpinning the *pacta sunt servanda* concept are exposed and discussed in context by Lukashuk I I “The Principle of Pacta Sunt Servanda and Nature of Obligation under International Law” (1989) 83 *American Journal of International Law* 513 -518.

obligations are to be implemented. Members will inevitably give effect to the TRIPS' obligations in the context of their jurisdictions by passing TRIPS compliant legislation. Article 1.1 also allows for diversity in the methods of implementing the agreement through relevant legislation, in the absence of which the pertinent TRIPS provision will have to be considered as self-executing. This is very important in the context of this study which seeks to domesticate or municipalise TRIPS flexibilities to SADC members' legislation so that access to medicines may be improved.²⁰¹ IP refers to all the categories of intellectual property that are the subject of sections 1-7 of part 2 of TRIPS.²⁰²

Implementation of the TRIPS is problematic for the developing countries due to asymmetries in technological, economic and other spheres.²⁰³ The often cited submission that the TRIPS lays down minimum standards of IP protection is an inaccurate statement with no textual basis in the agreement itself.²⁰⁴ While the adoption and use of TRIPS-plus protection has been resorted to before for reasons other than altruistic, the route largely remains facultative.²⁰⁵ The reason for this submission is that TRIPS provides that no member is obliged to implement in its national law 'more extensive protection than is required in this agreement'.²⁰⁶

²⁰¹ The domestication of TRIPS provisions will depend on whether a particular country adopts a dualist or monist approach to international law. For a detailed note on the differences between monist and dualist approaches, see Dugard J "International Law and the South African constitution" (1997) 8 *European Journal of International Law* at 77; Olivier ME "The Status of International Law in South African Municipal Law: Section 231 of the 1993 Constitution (1994) 19 *South African Yearbook on International Law* at 5; Olivier ME, "Interpretation of the Constitutional Provisions Relating to International Law" (2003) 6 *Potchefstroom Electronic Law Journal* at 26 and Scholtz W "A Few Thoughts on s231 of the South African Constitution" (2004) 29 *South African Yearbook on International Law* at 202.

²⁰² The list includes copyright and related rights, industrial designs, patents, layout designs of integrated circuits and industrial information. See further the *US – Section 211 Omnibus Appropriations Act* of 1998, WT/DS176/R, 6 August 2001, para 8.26 on the interpretation of the terms 'intellectual property' and 'intellectual property rights' in Article 1.2 of TRIPS.

²⁰³ Correa above at 23.

²⁰⁴ Gervais above at 286.

²⁰⁵ Ibid.

²⁰⁶ It has been submitted by some authorities such as Gervais above at 286 and Correa above at 24 that the cited portion is probably based on article 20 of the Berne Convention for the Protection of Literary and Artistic Works (1896) as revised and amended variously until 1979. Article 20 deals with 'Special Agreements among Countries of the Union'. The full text of the Berne Convention is available at http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html (last visited 19/04/2012).

The TRIPS is subject to the WTO principles that ensure non-discrimination, namely the national treatment and the most favoured nation principles.²⁰⁷ In the next section, the two major pillars of non-discrimination are outlined *seriatim* and contextualized to access to medicines.²⁰⁸

2.4.4.3 National Treatment and TRIPS

The TRIPS is subject to a whole system of rules and disciplines incorporated into the GATT 1994 despite its *sui generis* status in the WTO.²⁰⁹ In terms of TRIPS, members shall accord nationals of other States treatment no less favourable than that accorded to nationals with regard to the protection of IP.²¹⁰ It is important to note that national treatment here, unlike in the GATT 1994 context of trade in goods, is targeted at the treatment of *nationals* (my emphasis) and not goods or products.²¹¹ Whereas GATT, on the one hand talks of ‘like products’, TRIPS on the other hand, talks of ‘like persons.’²¹² The concept of ‘nationals’ is very crucial as spelt out by the panel report on *EC – Protection of Trademarks*,²¹³ wherein the panel opined that ‘nationals’ of a member and the other member need to be defined.²¹⁴ Who the nationals are can be determined by reference to the principles of public international law.²¹⁵ The most important principles in this context are domicile and real and effective industrial or commercial establishment.²¹⁶

Exceptions do, however, exist, specifically in situations where such exceptions are necessary to secure compliance with laws and regulations which are not consistent with TRIPS provisions.²¹⁷

²⁰⁷ The most favoured nation treatment is provided for in article I of GATT 1994 while national treatment is provided for in article III of same.

²⁰⁸ See paras 2.3.4.3 and 2.3.4.4 below.

²⁰⁹ See specifically in this regard *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R 1998, para 7.19.

²¹⁰ Article 3.1 of TRIPS.

²¹¹ In the context of GATT 1994, imported goods originating from other members’ customs territories shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, purchase, transportation, distribution or use as provided for in Article III:4 of GATT.

²¹² See relatedly Article XVII of the General Agreement on Trade in Services (GATS) which refers to ‘like service sectors’.

²¹³ For a scholarly analysis of this dispute, see Martin S “Towards a Horizontal Standard for Limiting Intellectual Property Rights? WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law” (2006) 37 *International Review of Intellectual Property and Competition Law* at 407-438.

²¹⁴ *EC-Protection of Trademarks*, panel Report, WT/DS1741R, 15 March 2005, para 7.150.

²¹⁵ *Ibid.*

²¹⁶ Van Den Bossche P *The Law and Policy of the World Trade Organisation: Text, Cases and Materials* 2nd Ed (2008) at 757. See further Footnote 1 of Article 1 (3) of the TRIPS Agreement.

²¹⁷ Article 3.1 of TRIPS.

National treatment was common even in pre-TRIPS international conventions on intellectual property rights.²¹⁸

The way the national treatment obligation is couched in TRIPS leaves great flexibility to design intellectual property laws since it does not commit states to a provision of certain levels of protection.²¹⁹ Other pre-TRIPS Conventions include both national treatment and an important set of standards to be used.²²⁰ Incorporation of the national treatment in the TRIPS implies that it will now be applied in WTO disputes in the context of WTO jurisprudence.²²¹

Discrimination that violates the national treatment principle in the TRIPS context can either be *de facto* or *de jure*.²²² *De jure* discrimination may come about as a consequence of rules in the national law formally according more favourable treatment to nationals *vis-à-vis* foreigners in the same factual and legal context. However, not all such forms of *de jure* discrimination will be actionable since it has already been pointed out that exceptions do exist.²²³ On the other hand, rules that formally treat on an equal footing nationals and foreigners, but the effect of which may be deemed discriminatory, result in *de facto* discrimination. For example, such a situation may arise when copyright collecting societies distribute revenue to national authors only, in instances where there are no reciprocal arrangements with other countries.²²⁴ In *Canada – Patent*

²¹⁸ In *United States – Section 211 Omnibus Appropriations Act* 1998, Appellate Body Report, WT/DS176/AB/R, 2 January 2002 para 241, the Appellate Body observed that national treatment had been the cornerstone of the Paris Convention and other international IP agreements.

²¹⁹ Correa above at 52.

²²⁰ For example, Article 5 A (1) of the Berne Convention provides that, '[A]uthors shall enjoy, in respect of works for which they are protected under the convention, in countries of the Union other than the country of origin, the rights which their respective laws do now or may hereafter grant to their nationals as well as the rights *specifically granted by this convention*' (my emphasis). The Rome Statute provided in Article 2(2) that national treatment was to be subject to the protection guaranteed, and the limitation specifically provided for in that convention.

²²¹ In *United States – Section 211 Omnibus Appropriations Act* 1998, Appellate Body Report, WT/DS176/AB/R, 2 January 2002, para 242, it was held that the jurisprudence of Article III: 4 of GATT will be instrumental in interpreting Article 3 of TRIPS; see also *European Communities – Protection of Trademarks and Geographical Indicators for Agricultural Products and Foodstuffs* WT/DS290/R, 15 March 2005 para 7.135.

²²² See Correa 53 -59 for an exposition, examples and pertinent WTO jurisprudence.

²²³ An example would be action taken in compliance with judicial administrative procedures as spelt out in Article 3.1 of TRIPS. See also *United States – Section 110(5) of the Copyright Act*, Appellate Body Report WT/DS160/R, 15 June 2000 wherein the Appellate Body relied on GATT jurisprudence in *United States – Section 337 of the Tariff Act* 1930, Panel Report, BISD36S/345, adopted 7 November 1989.

²²⁴ Correa above at 54.

Protection of Pharmaceutical Products,²²⁵ the Panel noted that claims for both formal and practical discrimination are possible under the TRIPS.²²⁶

Because national treatment in the TRIPS Agreement requires that foreign nationals be given treatment ‘no less favourable’ than nationals, it is therefore possible that foreigners may be given treatment more favourable than nationals.²²⁷ The pre-TRIPS era provided that foreigners be given the same treatment as nationals.²²⁸ The term ‘less favourable’ was addressed by the Panel in *EC – Protection of Trademarks and Geographical Indications for Agricultural Products*, wherein the Panel held that an examination of ‘less favourable’ would hinge on a close scrutiny of the ‘fundamental thrust and effect of the measure itself’.²²⁹

2.4.4.4 Most Favoured Nation Treatment under TRIPS

The most favoured nation (MFN) principle traditionally applied to trade in goods under the GATT 1994.²³⁰ In the strict trade-in-goods context under GATT, Article I thereof deals with customs duties and charges of any kind imposed on or in connection with the importation or exportation of goods and also the method of levying such duties and charges.²³¹ The article enjoins a WTO member giving any advantage, favour, privilege or immunity to any product originating in or destined for any other country to immediately and unconditionally extend to the like product originating in or destined for the territories of all other members the same advantage, favour, privilege or immunity. Therefore, the most favoured nation principle in this context operates to preclude a WTO member from discriminating against or between WTO Members in respect of all matters pertaining to the import or export of goods.

It is important to point out that the MFN principle was absent from pre-TRIPS international Conventions.²³² In the specific context of TRIPS, the MFN’s application is limited to the rights delimited by sections 1 – 7 of TRIPS, as spelt out in Article 4. The relevant Article provides that

²²⁵ *Canada – Patent Protection of Pharmaceutical Products*, Panel Report WT/DS114/R, 17 March 2000.

²²⁶ *Ibid* para 7.176.

²²⁷ Correa above at 56.

²²⁸ See Article 2(1) of the Paris Convention and Article 5(1) of the Berne Convention.

²²⁹ *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, Panel Report WT/SS174/R, 15 March 2005, para 7.136. The Panel relied heavily on WTO case law, namely *US – FSC (Article 21.5 – EC)* para 215.

²³⁰ Correa above at 66. In the GATT, this principle is provided for in Article I.

²³¹ More specifically Article I: 1 of GATT 1994.

²³² Correa above at 67.

with specific regard to intellectual property, any advantage, favour, privilege or immunity granted by a Member to the national of any other country shall be accorded immediately and unconditionally to the nationals of all the other Members.²³³ However, the following advantages, privileges, favours are excepted: advantages premised on international agreements on judicial assistance;²³⁴ advantages accorded in terms of the Berne (1971) and Rome Convention;²³⁵ advantages in respect of the rights of performers, producers of phonographs²³⁶ and advantages deriving from intellectual protection before the advent of TRIPS.²³⁷

The MFN principle has been described variously as a fundamental cornerstone of the world trading system.²³⁸ The implication is that the MFN ensures that nationals of the members receive the best treatment accorded to a member to nationals of other countries.²³⁹

2.4.4.5 The TRIPS and International Intellectual Property Rights Conventions

It is important in a study of this nature, which deals with the application of an international legal regime such as TRIPS, strongly rooted in past legal practices based on international IP law, to spell out, albeit briefly, the role the pertinent international conventions still play and will continue to play.

Initially, negotiators of TRIPS wanted it to comply with the main international conventions on intellectual property.²⁴⁰ All members are obliged to comply with substantive provisions of the Paris Convention as well as the rules governing ‘special agreements’ and with substantive provisions and the Appendix of the Berne convention as revised in 1971.²⁴¹ Current WTO members²⁴² were not necessarily members of the Paris Convention.²⁴³ However, Article 2.1 of

²³³ Article 4 of TRIPS.

²³⁴ Article 4 (a) of TRIPS.

²³⁵ Article 4 (b) of TRIPS.

²³⁶ Article 4 (c) of TRIPS.

²³⁷ Article 4 (d) of TRIPS.

²³⁸ *US – Havana Club, WT/DS160/AB/R*, Appellate Body Report, 15 June 2005, para 297.

²³⁹ Correa 66.

²⁴⁰ Correa 44 specifically notes that the European Communities in particular advocated the incorporation of existing IP Conventions by reference.

²⁴¹ Article 1.1 of TRIPS refers to the Paris Convention and Article 2.2 to other Conventions such as the Berne, Rome and the Treaty on IP in respect of Integrated Circuits and such a differentiation must be noted. Article 2.2 also does refer to the Paris Convention thus emphasizing the need to comply with its obligations and making it clear that nothing in Article 1.1 shall derogate from existing obligations under the Convention.

²⁴² As of 10 February 2011, WTO membership stood at 153 members (source http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, last visited 19/04/2012).

²⁴³ The current Paris Convention membership stands at 185 member states (source <http://www.wipo.int/members/en/> last visited 19/04/2012).

TRIPS is formulated in the form of a positive mandate²⁴⁴ and, therefore, it must be complied with even by members who are not contracting parties to the Paris Convention.

In the 1970s, many developing countries were reluctant to accept what they considered to be provisions restrictive to their freedom to regulate industrial property; hence they did not join the Paris Convention.²⁴⁵ The Appellate Body had the opportunity to interpret Article 2.1 in the *US – Section 211 Omnibus Appropriation Act*²⁴⁶ dispute, in which it was held by the Appellate Body that Article 6 of the Paris Convention²⁴⁷ as well as other specified provisions of the convention have been incorporated by reference in the TRIPS, and thus, the WTO Agreement.²⁴⁸ The Appellate Body further noted that members, whether of the Paris Union or not are obliged under the WTO Agreement to implement those specified provisions of the Paris Convention that are incorporated into the WTO.²⁴⁹

The wording of Article 1.2 of TRIPS (...‘members shall comply with’...) suggests that Articles of the Paris Convention mentioned therein override the TRIPS. Such an interpretation of the specific provision accords with the Vienna Convention, which provides that ‘when a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that treaty prevail.’²⁵⁰ Article 2.2 confirms the currency and continued application of the conventions mentioned therein,²⁵¹ and ensures that members do not apply TRIPS in a manner that leads to a violation of the obligations under the mentioned conventions.²⁵² Therefore, the implication from Article 2.2 is that in areas not covered by the TRIPS such as utility models, contracting parties continue to be bound by the previous conventions they have adhered to. In the case of ‘convention minus’ issues,²⁵³ it does not mean

²⁴⁴ The pertinent provision is couched in peremptory language and provides in Article 2.1 that, ‘In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)’.

²⁴⁵ Correa above 47.

²⁴⁶ *United States – Section 211 Omnibus Appropriation Act of 1998*, Appellate Body Report, paras 124 -125.

²⁴⁷ Paris Convention of 1967.

²⁴⁸ *United States – Section 211 Omnibus Appropriation Act of 1998*, Appellate Body Report, paras 124 -125.

²⁴⁹ Ibid.

²⁵⁰ Article 30 (2) of the Vienna Convention on the Law of Treaties, 23 May 1969. See also Correa 46 and Article 19 of the Paris Convention.

²⁵¹ Correa above at 46.

²⁵² The Patent Law Treaty in Article 15 (2) (a) also contains similar provisions when it states: ‘Nothing in this treaty shall derogate from the obligations that contracting parties have to each other under the Paris Convention.’

²⁵³ A good example is moral rights covered by Article 6bis of the Berne Convention.

the WTO members who were party to the Paris Convention are now exempt from the specific obligations in question.²⁵⁴

In the context of this study, Correa argues that since Article 5(A) of the Paris Convention recognizes the right of a contracting party to grant, under certain circumstances compulsory licences, other parties cannot challenge such a granting if it is consistent with the provisions of the Convention.²⁵⁵ The United States challenged Brazil's compulsory licensing system requiring a local working obligation for patented inventions; arguing that it was in breach of Article 27.1 of TRIPS, thereby discriminating against imported products. The matter did not go through the full Panel process but Brazil could easily have relied on Article 5 (A) (2) of the Paris Convention which allows a member 'the right to take legislative measures which provide for the granting of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.'²⁵⁶ Given the linkage between TRIPS and the Paris Convention,²⁵⁷ then such compulsory licences are arguably not challengeable under the TRIPS.²⁵⁸ In the *Canada – Patent Protection of Pharmaceutical Products* dispute,²⁵⁹ the Panel noted that apart from looking at the text, preamble and annexes of TRIPS in the interpretation thereof, the panel may have recourse to provisions of international instruments on intellectual property incorporated into the TRIPS Agreement, as well as other agreements between parties relating to the agreement.²⁶⁰

On a related interpretative note of the TRIPS in light of international intellectual property agreements, in the *United States – Section 110 (5) of the US Copyright Act*, the Panel supported its interpretation by reference to the interpretive history of the Berne Convention that has become part of the TRIPS Agreement.²⁶¹ In the case of *United States – Section 211 Omnibus*

²⁵⁴ See *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Arbitration by the European Communities under Art 22.6 of DSU, Decision by the Arbitrators*, WT/DS27/ARB/ECU, para 149.

²⁵⁵ Correa above at 47.

²⁵⁶ Correa above at 47.

²⁵⁷ As established by Article 2.1 and 2.2 of TRIPS read together with Article 19 of the Paris Convention.

²⁵⁸ Correa above at 48.

²⁵⁹ WT/DS14/R, 17 March 2000 paras 7.70 -7.72.

²⁶⁰ Ibid. Such an interpretation was said to be within the meaning of Article 31 (2) of the Vienna Convention.

²⁶¹ See also *United States – Section 110 (5) of the US Copyright Act*, Appellate Body Report WT/DS160/AB/R, 5 June 2005 para 6.18.

Appropriations Act of 1998,²⁶² the Panel had referred to and used preparatory work of the Paris Convention in its analysis of the dispute while the European Communities had objected to such an approach on the basis that Article 32 of the Vienna Convention could not apply because none of the conditions for that application of that rule were present in the case.²⁶³ Furthermore, it was submitted that the history of the Paris Convention failed to provide a clear indication of what the negotiators intended. On appeal, the Appellate Body relied on the negotiation history of the Paris Convention in order to confirm its own interpretation of the relevant provision of the Paris Convention²⁶⁴ and found that section 211(1)(a) was not inconsistent with the Paris Convention.²⁶⁵ Therefore, Panels and the Appellate Body do have recourse to the negotiating history of the applicable international intellectual property conventions to establish TRIPS' obligations and the scope of violations. However, such an approach may not be favourable to the developing countries that were not party to the negotiations and were, therefore, non-members.²⁶⁶ However, some aspects taken from conventions to which the developing countries were not party may be favourable to the same complaining countries. For example, Article 5A of the Paris Convention has often been cited as a basis for legitimising the granting of compulsory licences due to the lack or insufficient local working of a patented invention.²⁶⁷

The other important consideration in the context of contextualizing this study has been the question of whether or not other conventions (whether pre or post TRIPS) not incorporated by reference in the TRIPS may be used to interpret TRIPS. It has been argued that the adjudicator should seek a fit between his readings of the specific provisions of WTO law and his

²⁶² Dispute DS176, panel report of 2 August 2001 available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds176_e.htm (last visited 12/04/2011)

²⁶³ Article 32 of the Vienna Convention on the Law of Treaties allows for a recourse to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31 leaves the meaning ambiguous or obscure; or leads to a result which is manifestly absurd or unreasonable. The full text of the Convention is available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (last visited 12/04/2012).

²⁶⁴ Paris Convention Art. 6quinquies A (1).

²⁶⁵ See Appellate Body report WT/DS176/AB/R, 2 January 2002, paras 145-146.

²⁶⁶ Correa above at 49.

²⁶⁷ This is very relevant to the present study (see chapter four and five). See further, the submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela IP/C/W/296, 20 June 2001 entitled "TRIPS and Public Health". In the submission, compulsory licenses are proposed as an essential tool for Governments to carry out public health policies, as they may facilitate access to medicines through prevention of abuses of rights, encouragement of domestic capacities for manufacturing pharmaceuticals and in cases of national emergency or other circumstances of extreme urgency, or of public non-commercial use. The full submission is available at http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm [last visited 12/04/2012]

construction or imagination of the entire international legal system.²⁶⁸ Relatedly, Howse argues that the adjudicator must take into account pre-existing and evolving international law to reach an equitable decision.²⁶⁹ On a related note, it was held by the Appellate Body in *United States – Import Prohibition of Certain Shrimp and Shrimp Products* that, ‘certain terms in the WTO Agreement are not static but evolutionary’.²⁷⁰

Correa argues against the above evolutionary approach on the premise that it will deepen imbalances already evident in TRIPS and gravitate towards broader and higher levels of protection with advances in new technology.²⁷¹ A further radical argument against the evolutionary approach is that such an interpretation panders to the whims of ‘big pharma’ in the developed world.²⁷²

Possible safeguards against the evolutionary approach outlined in the preceding paragraph may be gleaned from the mandates of the TRIPS Council and a contextual historical approach to interpretation. The TRIPS Council is mandated to review the TRIPS Agreement in light of any relevant new development which may warrant modification or amendment of the Agreement.²⁷³ This mandate, therefore, implies that at all material times, TRIPS provisions must reflect contemporary happenings so that the Agreement is continuously relevant. This will indeed be a better approach than being too evolutionary in interpreting the TRIPS. The mandate of the TRIPS Council should be read as complementary to the evolutionary approach. In the contextual historical approach, Panels and the Appellate Body must confine themselves to the meaning of the terms as understood at the time of their adoption. This is necessitated by the axiom that there

²⁶⁸ See Mitchell AD ‘The Legal Basis for Using Principles in WTO Disputes’ (2007) 10 *Journal of International Economic Law* at 795 – 835.

²⁶⁹ Howse R ‘The jurisprudential achievement of the WTO Appellate Body: a Preliminary Appreciation’ available at <http://www.iilj.org/courses/documents/HC2003.Howse.pdf> (last visited 12/04/2011).

²⁷⁰ *United States – Import Prohibition on Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R, 1998, paras 127 -130 with specific reference to the term ‘exhaustible natural resources’. The extended meaning of the term exhaustible natural resources was acknowledged and applied in the case of *United States – Standards for Reformulated and Conventional Gasoline*, panel report and Appellate body report, adopted 20 May 1996, WT/DS2/R and WT/DS2/AB/R (commonly referred to as *US-Gasoline* dispute).

²⁷¹ Correa above at 50.

²⁷² Ibid. ‘Big pharma’ is a common and widely used pejorative term referring to big pharmaceutical companies.

²⁷³ Article 71 of TRIPS.

is a real danger of an evolutionary approach leading to an imposition of obligations not negotiated and adopted during specific negotiations, such as the Uruguay Round.²⁷⁴

Having rendered an expository account of the basic aspects of intellectual property law, theories of intellectual property, international intellectual property, conventions and aspects of the TRIPS Agreement, it is now appropriate to conclude this chapter by focussing on case studies which highlight the vicissitudes of the access to medicines debate.

2.5 The Legal Historical Evolution of the Access to Medicines Debate – Access to Medicines Narratives²⁷⁵

General

It is now safe to posit that the access to medicines debate is essentially a conflict between WTO law and human rights.²⁷⁶ The conflict pits patent law obligations under the TRIPS against access to essential medicines. The debate was essentially triggered and fuelled by the HIV/AIDS pandemic in sub-Saharan Africa and some parts of the developing world.²⁷⁷ The first medication targeting HIV/AIDS was produced by publicly funded institutions,²⁷⁸ but a British private company, Burroughs Wellcome obtained a patent on the use of the drug in several countries and priced the drug out of the reach of many.²⁷⁹ However, it is important to highlight that the access to medicines issue is not limited to HIV/AIDS only.²⁸⁰

2.5.1 HIV/AIDS²⁸¹ and the Pharmaceutical Price Wars

In the 1980s, a rare skin disease was discovered among US homosexuals, later the disease spread to all other people. A Catholic Development Commission sponsored study in Zaire found that the

²⁷⁴ In *Canada – Patent Protection of Pharmaceutical Products*, the Panel examined the status of the legislation complained of at the time of negotiation of the Agreement to determine the concept of ‘legitimate interest’ as contained in Article 30 of TRIPS.

²⁷⁵ This section draws largely from Hestermeyer H *Human Rights and the WTO: The case of Patents and Access to Medicines* (2007).

²⁷⁶ Hogerzeila HV “Essential medicines and human rights: what can they learn from each other?” (2006) 84 *Bulletin of the World Health Organization* 371 -375 at 371. For a detailed discussion and a conspectus of academic views on the relationship between access to medicines and human rights, see Chapter three below.

²⁷⁷ Hestermeyer 1. See also on a general note, Hassim A, Heywood M and Berger J *Health and Democracy: A Guide to Human Rights, Health Law and Policy in Post-Apartheid South Africa* (2007).

²⁷⁸ Ibid.

²⁷⁹ Ibid.

²⁸⁰ See for example the Cipro-Anthrax enigma discussed in para 2.5.2 below.

²⁸¹ For an overview picture on the origins of the HIV/AIDS scourge, see Sharp PM and Hahn BH “Origins of HIV and the AIDS Pandemic” (2011) 1 *Cold Spring Harbor Perspectives in Medicine* at 1 -23.

disease was already prevalent there, and the publication of the results of the study led to the realisation of the HIV/AIDS phenomenon worldwide.²⁸²

In May 1983, scientists at *Institut Pasteur* isolated the human immunodeficiency virus and developed tests for the new disease.²⁸³ The US Cancer institute isolated a virus too, mass produced it and developed a test for anti-bodies.²⁸⁴ The patent on an anti-body test kit was awarded to the US Company Gallo, to the chagrin of *Institut Pasteur*.²⁸⁵ The virus had been identified but no AIDS medication was available.

Before even HIV/AIDS was discovered, one public institution, US Detroit Institute for Cancer Research, synthesized a chemical entity called Azidothymidine (AZT) to stop malignant cells in 1964 (the scientist responsible for this was Horwitz).²⁸⁶ The compound failed and was never patented by Horwitz and thus fell into the public domain.

Ten years later, Ostertag, a scientist employed by *Max Planck Institut fur Experimentell Medizin*, a publicly funded German institute, experimented with AZT and found that in some instances, AZT could treat retroviruses.²⁸⁷ A decade later, a British company, BW (Borrough Wellcome) obtained a patent for AZT in the United Kingdom and the United States claiming *inter alia* '[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of AZT'.²⁸⁸ For many years, AZT was to remain the only drug for HIV treatment.

Because AZT was the only available drug for HIV/AIDS for a desperate population, BW set the retail price for a year's supply for one patient at US\$10 000.²⁸⁹ The exorbitant price did not go down well with HIV/AIDS patients, who began to set up highly activist groups to fight the price

²⁸²Herstermeyer above at 2.

²⁸³ See Barre –Sinoussi et al 'Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)' (1983) 220 *Science* at 868.

²⁸⁴ Arno PS and Feiden KL *Against the Odds: The Story of Aids Drug Development, Politics and Profits* (1992) at 12.

²⁸⁵ The patent was awarded and registered under US Patent No: 4520, 113 – Serological Detection of anti-bodies to HTLV-III in sera of patients with AIDS and pre-AIDS conditions.

²⁸⁶ Herstermeyer above at 3.

²⁸⁷ Herstermeyer above at 4.

²⁸⁸*Ibid.* The patent was granted under US Patent No. 4, 724, 232.

²⁸⁹ Herstermeyer above at 4.

and improve access.²⁹⁰ The outcry reached the ears of the US Congress and the pricing decision was scrutinised. BW attempted to justify its price on the basis of the cost of research, development, synthesizing, marketing of the drug and the need to generate revenue in light of the likelihood of new therapies coming soon.²⁹¹

The access to medicines debate had been ignited and the world was suddenly seized with the matter and action, albeit belatedly had to be taken in the context of intellectual property law reform under the auspices of the TRIPS. From an African country's perspective, the access debate was highlighted and publicized by the Treatment Action Campaign in the South African Medicines Act debacle in 1998.²⁹² The South African Medicines Act debacle highlighted the access problem in the context of accessing HI/AIDS vaccines. However, the access debate also raged fiercely in other areas apart from the HIV/AIDS context as shown immediately below.²⁹³

2.5.2 The Access Debate in Other Areas: The Anthrax Scare Case

2.5.2.1 Preliminary Remarks

The HIV/AIDS prevalence and spread necessitates that the conflict between patents and access to medicines be largely around this theme. This disease, therefore, is the single most important example of the conflict as illustrated in paragraph 2.5.2 above. However, other disease examples do exist in other areas such as the case of Novartis' cancer drug, Glivec and Tami flu for the treatment of avian influenza or 'bird flu'.²⁹⁴

2.5.2.2 Bayer's CIPRO

In October 2001 after the September 11 twin towers' attacks in the United States; mysterious letters containing anthrax were sent to prominent politicians and media houses. Bayer, a German company was the sole producer of the only medication approved to treat anthrax in the United States. The medication in question was the anti-biotic Cipro. The drug had initially been patented in the United Kingdom and the UK patent had expired but was still current in the US and Canada

²⁹⁰ The most vocal activist group was the AIDS Coalition to Unleash Power; others who later took the cause further were *Medicins Sans Frontieres*, the Consumer Project on Technology, Oxfam, Health GAP and Treatment Action Campaign in South Africa.

²⁹¹ Hertermeyer above at 5.

²⁹² This case and other developing countries access cases are discussed and critiqued in chapter six below.

²⁹³ See the brief narrative in para above.

²⁹⁴ Despite the chances of bird flu spreading to humans being rare, the fear of the virus mutating and enabling human-to-human transmission led to stockpiling of Tamiflu. Similarly, Roche's drug had to be produced under sub-licensing schemes for fear of the imposition of compulsory licenses.

which were additional jurisdictions in which Bayer had also registered the same patent. Demand for the drug skyrocketed due to individual and government fears of biological warfare from militants and terrorists. Bayer could not meet the demand required by the US government for drug supplies to last 12 million people in 60 days. Demand outpaced the supply despite an increase in the drug production volumes.

Meanwhile, an Indian company Cipla, which had been producing a generic version of Cypro for a decade at a fraction of the cost offered to supply the US government. The offer prompted Bayer to announce that it would triple production to 200 million tablets over three months, because the US government would not disregard patent rights. However, Canada was interested in purchasing the generics from Cipla and offered to buy 900 000 tablets at half the price. Bayer capitulated to Canadian pressure and offered the patented drug to Canada at a very cheap price.²⁹⁵ The US government was aggrieved by Bayer's concession to the Canadians and threatened to disregard patent rights and resort to generics if Bayer did not extend the price concession to the US as well. Because Bayer's options were very limited in the specific context and the threat of resorting to generics by the US was a real one, the pharmaceutical giant made a concessionary offer of 100 million tablets at \$0.95 per tablet with the option for an additional 200 million tablets.

In this access to medicines narrative, the US position starkly contrasts with its pro patents rights approach in the South African medicines case and smacks of duplicity.²⁹⁶ Despite the Cypro case, the US has stridently remained an ardent defender of stringent patent protection in sympathy with its pharmaceutical industry. From the case studies narrated above, it becomes very clear that the access to medicines problem was triggered by public health concerns of the two countries. In South Africa, the real fear that the young population could be decimated by the HIV/AIDS scourge spurred the government to Act.²⁹⁷

²⁹⁵ It is reported that the drug was sold at \$1.30 per pill instead of the usual \$1.80 price.

²⁹⁶ See chapter five below.

²⁹⁷ According to the website of Statistics South Africa, the national custodian of demographic and other statistics, available at <http://www.statssa.gov.za/publications/P0302/P03022011.pdf> (last visited 10/07/13), in 2011, South Africa had an estimated overall HIV prevalence rate of approximately 10,6%, while the total number of people living with HIV was estimated at approximately 5,38 million, with an estimated 16,6% of the adult population aged 15–49 years being HIV positive.

In the United States, on the other hand, the government was apprehensive of the fact that there was a real possibility of a biological war being waged by the so called terrorists. In both instances, there was a dire need for life-saving drugs which were in the hands of big pharmaceutical companies who enjoyed exclusive monopolies in terms of patent rights.

Irrespective of the outcome of the case in each of the above case studies, what is evident is that patient rights were likely to be trumped by patent rights had concessions not been struck. Furthermore, the conflict between patent rights and human rights, specifically the right to health, is evident in the narratives. It is, therefore, aptly appropriate that the next chapter focuses on access to medicines as a human right.²⁹⁸

Conclusion

The conceptual and theoretical framework underpinning the access to medicines discourse, outlined above, which dates back to the 1980s, clearly mirrors the issues and concerns that underlie access to medicines. The recurrent themes in the debate include but are not confined to the definition of intellectual property and the monopolistic nature of the attendant rights specifically in the context of patents; theories that best explain the relationship between the patentee's rights vis-à-vis third parties; intellectual property rights in the context of the relevant international conventions and World Intellectual Property Organisation; intellectual property in the GATT/WTO state of play and the evolution of the access debate to medicines as exemplified by the selected case studies.

The thesis of this study hinges on the premise that TRIPS allows for flexibilities that may be used by members to improve their lot in the context of accessing medicines. It is this study's contention that SADC member states can take full advantage of the flexibilities through legal and policy reforms that encapsulate the flexibilities and anticipate the need to access patented medicines for the region's citizens. It is envisaged that the law reform will incorporate human rights principles, discussed in the next chapter and a blended theoretical approach, briefly broached in this chapter as a possible solution to the access problem, and discussed in detail in

²⁹⁸ While there may not be a clear cut right to access to medicines, the authorities consulted in chapter three below clearly show that a human rights approach to access to medicines may be the solution.

Chapter seven as a lasting solution for the SADC region. For obvious reasons, the WTO provisions dealing with the flexibilities are not discussed here because they are discussed in their proper context in chapters four and five below. It is now appropriate, therefore, to introduce the concept of access to medicines as a human right for further contextualization of this study.

CHAPTER THREE

ACCESS TO MEDICINES AS A HUMAN RIGHT

3. Introduction

In the previous chapter we focused on basic concepts, distinctions and theories of intellectual property. The chapter also touched on aspects of international patent law under the auspices of the World Trade Organisation TRIPS Agreement and the World Intellectual property Organization (WIPO) and access case studies to medicines. The foregoing chapter's main aim was to contextualize the study and this contextualization continues in this chapter albeit with a different focus.

In this chapter, the access to medicines debate is pursued from a different conceptual and normative perspective and the human rights dimension is introduced and its potential applicability to resolving the access problem explored. The conflict between intellectual property rights and human rights, namely the right to health, is explored against the backdrop of both an international and SADC dimension. The main question which this chapter seeks to answer is whether the access to medicines problem for the SADC region may not be resolved through the adoption of the rights-based approach. It is appropriate to explore the link between human rights and intellectual property so that the TRIPS flexibilities as potential solutions to the access problem may be viewed in their proper context in chapter four below.

For the foregoing reasons, this chapter explores the nature of intellectual property rights and lays bare some of the theoretical arguments that seek to equate intellectual property rights to mainstream human rights. Secondly, intellectual property rights are juxtaposed with the right to health and the main international human rights provisions dealing with the right to health are analysed and linked to the problem of access to medicines. Thirdly, the concept of a rights-based approach is exposed and its potential applicability to resolving the access problem cursorily pursued. Finally, African and SADC regional instruments that have been identified are analysed in order to explore the potential of their deployment to resolving the access problem using the right to health as a legal normative tool.

It is envisaged that once a strong case for the link between human rights and intellectual property has been made in the context of access to medicines, it will then be appropriate to pursue an access solution for the SADC region through the deployment of TRIPS flexibilities outlined in chapter four below. Some of the documented flexibilities, namely compulsory licenses, parallel importation and differential pricing, initially proffered as possible solutions to the SADC access problem in chapter four, influenced the direction of this study in chapters five, six and seven. The solutions that have been proffered in chapter seven have taken into account human rights norms. Hence, laying the human rights foundation and establishing a rational link is an indispensable inclusion in this chapter.

3.1 Establishing the Link between Human Rights and Intellectual Property Law

3.1.1 Conceptual linkages

Intellectual property law and human rights law share a related Western European societal developmental origin.¹ Therefore, in the context of this study, intellectual property rights which, together with other access barriers continue to militate against access to medicines are western impositions which remain an access encumbrance to be dislodged through the deployment of a rights-based approach. Dogmatically speaking, intellectual property law is based on private law while human rights, addressing primarily states, are of a public law nature.² If one accepts that the right to property is a human right,³ it is surely doubtful that the right to property can routinely outweigh the rights to life and health.

The World Intellectual Property Organisation (WIPO), United Nations Human Rights Council, the Committee on Economic Social and Cultural Rights, the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) are now aware of the human rights dimension of intellectual property.⁴ Some governments, courts and public interest non-governmental

¹ See Grosheide W, "Intellectual Property Rights and Human Rights: Related Origin and Development" in Grosheide W (ed) *Intellectual Property and Human Rights: A Paradox* (2010) at 3. Grosheide submits that the development happened between the 18th and 19th century.

² Grosheide above at 5.

³ Article 17 of the Universal Declaration of Human Rights guarantees the right to own property, and the right not to be arbitrarily deprived of property. It is therefore a recognized human right that no one be arbitrarily deprived of her property, or denied the right to own property, on *discriminatory grounds* (my emphasis). However, Both the International Covenant on Civil and Political Rights and the International Covenant on Economic Social and Cultural Rights do not recognize the right to property per se.

⁴ Helfer LR and Austin GW *Human Rights and Intellectual Property: Mapping the Global Interface* (2011) at 1.

organisations view intellectual property protection as implicating potential violations of the right to life,⁵ health, food, privacy, and freedom of expression and the enjoyment of the benefits of scientific progress.⁶

Applied directly to the aims and objectives of this study, the implication of the above submission by Helfer and Austin is that ‘the denial of access to essential drugs threatens the enjoyment of the right to life’,⁷ protected in Article 6 of the International Covenant on Civil and Political Rights (ICCPR).⁸ Furthermore, the denial of access to essential drugs militates against the right to ‘the highest attainable standard of physical and mental health’,⁹ as spelt out in the pertinent provision of the International Covenant on Economic Social and Cultural Rights (ICESCR).¹⁰

Both legal fields originated and grew quite apart out of social developments which were not interrelated.¹¹ However, the modern contemporary reality is that the relationship between intellectual property rights and human rights has now evolved into a problematic one.¹² The problematic aspect is exemplified, on the one hand, by the view that intellectual property rights and human rights are in conflict since the legal protection of private intellectual property rights is considered incompatible with community-based human rights; with human rights on the other hand viewed as legal instruments that limit and restrict the enforcement of intellectual property rights.¹³ If this view is pursued to its extreme ends, then human rights must always trump intellectual property rights. Applied to the context of this study, the implication would be that the

⁵ The fact that most countries must protect pharmaceutical patents, yet they are also required to protect the right to life renders the relationship between patents and human rights paradoxical (Helfer and Austin at 2).

⁶ Helfer and Austin above 2.

⁷ See Joseph S “Pharmaceutical Corporations and Access to Drugs: The ‘Fourth Wave’ of the Corporate Human Rights Scrutiny” (2003) 25 *Human Rights Quarterly* 425 – 452 at 430.

⁸ International Covenant on Civil and Political Rights, adopted 16 Dec. 1966, G.A. Res. 2200 (XXI), U.N GAOR, 21st Sess., Supp. No. 16, U.N Doc. A/6316 (1966), 999 U.N.T.S 171 (entered into force 23 March 1976). The Human Rights Committee, the monitoring Body under the ICCPR, has confirmed that Article 6 requires measures to be taken to combat epidemics (see UN doc.HRI/GEN/1/REV.5, 26 April 2001 at 115 –General Comment 6, originally adopted in 1982).

⁹ Per Article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR). On the other hand, Article 15 (1) (c) of the ICESCR guarantees authors rights to commercially exploit, among other things, their scientific inventions.

¹⁰ International Covenant on Economic Social and Cultural Rights, adopted 16 Dec. 1966, G.A. Res. 2200 (XXI), U.N GAOR, 21 Sess., Supp. No. 16, U.N. Doc. A/6316 (1966), 999 U.N.T.S 171 (entered into force 3 January 1976). The Committee on Economic Social and Cultural Rights confirmed in General Comment 14 on Article 12 that a core obligation under the provision is to provide access to essential drugs.

¹¹ Grosheide above at 5.

¹² Ibid.

¹³ Ibid. In the context of this study, such an argument is likely to be attractive to developing countries in countering the predominant view of the developed countries that intellectual property rights are sacrosanct.

problem of access to medicines would be easily resolved if intellectual property rights were to give way to human rights. However, matters are not that simplistic as the next paragraph shows.

The other opposing view is that intellectual property rights and human rights are compatible because they pursue the same aim. Therefore, intellectual property rights are embodied in human rights.¹⁴ In the access to medicines context, this view requires striking a balance between the protection of intellectual property rights and access to medicines. The major question that remains in the context of the aims of this study is: How should a proper balance be struck between the protection of intellectual property rights and access to products of intellectual property, namely medicines? I have attempted to answer this question cursorily in this chapter and in detail from chapter four to chapter seven.¹⁵

3.1.2 Intellectual Property and Human Rights in the International Context

Human rights protect the fundamental rights of individuals and groups.¹⁶ ‘Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being humans’.¹⁷ This is in direct contrast to property rights (like intellectual property rights), which can always be ceded in voluntary transactions.¹⁸ While human rights are said to be universal (exist irrespective of implementation), there seems to be two categories of human rights emerging namely, fundamental rights and non-fundamental rights.¹⁹ Whether a right is classified as fundamental or non-fundamental largely depends on whether the classifier thereof is a positivist or a naturalist.²⁰ Whether viewed through the eye of a naturalist or positivist, the whole concept of human rights

¹⁴ Grosheide above at 5.

¹⁵ The thesis of this work is that patents are a major barrier to access to medicines hence a solution that accommodates both the rights of patent holders and those of patients in the SADC region has to be found within the legal framework provided for by the TRIPS Agreement.

¹⁶ Cullet P “Patents and Medicines: the relationship between TRIPS and the human right to health” (2003) 79 *International Affairs* 139 – 160 at 140.

¹⁷ See Nussbaum MC “Capabilities, Human Rights and the Universal Declaration” in Weston BH and Marks SP (Eds) *The Future of International Human Rights* (1999) cited in Cullet above at 140.

¹⁸ Calabresi G and Melamed AD “Property Rules, Liability Rules, and inalienability: One View of the Cathedral” (1972) 85 *Harvard Law Review* at 1089.

¹⁹ Grosheide above at 19. An example of a fundamental right is the prohibition of slavery while an example of a non-fundamental right is the right to property.

²⁰ Grosheide above at 20. Positivists firmly believe that the content of human rights must be determined by the texts agreed upon by states and embodied in valid treaties or determined by obligatory state practice attaining the status of binding international custom. On the other hand, naturalists regard the content of human rights as primarily based on immutable values that endow standards norms with a universal validity.

is a fruit of western thinking which does not concur in every respect with non-western thinking.²¹ If the Western thinking is pursued to its extreme end, the implication for access to medicines will be that governments of poor countries must protect intellectual property rights at all costs, even when upholding such “universal” rights will result in extinguishing the right to life for citizens. This will be inequitable and will militate against access to affordable medicines for those in dire need of it hence it is this study’s thesis that a departure from this conception of human rights and IP rights is called for.²²

Conceptualising something as a human right signifies its importance as a social or public good.²³ Rights focus on the dignity of persons, equality and non-discrimination.²⁴ Rights imply entitlement and are almost never absolute and may be limited, such limitation being subject to strict scrutiny.²⁵ A right ‘trumps’ many other claims or goods.²⁶ Health issues, especially issues around access to medicines are, therefore, important to warrant categorisation as rights, hence health may be regarded in this context as a ‘social good’.²⁷ The fact that the right to health is recognized locally and internationally gives legal and political legitimacy to the claims for its enjoyment.²⁸ Rights only have a meaning if it is possible to enforce them.²⁹

Human rights constitute the basic framework guiding state actions on the domestic and international levels.³⁰ Human rights are the ‘rights a person has by simply being born.’³¹ Human rights are minimum standards understood to be necessary for individuals to live in dignity.³² In terms of the United Nations Charter,³³ the United Nations shall promote universal respect for and

²¹ Grosheide above at 21. See further Yu PK “Reconceptualising Intellectual Property Interests in a Human Rights Framework” (2007) 40 *UC Davies Law Review* at 1039 – 149, on the distinction between civil and political rights and economic, cultural and social rights.

²² In this study, this departure will take the form of a rights-based approach to access to medicines.

²³ Helfer and Austin above at 100.

²⁴ See generally Leary V “The Right to Health in International Human Rights Law” (1994) 1 *Health and Human Rights* 35 – 40.

²⁵ Leary above 36.

²⁶ Dworkin R *Taking Rights Seriously* (1977) cited in Baker L “Dworkin’s Rights Thesis: Implications for the Relationship between the Legal Order and the Moral Order” (1980) *Bingham Young University Law Review* 837 – 856 at 845.

²⁷ Helfer and Austin above at 100.

²⁸ Helfer and Austin above at 101.

²⁹ Neier A “Social and Economic Rights: A Critique” (2006) 13 *Human Rights Brief* at 1 – 3.

³⁰ Per preamble of the International Covenant on Economic Social and Cultural Rights.

³¹ Tarantola D “A Perspective on History of Health of Health and Human Rights: From the Cold War to the Gold War” (2008) 29 *Journal of Public Health and Policy* 42-53 at 42.

³² Ibid.

³³ See Article 55 (c) thereof.

observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language or religion. The Charter is important in that human rights which were once only a matter of domestic concern have now been elevated to a subject of international treaty obligations.³⁴

The Universal Declaration of Human Rights (UDHR)³⁵ enumerates the basic rights of the individual and was the first international legal instrument to do so.³⁶ It took almost two decades to move the aspirational concepts laid out in the UDHR into legally binding obligations.³⁷ The ‘right to freely participate in the cultural life of the community, to enjoy the arts and to share in the scientific advancement and its benefits is the most relevant to intellectual property generally and to this study in particular.³⁸

It is important to highlight that the UDHR was passed by the General Assembly as a resolution with no force in law because it was never intended to create binding legal obligations.³⁹ Notably, it was not signed because it was never intended to be signed.⁴⁰ Today, however, the UDHR imposes some legal obligations on nation states.⁴¹ There is legal uncertainty over whether all rights proclaimed in the UDHR are binding and under what circumstances. Furthermore, there is no settled legal position on whether the obligatory character of the UDHR derives from its status as an authoritative tool for interpreting human rights as contained in the Charter or its status as customary international law.⁴²

Be that as it may, there are specific covenants which have been passed with the aim of transforming the general principles in the UDHR into binding treaty obligations.⁴³ The covenants also seek to establish the international machinery to ensure governmental compliance. Very

³⁴ Helfer and Austin above at 6.

³⁵ Universal Declaration of Human Rights was adopted by the U.N General Assembly on 10 December 1948. The full text is available at <http://www.un.org/en/documents/udhr/index.shtml> (last visited 12/03/13)

³⁶ Helfer and Austin above at 7.

³⁷ Tarantola D. “A Perspective on the History of Health and Human Rights: From the Cold War to the Gold War” (2008) 29 *Journal of Public Health and Policy* 42 -53 at 43.

³⁸ See Article 27 of the Universal Declaration of Human Rights.

³⁹ Helfer and Austin above at 8.

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² Ibid.

⁴³ Pertinent examples of such covenants being the International Covenant on Civil and Political Rights, Optional Protocol to the Covenant on Civil and Political Rights and International Covenant on Economic Social and Cultural Rights.

pertinent to this study is the fact that the International Covenant on Economic Social and Cultural Rights guarantees the right to enjoy the highest attainable standard of physical and mental health.⁴⁴ The realisation of the right, however, has to take place progressively within the limits of the state's available resources.⁴⁵ This provision is directly relevant to access to medicines.

Historically, the protection of intellectual property rights was viewed in the context of the territorial, international and global periods.⁴⁶ The territorial period was inward looking and the protection of intellectual property rights remained largely a matter for domestic legislation through statutes. Therefore, the protection of rights did not extend beyond the borders where the rights had been granted in the first place.⁴⁷ On the other hand, the international period was characterized by growing interest in cooperation between nation states in the domain of intellectual property law.⁴⁸ This period saw the introduction of the required international legal regulatory framework such as the Berne and Paris Conventions.⁴⁹ The global period was driven by a bid to transform the existing international framework for intellectual property law into a harmonized interstate regulatory regime in sympathy with international commercial interdependency of the developed world.⁵⁰ The move from the international to the global period saw a proliferation of international intellectual property regimes leading to harmonization in specific areas.⁵¹

⁴⁴ Article 12 of the International Covenant on Economic Social and Cultural Rights.

⁴⁵ Cullet above at 148.

⁴⁶ Grosheide above at 7.

⁴⁷ Ibid. This period was largely characterised by bilateralism between states and the proliferation of bilateral treaties and other agreements.

⁴⁸ Grosheide above at 8.

⁴⁹ According to Grosheide, the Berne and Paris Conventions were driven by private commercial interests in a bid to expand to foreign markets and not the need for interstate convergence.

⁵⁰ Ibid.

⁵¹ Notable examples being the Madrid Agreement of 1891 covering trademarks, Madrid Agreement 1891 covering indications of source, Hague Agreement of 1925 covering designs, Rome Convention of 1961 protecting performing arts, 1961 International Convention for the Protection of New Varieties of Plants, Patent Cooperation Treaty of 1970 and Integrated Circuits Treaty of 1989 (semi-conductor chips). These international agreements led to the establishment of international organisations such as the United International Bureau for the Protection of Intellectual Property in 1893 and the World Intellectual Property Organisation (WIPO) in 1967, which became a specialised agency of the United Nations in 1974.

The Berne⁵² and Paris⁵³ conventions are silent on human rights and this may be due to human rights having been a non-issue at the time of signing the conventions.⁵⁴ The TRIPS Agreement generally does not “*expressis verbis*” refer to either any human rights law instrument or any human right in particular.⁵⁵ However, in the preamble to the TRIPS, reference is made to protections granted to authors and inventors as ‘rights’ (‘recognising that intellectual property are private rights’). If intellectual property rights are regarded as property rights as implicated in the preamble of TRIPS, they would then fall under article 27 of the Universal Declaration of Human Rights⁵⁶ and article 1 of the First Protocol to the European Convention for the Protection of Human Rights and Fundamental Freedoms.⁵⁷ The International Covenant on Economic Social and Cultural Rights (ICESCR)⁵⁸ establishes one’s right to:

- (a) take part in the cultural life,
- (b) the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author, as
- (c) a human right.⁵⁹

Rights granted under paragraphs (a) and (b) of Article 15 of the ICESCR converge with the objectives of the WTO Agreement to which the TRIPS Agreement is an annex; more specifically with reference to the emphasis put on the public interest rationale of intellectual property protection.⁶⁰ The United Nations Committee on Economic, Social and Cultural Rights reflected

⁵² Berne Convention for the Protection of Literary and Artistic Works, Sept. 9 1886. 1161 U.N.T.S. 31, last revised in Paris, July 24 1971.

⁵³ Paris Convention for the Protection of Industrial Property, March 20, 1883 21 U.S.T 1583, 828 U.N.T.S 305, last revised at Stockholm, July 14, 1967.

⁵⁴ Grosheide above at 13.

⁵⁵ Grosheide above at 14. However, the preamble to the TRIPS may be said to refer to human rights if intellectual property rights are accepted as a category of property rights generally.

⁵⁶ An article 27 of the UDHR gives everyone the right to *inter alia* freely participate in the cultural life of the community, enjoy the arts and to share in the benefits of scientific progress.

⁵⁷ The full text of the Convention is available at <http://conventions.coe.int/treaty/en/treaties/html/005.htm> (last visited 12/03/13)

⁵⁸ Per article 15.1 (a) (b) and (c).

⁵⁹ This provision was in 2000 presented as a basis for the human rights qualification of intellectual property rights by the United Nations Committee on Economic, Social and Cultural Rights per the report of the High Commissioner entitled, “The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights”, E/CN.4/Sub.2/2001/13 27 June 2001, available at <http://www.unhchr.ch/Huridocda/Huridoca.nsf/Symbol/E.CN.4.Sub.2.2001.13.En?Opendocument> (last visited 21/01/2014).

⁶⁰ Grosheide above at 15. Article 7 of TRIPS puts emphasis on the public interest rationale of intellectual property protection.

on Article 15.1 (c) of the ICESCR and produced General Comment no. 17,⁶¹ wherein intellectual property rights were cited as different from human rights due to their general temporary nature which can be revoked, licensed or assigned to someone else.⁶² Human rights do not have the above characteristics and are timeless expressions of fundamental interests of the human person.⁶³

Focusing specifically on the TRIPS Agreement, it does not reflect the fundamental nature and indivisibility of human rights, including the ‘right of everyone to enjoy the benefits of scientific progress and its applications’.⁶⁴ Hence, there is an apparent conflict between the intellectual property rights regime embodied in TRIPS, on the one hand, and international human rights law on the other.⁶⁵ The attention of the human rights system was first drawn to the TRIPS Agreement in 2000.⁶⁶ The debate led to the adoption of the Resolution on Intellectual Property and Human Rights.⁶⁷ The resolution is critical of the TRIPS Agreement and states that ‘actual or potential conflict exists between the implementation of’ the treaty ‘and the realization of economic, social and cultural rights’.⁶⁸ Specific areas causing the conflict include *inter alia*, transfer of technology to developing countries, the right to food and plant variety rights, genetically modified organisms, bio-piracy, reduction of commercial control over own genetic and natural resources

⁶¹ 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, available at: <http://www.unhcr.org/refworld/docid/441543594.html> (last visited 12/03/2013).

⁶² General Comment No. 17 para 2.

⁶³ General Comment No. 17 para 2.

⁶⁴ See generally U.N General Assembly “The Right to Benefit from Scientific Progress and its applications”, Report of the Special Rapporteur in the Field of Cultural Rights, Farida Shaheed, A/HRC/20/26, available at http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf (last visited 21/01/2014).

⁶⁵ See Sub-Commission on the Promotion and Protection of Human Rights, Intellectual Property Rights and Human Rights, Fifty Second Session, Agenda item 4, E/CN.4/Sub.2/2000/7, adopted on 17 August 2000.

⁶⁶ In July 2000, the UN Sub-Commission on the Promotion and Protection of Human Rights received a statement from a consortium of public interest Non-governmental Organisations that challenged the TRIPS compatibility with international human rights law. See further Weissbrodt D and Schoff K “Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7” (2003) 5 *Minnesota Intellectual Property Law Review* 26 – 27.

⁶⁷ Resolution on Intellectual Property and Human Rights, Res, 2000/7, U.N DOC. E/CN.4/Sub.2.RES/2000/7, 17 August 2000.

⁶⁸ Ibid at preamble paragraph 11.

and *restrictions on access to patented pharmaceuticals and implications for the enjoyment of the right to health* (my emphasis).⁶⁹

To resolve the conflict, the Sub-Commission urged states, inter-governmental organisations and NGOs to recognize that human rights have ‘primacy....over economic policies and agreements’.⁷⁰ However, it is disheartening that Sub-Commission resolutions are by their very nature non-binding. Hence, they do not impose immediate legal consequences.⁷¹

In the decade since the resolution’s adoption, the overwhelming positive responses it has elicited have been reflected in numerous resolutions,⁷² reports,⁷³ comments⁷⁴ and statements⁷⁵ relating to TRIPS and intellectual property protection more generally. The most important reaction which goes to the core of this study was the publication in 2008, of *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*.⁷⁶ The publication urges

⁶⁹ Ibid.

⁷⁰ Id para 3.

⁷¹ Helfer and Austin above at 53.

⁷² For examples: see Commission on Human Rights, Res. 2003/29, U.N. DOC. E.CN.4/RES/2003/29 of 22 April 2003 urging states to ensure *Access to Medication in the context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria* (emphasis added) and a resolution of the Sub-Commission which identifies numerous conflicts between TRIPS and human rights including the right to self-determination, food, housing, work, health, education and transfer of technology to developing countries (Sub-Committee on the Promotion and Protection of Human Rights, Intellectual Property and Human Rights, Res. 2001/21, U.N. Doc E/CN.4/Sub.2/RES/2001/21, August 16 2001).

⁷³ See Report by two special Rapporteurs on globalisation, which report asserts that intellectual property protection undermines human rights objectives (Sub-Commission on the Promotion and Protection of Human Rights, Globalisation and its full impact on the full enjoyment of human rights paras 19-34, U.N Doc. E/CN.4/Sub.2/2001/10, Aug 2 2001), Report of UN Secretary General on Intellectual Property and Human Rights based on information submitted by states, inter-governmental organisations and public interest NGOs (Report of the Secretary General on Economic, Social and Cultural Rights, Intellectual Property Rights and Human Rights, U.N Doc. E/CN.4/Sub.2/2001/12, June 14 2001) and Report of the U.N High Commissioner for Human Rights on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, para 68. Thus far, the U.N Commissioner for Human Rights’ effort to seek observer status with the WTO to participate in reviews of the TRIPS has been unsuccessful.

⁷⁴ See 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 is author, Article 15.(1)(c) U.N Doc.E/C.12/GC/17, Jan.12 2006.

⁷⁵ See statement that intellectual property rights must be balanced with the right to take part in the cultural life and enjoyment of the benefits of scientific progress and its applications, and that national and international intellectual property regimes must be consistent with the obligations of state parties as set out in the International Covenant on Economic Social and Cultural Rights, reproduced in Committee on Economic, Social and Cultural Rights, Substantive Issues Arising in the Implementation of the International Covenant on Economic Social and Cultural Rights, U.N Doc.E/C12/2001/15, Dec. 14 2001.

⁷⁶ U.N special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Human rights Guidelines for Pharmaceutical Companies in Relation to access to Medicines, U.N Doc/A/63/263, preamble, Aug. 11 2008.

pharmaceutical companies to ‘make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by the TRIPS’.⁷⁷

The Council for Europe’s Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)⁷⁸ and the First Protocol thereto, are both silent on intellectual property.⁷⁹ However, there is one notable case of the European Commission on Human Rights dealing with intellectual property as a right.⁸⁰ In this case, a patent right is recognized as a property right in the context of the ECHR. There is likely to be a practical legal enigma if a corporation can be regarded as an owner of intellectual property and hence an enjoyer of human rights.⁸¹

In the European Union (EU) context, the recently adopted Charter of Fundamental Rights⁸² provides that intellectual property shall be protected. However, the provision falls short of introducing the human right to intellectual property rights because it is addressed to institutions of the EU rather than the right holders.⁸³

Constitutional and related legislations of many countries pay attention to acknowledging and securing the promotion and protection of creativity and innovation in various ways.⁸⁴ However, in the constitutional context, what is contemplated is the vertical application and enforcement of the intellectual property rights against the state rather than the horizontal application of the rights between citizens.⁸⁵

3.1.3 Intellectual Property and Human Rights in Legal Literature: Some Problematic Areas

Having briefly traced the background to the relationship between intellectual property law and human rights above, it is now appropriate to give a brief overview of the converging and

⁷⁷ Ibid preamble para I and guideline 26.

⁷⁸ See footnote 56 above.

⁷⁹ Grosheide above at 18.

⁸⁰ *Smith Kline and French Laboratories v the Netherlands*, Dep & Rep. 77, 79 (1990).

⁸¹ Grosheide above at 18. See the case of *Anheuser-Busch v Portugal* IPPT20070111, European Court of Human Rights, 1 November 2007, available at http://www.ippt.eu/files/2007/IPPT20070111_ECHR_Anheuser-Busch_v_Portugal.pdf (last visited 12/03/13).

⁸² See Article 17 (2) thereof.

⁸³ Cullet P “Human Rights and Intellectual Property Rights in the TRIPS Era (2007) 29 *Human Rights Quarterly* 403 -430 at 438.

⁸⁴ See for instance Article 5 XVI-XIX of the Brazilian Constitution (available at <http://web.mit.edu/12.000/www/m2006/teams/willr3/const.htm>) and Article 43 (1) of the Constitution of Slovakia (available at http://aceproject.org/ero-en/regions/europe/SK/Constitution_slovakia.pdf), wherein the right to ownership of creative and intellectual property is protected by law.

⁸⁵ Grosheide above at 19.

diverging scholarly views on the problematic relationship. Many scholars have made incisive and telling contributions that attempt to unravel the conceptual and paradoxical relationship between intellectual property rights and human rights. In the following paragraphs, a summary of some of the leading views is given.

Intellectual property rights are instrumental in promoting and protecting human rights, hence they need to be implemented into domestic law.⁸⁶ Human rights can be used as instruments to deflect the moral appeal of certain affirmative rights of intellectual property holders by, for example, justifying compulsory licences in the interest of public health.⁸⁷ This submission would make more sense when viewed against Chapman's analysis of Article 27 (2) of the UDHR and Article 15.1 (c) of the ICESCR, wherein he opines that participating states are under an obligation to develop intellectual property law regimes that have an explicit human rights orientation.⁸⁸

Intellectual property rights are not first and foremost 'economic commodities' but have an intrinsic value as an expression of human dignity and creativity.⁸⁹ An understanding of intellectual property as a human right is lacking in the WTO and by extension in the TRIPS Agreement.⁹⁰ There is, therefore, a need to take a non-uniform view of intellectual property since not all intellectual property rights can be considered as human rights.⁹¹ The imposition of WTO-wide minimum standards for intellectual patent protection has been contested on the basis that public health concerns require weaker or more flexible patent protection in the

⁸⁶ Drahos P *The Universality of Intellectual Property Rights: Origins and Development* (1999).

⁸⁷ See Okedjii RL "Back to Bilateralism? Pendulum Swings in Intellectual Property Protection" (2004) 1 *University of Ottawa Law and Technology Journal* at 125.

⁸⁸ Chapman AR "The Human Rights Implications of Intellectual Property Protection" (2002) 5 *Journal of International Economic Law* at 861 -882.

⁸⁹ Grosheide above at 24. For example, the author and creator can be an individual or a group or the community and contribute to promotion of cultural diversity.

⁹⁰ Chapman above at 865.

⁹¹ Good examples are trademarks, works made for hire, employee inventions, neighbouring rights and database rights. See in this specific regard Yu PK "Common Questions about Intellectual Property and Human Rights" (2007) 23 *Georgia State University Law Review* 709 – 753. At 740, Yu opines that existing international human rights instruments have already isolated the human rights and non-human rights attributes of intellectual property rights by recognizing only certain attributes.

pharmaceutical field.⁹² This argument has often been advanced by or on behalf of developing countries.⁹³

If corporations are bound by human rights norms, then pharmaceutical companies would be bound by the right to access medicine, if it exists (see below) and thus be held accountable where their pricing violates the obligations imposed under the right.⁹⁴ However, it will be difficult to attribute state-like attributes to corporations in the absence of an express categorization of human rights obligations in light of the fact that international law traditionally binds states.⁹⁵ Fundamental rights would not only serve as a guide for the application of intellectual property law but also for the reorganization of intellectual property law in future.⁹⁶

If intellectual property is viewed as a ‘right to benefit’, due to the intellectual property system having been established as the primary means by which to access this ‘benefit’, then, intellectual property rights are in effect aligned with human rights.⁹⁷ This view and the others expressed before it sharply contrasts with Drahos’ view in which he argues that intellectual property rights are universally recognized notwithstanding the fact that this does not make them universal human rights, since they depend on legislative declaration and are for a limited time (usually 20 years). It is notable, therefore, that they do not belong to all human beings and also that not all intellectual property rights protect personal interests of their originators.⁹⁸

While the UDHR recognizes intellectual property as a human right,⁹⁹ promoting universal intellectual property protection is incompatible with the promotion of human physical wellbeing.¹⁰⁰ Indeed, if intellectual property is regarded as a guaranteed human right, developing countries would be put at a disadvantage, both in developing policies to sustain economic growth and in increasing global markets.¹⁰¹ It is submitted that in the same way as there is a hierarchy of laws, there is also a hierarchy of human rights hence it should be conceded that some human

⁹² Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007) at 76.

⁹³ Ibid.

⁹⁴ Helfer and Austin above at 95.

⁹⁵ Ibid.

⁹⁶ Geiger C (2008) “The Constitutional Dimension of Intellectual Property Law” in Torremans P (Ed) *Intellectual Property and Human Rights* 101 – 131 at 136.

⁹⁷ Macqueen H, Waelde C and Laurie G *Contemporary Intellectual Property Law and Policy* (2008) at 28.

⁹⁸ See generally Drahos P (1999) *The Universality of Intellectual Property Rights: Origins and Development*.

⁹⁹ Per Article 27 thereof.

¹⁰⁰ Ostergard RL “Intellectual Property a Universal Human Right? (1999) *Human Rights Quarterly* at 156 – 178.

¹⁰¹ Ostergard above at 177.

rights take priority over other human rights. In the context of this study, it would seem likely that the right to physical wellbeing (read medicines) will have to trump intellectual property rights. For developing countries generally, and specifically those in the SADC region, recognising that this hierarchy exists will go a long way towards resolving the access to medicines enigma.

There is a need to protect everyone who is likely to be negatively affected by strengthened intellectual property rights standards (like Ostergard) and also to consider the broader question of the role of science and technology in a human rights framework.¹⁰² The ability of WIPO and the WTO to infuse human rights into the intellectual property legal regime they promote is in serious doubt.¹⁰³ The main reason for this could be due to the fact that both organisations have been established to promote the facilitation of international commerce at the behest of the private sector in the West rather than to promote human welfare in the world, especially in the South.

On the other hand, characterizing intellectual property as a human right implies construing the right to enjoy monopoly right and rent as a human right even if it is at the expense of society at large.¹⁰⁴ This goes against the basis of Article 15.1 (c) of the ICESCR which talks of striking the balance between intellectual property and human rights. Viewed in this light, intellectual property rights and human rights are incompatible because intellectual property rights get in the way of countries seeking enforcement of human rights.¹⁰⁵

The above outline highlights the problematic relationship between intellectual property and human rights and summarizes some of the major juridical views on the subject. It is generally not desirable to highlight problems without proposing solutions thereto. Therefore, the following section continues outlining the major writings on intellectual property and human rights but with a bias towards offering solutions to the problematic relationship. Where possible, the solutions are contextualized to the access to medicines problem, in order not to blur the focus of the study.

3.1.4 Intellectual Property and Human Rights in Legal Literature: Some Possible Solutions

According to Grosheide,¹⁰⁶ there are three possible approaches that may be adopted in order to resolve the problematic relationship between intellectual property and human rights. The first

¹⁰² Cullet above at 412.

¹⁰³ Ibid.

¹⁰⁴ Grosheide above at 31.

¹⁰⁵ Ibid.

¹⁰⁶ Grosheide above at 31 – 33.

possible approach is to reshape the existing national and international intellectual property law so that the apparent tensions between the law and human rights would fall away.¹⁰⁷ This would entail infusing human rights norms into intellectual property law.

The other solution the author suggests would require governmental intervention which would focus on an instrumental approach aimed at introducing a ‘human rights framework for the execution of intellectual property rights’.¹⁰⁸ The crux of this solution is that human rights should be used to restrict intellectual property rights in a horizontal fashion, and intellectual property law should be instrumental in the implementation of human rights.¹⁰⁹

Thirdly, a solution that differentiates human rights qualities of individual intellectual property rights is suggested.¹¹⁰ This approach is dubbed the application of a ‘human rights hierarchy’ and will result in some intellectual property rights acquiring a human rights status while others will not. There is a positive outlook to this proposed solution, namely that if intellectual property is given a human rights face, this may positively lead to the protection of cultural expressions.¹¹¹

If the foregoing approach is adopted, stressing the human rights quality of intellectual property rights, which stands in the way of patented medicine, will be overcome.¹¹² This proposed solution, which is quite pertinent to the objectives of this study, will be welcomed by developing countries grappling with access issues. It is submitted that intellectual property law will have to be reshaped through a concerted effort by WIPO and the WTO, and expanding the way in which human rights law may be applied horizontally and the execution of intellectual property rights between private parties will be a less drastic action.

Rights language in relation to intellectual property runs through many international instruments.¹¹³ The paradox arises when one human right is pitted against another such as when

¹⁰⁷ Grosheide above at 31. The author reasons that the reshaping is necessary in light of the disparate political justifications and legal ramifications between intellectual property and human rights.

¹⁰⁸ Grosheide above at 32.

¹⁰⁹ Grosheide above at 32. This would require the internalization of human rights into intellectual property law.

¹¹⁰ Grosheide above at 32.

¹¹¹ Ibid.

¹¹² Ibid.

¹¹³ See for example, Article 27 (2) of the UDHR and Article 15 (c) of the ICESCR; both instruments articulate rights of creators.

intellectual property rights are used to restrict access to information that could, at no cost to the developer, satisfy human needs.¹¹⁴

Elevating intellectual property rights to human rights has unfortunate pragmatic consequences.¹¹⁵ Using the human rights approach will ensure that the benefits of an invention can be distributed, without the patentee's authorization only to meet social needs classified as universal.¹¹⁶ This approach may clash with the utilitarian goal of limiting protection from free riders as a means of encouraging the advancement of knowledge.¹¹⁷ It is submitted that access to medicines is too closely tied to the fundamental right to health.¹¹⁸ The implication thereof is that limiting it in this context would amount to a violation of the right.

Patent law anticipates a human rights welfare maximising approach at the international level.¹¹⁹ Although the TRIPS' objectives are cast in utilitarian rather than human rights terms, the rights must be balanced against social welfare concerns 'in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.¹²⁰ Rights talk creates an adversarial climate in which each side ups the ante, further limiting access to important developments, and interfering with the proper operation of the system as a whole.¹²¹

The utilitarian perspective, therefore, remains a viable solution which allows policy makers to use available tools to make law responsive to changes in innovation and align the system with other social interests including but not limited to those deemed fundamental.¹²²

Similarly, Brinkhof¹²³ recommends the adoption of the utilitarian approach as far as possible but when it comes to infringement cases, adopts a human rights approach to granting an interdict to users.¹²⁴ The recommendation is inspired by a provision of the Dutch Civil Code, which

¹¹⁴ Dreyfuss RC "Patents and Human Rights: Where is the Paradox" in Grosheide above at 72 (hereafter Dreyfuss).

¹¹⁵ Dreyfuss above 74.

¹¹⁶ Ibid. The implication thereof is that every incursion on a patent right would need to be justified by showing that it involved an interest that is not only socially desirable but, but that it can be categorized and a human right.

¹¹⁷ Dreyfuss above 74.

¹¹⁸ See para 3.2 below.

¹¹⁹ For example, Article 27 (2) and (3) of TRIPS envisions national exceptions to patent protection while Articles 30 and 31 permit compulsory licenses.

¹²⁰ See Article 7 of TRIPS.

¹²¹ Dreyfuss above at 94.

¹²² Ibid.

¹²³ Brinkhof J "On Patents and Human Rights" in Grosheide above at 140.

¹²⁴ Brinkhof above at 141.

allows a judge to refuse an injunction (interdict) where the acts leading to the injunction are viewed as tolerable because of some interest which is fundamental to society.¹²⁵ If this view is followed, it can bring relief to countries seeking access, which may issue compulsory licenses without going through the whole cumbersome TRIPS process and justify this on the basis that the compulsory license must be tolerated because it will bring social welfare and a healthy nation ('important societal interest').¹²⁶

Because law is not a human right but an instrument of economic policy,¹²⁷ it is indefensible in law to claim that an entitlement to patent protection is a human right.¹²⁸ While there is mention of intellectual property rights and in some specific instances patent rights in international human rights instruments,¹²⁹ the overall tenor of the human rights provisions thereof is extremely vague as to what might be understood to form part of the content of the 'right to protection'.¹³⁰

The EU Charter of Fundamental Rights in Europe¹³¹ provides that intellectual property shall be protected but does not refer to inventors being entitled to patents; neither is there any reference saying that patents are to be considered as human rights.¹³² Patents which have been granted will in all likelihood qualify as property and therefore enjoy the protection of fundamental human rights.¹³³

The question immediately arising out of the foregoing submission is: If the granted patents are property and enjoy the rights normally associated with property, can they be expropriated using domestic legislation or principles applicable to appropriation of alien property in terms of sovereignty over natural resources? If one were to go pedantically legalistic, the answer will be in the affirmative. With specific reference to local patents, this approach may be useful in partly

¹²⁵ See Article 6:168 of the Netherlands Civil Code which states that: 'The judge may reject an action to obtain an order prohibiting unlawful conduct on the ground that such conduct should be tolerated for reasons of important societal interests. The victim retains his right to reparation of damage'.

¹²⁶ Contrast this with the judgment in the decision of the Dutch Supreme Court case of *Boehringer v Kirin Amgen* 21 April 1995, NJ 1996,462, wherein it was held that the rights of 3rd parties such as patients should not be protected by committing a patent infringement or allowing one to continue.

¹²⁷ Brinkhof above at 146.

¹²⁸ Ibid at 153.

¹²⁹ Preamble to U.N Human Rights Charter, Art. 27 of UDHR, Art. 15 (1) (c) of ICESCR, Dec. 14 2001 agenda item 6 of the Committee on Social and Cultural Rights.

¹³⁰ Brinkhof above at 146.

¹³¹ See Arts. 17(1) and (2) of the EU Charter of Fundamental Rights in Europe OJ [2000] c 364/01.

¹³² Brinkhof above at 153.

¹³³ Ibid.

resolving the access problem through expropriation of patent rights and justifying this on the basis that property may be expropriated for a public purpose and accompanied by prompt and adequate compensation.¹³⁴ Expropriation could then be justified on the basis of rights, with specific reference to the right to health and life.

While patent rights are not fundamental human rights, patent law is subordinate to human rights and should a conflict arise between the two, patent law must give way.¹³⁵ This interpretive submission is to be welcomed in light of its potential for increasing and improving access to essential medicines.

If patent rights are elevated to fundamental rights, patent rights may be expanded against the desires of impoverished peoples to manufacture and distribute inexpensive versions of patented drugs.¹³⁶ When the poor claim the right to human health¹³⁷ and to share in the scientific progress by being allowed access to cheap patented medication (either through compulsory licenses, parallel importation or differential pricing), this may be countered by reference to an imagined right to patents by pharmaceutical companies.¹³⁸ Therefore, it is undesirable to equate patent rights to fundamental human rights. Pharmaceutical companies, being corporations, have rights which under positive existing law are of a different nature and not protected at the level of human rights.¹³⁹ Human rights must inevitably provide external limitations to the exercise of intellectual property rights.¹⁴⁰ Intellectual property law must be viewed as designed to fulfil human rights' objectives; hence human rights and intellectual property are compatible and can co-exist.¹⁴¹ Both intellectual property and human rights aim at enhancing welfare and the benefit for society.¹⁴²

¹³⁴ For the requirements of an expropriation at the international level see generally Mendelson MH "Compensation for Expropriation: The Case Law (1985) 79 *American Journal of International Law* at 414-420.

¹³⁵ Brinkhof above at 153.

¹³⁶ See generally Gordon W.J "Current Patent Laws Cannot Claim the Backing of Human Rights" in Grosheide above 155 – 179.

¹³⁷ See 3.2 below.

¹³⁸ Gordon above at 157.

¹³⁹ Hestermeyer above at 168 citing from para 7 of General Comment no.17.

¹⁴⁰ Hestermeyer above at 168.

¹⁴¹ Van Overwalle G "Human Rights' Limitations in Patent Law" in Grosheide above at 236 – 237.

¹⁴² Geiger C "Constitutionalising Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union" (2006) 37 *IIC* 371 – 500.

3.2 Access to Medicines in the Context of the Right to Health

3.2.1 Preliminary Remarks

In general, human rights are legally guaranteed by international, regional and national human rights law, protecting individuals and groups against actions that interfere with fundamental freedoms and human dignity.¹⁴³ Most human rights are interdependent and as a good example of such interdependence, the right to health is closely associated with the right to life and is indispensable for the exercise of most other human rights.¹⁴⁴

The right to health includes ‘underlying determinants of health such as access to safe and portable water and adequate sanitation, adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information’.¹⁴⁵ Additionally, the right to health requires the availability and accessibility of ‘functioning public health and health-care facilities, goods and services, as well as programmes’.¹⁴⁶ Access to medicines is conceptualized as a sub-component of the broader right to adequate health.¹⁴⁷

In this section of the chapter, aspects of the right to health are discussed by linking them with access issues from an international and regional perspective. The specific provisions talking directly to the right to health are identified and their potential for resolving access to medicines issues, specifically from a developing world and SADC perspective is explored.

3.2.2 An Overview of regional and International activity on the Right to Health and Access to Medicines

A number of human rights institutions and actors have played a critical role in the development of human rights norms in the context of the right to health.¹⁴⁸ These include treaty bodies such as

¹⁴³ Hogerzeil HV “Essential Medicines and Human Rights: What can they learn from each Other?” (2006) *Bulletin of the World Health Organisation* 371 – 375 at 371.

¹⁴⁴ Hogerzeil above at 371.

¹⁴⁵ Committee on Economic, Social and Cultural Rights, General Comment No. 14: *The Right to the Highest Attainable Standard of Health* (art. 12) U.N. Doc/E/C. 12/2000/4 (11 August 2000).

¹⁴⁶ Ibid para 12 (a).

¹⁴⁷ Narula S “The Rights-based approach to Intellectual Property and access to Medicine: Parameters and Pitfalls” (2011) *NELLCO Legal Scholarship Repository* 1 – 25 at 2. See further for example, U.N Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, *Addendum: Mission to the World Trade Organisation*, para 18, U.N. Doc. E/CM.4/2004/49/Add.1 (1 March 2004) (prepared by Paul Hunt) (asserting that the right to health encompasses ‘access to essential medicines’).

¹⁴⁸ For a comprehensive compilation of relevant texts from international actors, see Helfer and Austin above at 53 - 56.

the Committee on Economic, Social and Cultural Rights;¹⁴⁹ intergovernmental bodies such as the U.N Human Rights Council (formerly the Commission on Human Rights);¹⁵⁰ and special procedures and individual office holders such as the U.N Commissioner for Human Rights,¹⁵¹ and the U.N Special Rapporteurs on the right to health and food.¹⁵²

Regional¹⁵³ and domestic actors are also increasingly involved in the development and implementation of human rights norms as they relate to access to medicines. At the regional level, these include the Inter-American Commission on Human Rights¹⁵⁴ and the African

¹⁴⁹ See for example, Committee on Economic, Social and Cultural Rights, General Comment No. 17: *The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary and Artistic Production of which he is the Author*, Art 15(1) (c), U.N. Doc.E/C.12/GC/17 (12 Jan. 2006) [hereafter General Comment No. 17] (asserting that state parties must ‘ensure that intellectual property regimes contribute, in a practical and substantive way, to the full realization of the Covenant rights’); ECOSOC, Committee on Economic, Social and Cultural Rights, *Substantive Issues arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, U.N. Doc. E/C12/2001/15 (14 Dec 2001) (asserting that ‘national and international intellectual property regimes must be consistent with’ economic, social and cultural obligations) and Committee on the Rights of the Child, *General Comment No.3: HIV/AIDS and the Rights of the Child*, para 28 U.N. Doc. CRC/GC/2003/3 (17 March 2003) (asserting that the ‘obligations of the state parties under the convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs’).

¹⁵⁰ See Commission on Human Rights, Res. 2001/33 U.N. Doc. E/CN.4/RES/2001/33 (23 April 2001), in which states are urged to ‘adopt legislation or other measures, in accordance with applicable international law’ to ‘safeguard access’ to such medications ‘from any limitations by third parties’); Commission on Human Rights, *Access to Medication in the Context of Pandemics Such as HIV/AIDS*, U.N.Doc.E/CN.4/RES/2002/32 (22 April 2002) and Human Rights Council, *Access to Medicine in the Context of the Right of Everyone to the enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Res. 12/24, U.N.Doc.A/HRC/RES/12/24 (2 Oct. 2009).

¹⁵¹ See for example, Commission on Human Rights, *Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, U.N.Doc E/CN.4/Sub.2/2001/13 (27 June 2001) (analysing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and criticising TRIPS implementation from a human rights perspective).

¹⁵² See for example, U.N Special Rapporteur on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Report of the Special Rapporteur on the Right of Everyone to the enjoyment of the Highest Standard of Physical and Mental Health*, 61st Sess., U.N Doc.A/61/338 (2006); U.N Special Rapporteur on the right of everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, U.N Doc/A/63/263 (11 August 2008) (prepared by Paul Hunt) (addressing human rights obligations of pharmaceutical companies); U.N Special Rapporteur on the Right to Food, Report to U.N General Assembly, U.N. Doc. A/64/170 (23 July 2009) (prepared by Olivier De Schutter) (addressing the interaction between human rights and intellectual property); U.N Special Rapporteur of the Commission on Human Rights on the Right to Food, *Report to Commission on Human Rights*, U.N.Doc E/CN.4/2004/10, para 39 (9 February 2004) (prepared by Jean Ziegler) (addressing the interaction between human rights and intellectual property).

¹⁵³ In the specific context of this study, see *SADC Pharmaceutical Business Plan 2007 -2013*, published by the SADC Secretariat on 27 June 2007, and the more recent *Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013-2017*, published by the SADC Secretariat in September 2012.

¹⁵⁴ See for example, *Jorge Odir Miranda Cortez and Others v El Salvador*, case 12.249, Report No. 29/01, OEA/Ser. L/V/II.111 Doc. 20 Rev. at 284 (2000) in which an HIV infected individual claimed inter alia, that the El Salvador government had violated the right to life and health by failing to provide antiretroviral drugs. The Inter-American Commission issued a precautionary measures order and declared the complaint admissible, but the case

Commission on Human and Peoples' Rights.¹⁵⁵ Domestically, a number of courts have played a critical role in translating these norms into tangible rights and benefits.¹⁵⁶

3.2.2.1 The Right to Health and Access to Medicines in Specific International Human Rights Instruments

The right to health was not developed until the end of the Second World War when the World Health Organisation (WHO), a specialized agency of the United Nations,¹⁵⁷ was established.¹⁵⁸ The constitution of the WHO, which came into force on 7 April 1948, was the first international legal document to contain an explicit right to the 'enjoyment of the highest attainable standard of health'.¹⁵⁹ Health was defined, rather idealistically, as a 'state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity'.¹⁶⁰ It is not easy to find a clear and simple definition of health because the concept is very complex, encompassing many facets of human life and a variety of dimensions, such as health care and health conditions.¹⁶¹

Therefore, 'the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life'.¹⁶² It was further provided that the 'enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.¹⁶³

ended in a friendly settlement after the El Salvadorian Supreme Court ordered that drugs be provided in a similar case.

¹⁵⁵ See African Commission on Human and Peoples' Rights, Resolution on Access to Health and Needed Medicines in Africa, ACHPR/Res.141 (XXXXXIII) 08 (24 Nov. 2008), available at <http://www.achpr.org/sessions/44th/resolutions/141> (last visited 12/11/12). The resolution urges states to 'guarantee the full scope of access to needed medicines' and calls upon states to fulfil their duties by promoting, protecting and fulfilling access to medicines.

¹⁵⁶ See for example the South African case of *Minister of Health v Treatment Action Campaign (TAC)* (2002) 5 SA 721 (CC), in which it was held that the South African government's restrictions on the distribution of antiretroviral drugs to pregnant women amounted to a violation of the constitutional right to health; *Lopez Glenda yatrov v Instituto Venezolano de los Seguros Sociales (IVSS) s/ accion de amparo Expediente 00-1343*. (1999 Venezuelan Constitutional Court) in which the Venezuelan government was ordered to provide antiretrovirals on a regular and reliable basis to a group of individuals living with HIV/AIDS and the Argentinian case of *Viceconte, Mariela v Estado Nacional (Ministerio de Salud y Ministerio de Economia de la Nacion) s/ Accion de amparo*, (1998) Causa no. 31.777/96 in which the Argentinian Federal Administrative Court of Appeals found a violation of the right to health under Art 12 of the ICESCR and ordered the Argentinian government to produce and distribute a vaccine.

¹⁵⁷ See Article 57 of the U.N Charter.

¹⁵⁸ Hestermeyer above at 84.

¹⁵⁹ Ibid. See preamble thereto.

¹⁶⁰ Preamble to the WHO Constitution.

¹⁶¹ Riedel above 6.

¹⁶² General Comment No. 14 above.

¹⁶³ Preamble to the WHO Constitution.

With few exceptions, the relationship between health and human rights was not subject to close, serious examination until the 1990s.¹⁶⁴ The human right to health is now incorporated in many global¹⁶⁵ and regional¹⁶⁶ human rights agreements and two thirds of national constitutions.¹⁶⁷

The most basic document in the sphere of human rights is the UDHR which stipulates that ‘everyone has the right to a standard of living adequate to the health of himself and his family, including food, clothing, housing and medical care and social services’.¹⁶⁸ When it was adopted, the UDHR was somewhat legally non-binding but has since assumed the status of customary international law for most of its provisions.¹⁶⁹ Since the adoption of the UDHR, a number of U.N institutions and conferences have dealt with or addressed issues of health and have adopted various principles and declarations.¹⁷⁰ Of the eight U.N Millennium Development Goals (MGDs), three have a direct health care dimension while target 17 of MDG number 8 calls for cooperation with pharmaceutical companies in order to provide access to affordable essential drugs in developing countries.¹⁷¹

¹⁶⁴ See Human Rights Council Fourth Session Item 2 of the Provisional agenda *Implementation of General Assembly Resolution 60/251 of 15 MARCH 2006 Entitled Human Rights Council, Report of the Special Rapoteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, A/HRC/4/28 (17 January 2007).

¹⁶⁵ For a comprehensive list of international instruments, see Committee on Economic, Social and Cultural Rights, *The Right to the Highest Attainable Standard of Health* E/C.12/2000/4 (hereafter General Comment No. 14) para 2 available at [http://www.unchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (last visited 30/11/12). Apart from the provisions of the UDHR and the ICESCR, other international instruments like Article 5 (e) (iv) of the International Convention on the Elimination of all Forms of Racial Discrimination of 1965; Articles 11.1 (f) and 12 of the Convention on the Elimination of all Forms of Discrimination against Women (CEDAWO) of 1979 and Article 24 of the Convention on the Rights of the Child recognize the right to health.

¹⁶⁶ Several regional human rights instruments also recognize the right to health such as Article 11 of the Revised European Social Charter of 1961; Article 16 of the African Charter on Human and Peoples’ Rights; and Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988. Similarly, the right to health has been proclaimed by the Commission on Human Rights in its Resolution 1989/11, as well as the Vienna Declaration and Programme of Action of 1993.

¹⁶⁷ Kinney E.D and Clark B.A “Provisions for Health and Health Care in the Constitutions of the Countries of the World” (2004) 37 *Cornel International Law Journal* at 291.

¹⁶⁸ Per Article 25 (1) of the UDHR.

¹⁶⁹ See Riedel E “Health, Right to, International Protection” in *Max Planck Encyclopedia of Public International Law* (2007) at 2.

¹⁷⁰ For example, the *Vienna Declaration and Programme of Action*, adopted by the *Vienna World Conference on Human Rights* (1993) alludes to the right to health in its repeated acknowledgement of the importance health care and protection; also the *U.N Millennium Declaration*, adopted on 8 September 2000 by the U.N General Assembly stresses the importance of health care and prevention of disease by committing to the improvement of maternal and child health and the fight against HIV/AIDS, malaria and other diseases.

¹⁷¹ The SADC Pharmaceutical Business Plan was conceived in this specific context and this study aims at making a modest contribution towards the actualization of target 17 of MGD number 8. It has been widely reported that most SADC members will not be able to achieve the MGDs by the 2015 target (see specifically Sikuka K “A more Positive approach as Africa Prepares for Post-2015 Development Agenda” (2013) 15 *SADC Today*).

Additionally, other U.N instruments mention health in various contexts.¹⁷² All these instruments and several others relevant to health have either been adopted or approved by the U.N General Assembly although they have no legally binding effect on states/governments.¹⁷³ The instruments, however, form an important component within the international movement to promote and protect the physical and mental health of human beings throughout the world.¹⁷⁴

In addition to the U.N based Charter system outlined above, there is a robust international treaty based system featuring several conventions which state legally binding provisions for their respective signatories.¹⁷⁵ The most important treaty in this specific regard is the International Covenant on Economic, Social and Cultural Rights (ICESCR) which states that:

The state parties to the present covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The steps to be taken by the state parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth –rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.¹⁷⁶

In the context of this study, with the possible exception of sub-paragraph (b), medicines can be needed for all the aspects of health policies mentioned in paragraph 2.¹⁷⁷ The Committee on Economic, Social and Cultural Rights (ICESCR)¹⁷⁸ interprets Article 12 as attributing to states

¹⁷² See the following U.N General Assembly Resolutions: Resolution 48/104 of 20 December 1993 (refers to the right to the highest standard attainable of physical and mental health); Resolution 46/91 of 16 December 1991 (stresses the importance of access to adequate health care ‘to maintain or regain the optimum level of physical, mental and emotional well-being and to prevent or delay the onset of illness’); Resolution 46/119 of 17 December 1991 (focuses on mental health care as one aspect of the right to health); Resolution S-26/2 OF 27 June 2001 (promotes international awareness regarding HIV/AIDS) and Resolution 45/111 of 14 December 1990 and the *Standard Minimum Rules for the Treatment of Prisoners* of 1977 include many other references to health care and protection.

¹⁷³ Riedel above at 3.

¹⁷⁴ Ibid.

¹⁷⁵ Ibid.

¹⁷⁶ Article 12 of ICESCR.

¹⁷⁷ See Niada L (Niada 1) “The Human Right to Medicine in Relation to Patents in Sub-Saharan Africa: Some Critical Remarks” (2011) 15 *The International Journal of Human Rights* 700 – 727 705.

¹⁷⁸ The CESCR’s pronouncements are not binding per se but can be considered ‘authoritative interpretations’ of the Covenant, see for example, Skogly S.I and Gibney M “Transnational Human Rights Obligations” (2002) 4 *Human Rights Quarterly* 791. The Committee has been active in elaborating General Comments on various ICESCR provisions and on how to better implement the Covenant; issuing reporting guidelines for the ICESCR Parties, relating to issues and policies on which states have to focus their attention; analysing states’ implementation of the Covenant and expressing ‘concluding considerations’ on them [Niada L (Niada 2) “Hunger and International Law: The far Reaching Scope of the Right to Food” (2006) 22 *Connecticut Journal of International Law* 149]. CESCR comments are also considered by national courts in some instances, see for example *Government of South Africa v Grootboom and Others* 2000 (11) SA BCLR 1169 (CC) at paras 11-13.

obligations with regard to medicines.¹⁷⁹ The ICESCR clearly identifies the provision of essential medicines as one of the measures to be taken under sub-paragraph (d) that the Committee maintains, ‘includes the provision of equal and timely access to basic preventive, curative, rehabilitative health services and...the provision of essential drugs...’¹⁸⁰

Article 12 of the ICESCR can be violated by the ‘adoption of legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.’¹⁸¹ It is, therefore, relevant in the context of this study to argue that strong patent laws may constitute such incompatible legislation.¹⁸² Similarly, the failure to appropriately regulate non-state entities such as private pharmaceutical companies ‘so as to prevent them from violating the right to health of others’ may also amount to a breach of Article 12.¹⁸³ Some authorities have argued that the failure to cap big pharmaceutical companies’ (‘big pharma’) prices may be an example of such a culpable omission.¹⁸⁴

The ICESCR provides the main foundation for legal obligations in the field of health.¹⁸⁵ The ICESCR lists a number of steps to be taken by State Parties to achieve the full realisation of the right to health, including the right to: maternal, child and reproductive health, healthy natural and workplace environments; prevention, treatment and control of diseases; and ‘the creation of conditions which would make it possible for indispensable medical service and medical attention to be given in the event of sickness’.¹⁸⁶

The right to health implies, like other economic and social rights, that there is an obligation to be respected, protected and have that right fulfilled.¹⁸⁷ Therefore, states are urged to refrain from interfering directly or indirectly with the enjoyment of the right; furthermore, states should take

¹⁷⁹ ICESCR Article 12.

¹⁸⁰ General Comment no. 14 para 17.

¹⁸¹ Joseph S “Pharmaceutical Corporations and Access to Drugs: The ‘Fourth Wave’ of Corporate Human Rights Scrutiny” (2003) 25 *Human Rights Quarterly* 425 -452 438.

¹⁸² Ibid.

¹⁸³ General Comment no.14 para 51.

¹⁸⁴ Joseph above at 439. I do not entirely agree with this submission because it is possible that current government action which facilitates patents and high prices may be justifiable in international human rights law as a necessary means of ensuring on-going innovation in the pharmaceutical industry.

¹⁸⁵ Hogerzeil above at 372.

¹⁸⁶ Article 12.2 of ICESCR.

¹⁸⁷ Cullet above at 148.

measures to prevent third parties from interfering with the guarantees provided.¹⁸⁸ With specific reference to actions states can take internally to ensure the enjoyment of the right to health, they are further enjoined to adopt appropriate legislative, administrative and other measures ‘towards the full realization of the right’.¹⁸⁹

It is important to point out that the implementation of the ICESCR, a treaty that is binding to its membership of over 150 State parties, is monitored by the Committee on Economic, Social and Cultural Rights which regularly issues authoritative but non-binding comments to clarify the nature and content of individual rights and state obligations.¹⁹⁰ Therefore, the ICESCR has made a significant contribution to the codification of the human right to health and demarcated its scope.¹⁹¹

In General Comment no.14,¹⁹² the Committee stated that the medical service mentioned in the pertinent provision of the ICESCR¹⁹³ includes the provision of essential drugs ‘as defined by the WHO Action Programme on Essential Drugs’.¹⁹⁴ The notion of ‘the highest attainable standard of health,’¹⁹⁵ which is elaborated upon by General Comment no.14, takes into account both the individual’s biological and socio-economic preconditions and the state’s available resources.¹⁹⁶ In that vein, therefore, the ICESCR thus generally requires that member states take all feasible steps to the maximum of their available resources to progressively achieve the full realization of the protected rights.¹⁹⁷

Progressive realisation of the Right to health ‘means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full

¹⁸⁸ Cullet above at 148.

¹⁸⁹ Ibid.

¹⁹⁰ Hogerzeil above at 372.

¹⁹¹ Cullet P above at 139.

¹⁹² Committee on Economic, Social and Cultural Rights, *The Right to the Highest Attainable Standard of Health*, 11/08/2000/4, CESCR, para 12 (a).

¹⁹³ Namely Article 12.2 (d) thereof.

¹⁹⁴ According to Hogerzeil, the first *Model List of Essential Medicines* of 1977 preceded the famous 1978 Declaration of Alma Ata on health for all. The author further opines that essential medicines are those that satisfy the priority health care needs of the population are selected with due regard to disease prevalence, evidence on efficacy, safety and comparative cost effectiveness.

¹⁹⁵ Per Article 12.1 of the ICESCR.

¹⁹⁶ General Comment no. 14 above at para 9.

¹⁹⁷ Cullet above at 148.

realization of Article 12'.¹⁹⁸ The resource dependency of the fulfilment of the right to health undermines the universality of the right and leaves states with insufficient implementation guidelines.¹⁹⁹ The covenant also recognizes that the full realisation of the rights may require more than domestic measures. Hence, it provides that these measures should be taken by individual states and through international assistance and cooperation.²⁰⁰

The right to health in all its forms and at all levels contains specific interrelated and essential elements, namely: availability, accessibility, acceptability and quality.²⁰¹ It has been argued that states could ensure that medicines are available by making use of compulsory licenses as provided for under the TRIPS.²⁰² This will guarantee the availability of sufficient quantities of medicines within individual countries.²⁰³ Supporting research and development of drugs to address diseases that place a particular burden on the developing countries could be another way of making drugs available.²⁰⁴ Taking into account the state's developmental level, the presence of functioning public health and health-care facilities, goods and services, as well as programmes, will be an indicator of the availability leg of the right to health.²⁰⁵

Accessibility, which has four overlapping dimensions, namely non-discrimination,²⁰⁶ physical accessibility,²⁰⁷ economic accessibility²⁰⁸ and information accessibility,²⁰⁹ must be afforded to everyone within the jurisdiction of the state party.²¹⁰ Calls for both availability and accessibility

¹⁹⁸ General Comment no. 14 above para 31.

¹⁹⁹ Meier BM and Mori LM "The Highest Attainable Standard: Advancing a Collective Human Right to Public Health" (2005) *Columbia Human Rights Law Review* 101 at 114.

²⁰⁰ Cullet above at 148.

²⁰¹ See generally para 12 of General Comment no.14.

²⁰² Narula above at 6.

²⁰³ It must be noted that patents are not the only factor hampering access because even cheaper generic versions of drugs may not be affordable for people below the poverty line (Cullet above 143).

²⁰⁴ Narula above at 6.

²⁰⁵ General Comment No.14 para 12 (a).

²⁰⁶ General Comment No.14 para 12 (b). Health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds.

²⁰⁷ General Comment No. 14 para 12 (b). The implication is that health facilities, goods and services must be within a safe physical reach for all sections of the population especially the vulnerable or marginalized groups.

²⁰⁸ Economic accessibility simply refers to affordability in that health facilities and services must be affordable for all and that equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households (General Comment No. 14 para 12 (b)).

²⁰⁹ This entails the right to seek, receive and impart information and ideas concerning health issues. If information is accessible, then individuals can use the information as a basis for making informed decisions about the medicines they are taking (Narula above 7).

²¹⁰ General Comment No.14 para 12 (b).

have been especially pronounced in the face of various global pandemics such as HIV/AIDS, malaria, and tuberculosis.²¹¹

On the issue of acceptability, all health facilities, goods and services must be respectful of medical ethics and be culturally appropriate. The cultural appropriateness entails a health programme that is respectful of the culture of individuals, minorities, peoples and communities and sensitive to gender and life cycle requirements, as well as being respectful of confidentiality in order to improve the health status of those concerned.²¹²

Finally, it is almost obvious that states must ensure that medicines are of a good quality.²¹³ To ensure the availability of good quality medicines, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and portable water, and adequate sanitation must be present.²¹⁴

While the ICESCR allows for a ‘progressive realisation’ of the rights contained therein,²¹⁵ State parties have an immediate obligation to ensure non-discrimination in the provision of social, cultural and economic rights; and to take immediate steps towards the realization of these rights.²¹⁶ Furthermore, states may not engage in conduct that causes this realization of human rights to regress.²¹⁷ Since the ICESCR and the General Comment emphasize so much on the right to health and how it may be enjoyed in the context of accessing medicines, the next pertinent issue to consider is whether or not there is a right to have access to medicines, and if so, what the best approach towards realizing this right would be. The next section responds briefly to the two issues.

3.3 Is there a Right to Have Access to Medicines?

While there is almost universal consensus that access to drugs is one of the fundamental components of the human right to health,²¹⁸ it is not very clear whether there is a corresponding

²¹¹ Narula above at 7.

²¹² General Comment No. 14 para 12 (c).

²¹³ General Comment No.14 para 12 (d).

²¹⁴ Ibid.

²¹⁵ Article 12 of the ICESCR.

²¹⁶ Narula above at 9.

²¹⁷ Ibid.

²¹⁸ Cullet above 142. See further, Van Gulik C “The Impact of TRIPS on Access to Medicines and the Right to Health of Children” (2004) *Lawanddevelopment.org series 9*.

human right to access medicines or not.²¹⁹ Accessibility of medicines is a critical component not only of the right to health, but also the rights to life, non-discrimination, an adequate standard of living, benefits of scientific progress and many others.²²⁰

Some authors have, however, boldly referred to how ‘the human right to medicines can be, in practice, operationalized and implemented in sub-Saharan Africa with regard to the protection of patent rights’.²²¹ The African Commission on Human and Peoples’ Rights recently issued a resolution on access to medicines, which inter alia, recognizes that ‘access to needed medicines is a fundamental component of the human right to health and that States Parties to the African Charter have an obligation to provide where appropriate needed medicines, or facilitate access to them’.²²²

In terms of the United Nations General Assembly Resolution 179 of 2003,²²³ access to medication in the context of pandemics such as HIV/AIDS,²²⁴ tuberculosis and malaria is a fundamental element of the right to health. The Resolution calls upon states to pursue policies that would promote availability, accessibility and the quality of pharmaceutical products or medical technologies used to treat such pandemics or the most common opportunistic infections.²²⁵

Consequently, the obligation to respect access to medicines as part of a human right to health, culminating in the respect of the ‘human right to medicines’ are identifiable in international customary law.²²⁶

The provisions relating to access to medicines as a human right are, however, imprecise and international instruments such as the Alma Ata Declaration on Primary health Care²²⁷ and the

²¹⁹ Health is a fundamental human right indispensable for the exercise of other human rights (General Comment No.14 para 1).

²²⁰ Yamin AE “Not Just a Tragedy: Access to Medication as a Right under International Law” (2003) 21 *Boston University International Law Journal* 326-343 338.

²²¹ Niada above at 702.

²²² African Commission on Human and Peoples’ Rights, 2008, Resolution on Access to Health and Needed Medicines in Africa, OAU Doc.ACHPR/Res. 141 (XXXIII) 08, 24 November 2008, preamble, para 5 available at <http://www.achpr.org/sessions/44th/resolutions/141> (last visited 12/11/2012).

²²³ UN General Assembly Resolution 179 (2003), UN Doc.A/RES/58/179, para 1.

²²⁴ In the acute context of HIV/AIDS, access to medicines is a crucial factor to ensure health and life for millions who are now infected (Van Gulik above 9).

²²⁵ Ibid. The Resolution may be regarded as having been quite persuasive and having acquired the status of customary international law because it enjoyed near universal access (Niada above at 707).

²²⁶ Niada above at 708.

U.N General Assembly Resolution (2003) ²²⁸ explicitly commits state parties to the promotion of access to medicines as part of human rights law.²²⁹ Jonathan Mann,²³⁰ cited in Heywood²³¹ is said to have once argued that the ‘contribution of medicine to health, while undeniably important (and vital in certain situations), is actually quite limited’. However, side by side with the foregoing observation, when one looks at the emergence of ‘treatable pandemics (HIV/AIDS), the resilience of others (TB), breakthroughs in some crucial areas of medicine and paralysis in others,’ access to drugs as part of the right to health remains extremely crucial.

In the context of the WTO Agreement, at the first WTO Ministerial meeting in Doha, the Declaration on TRIPS and Public Health (hereafter Doha Declaration) clarified certain aspects of the TRIPS Agreement that were believed to be in conflict with human rights law thus affirming the primacy of the right to health in implementing intellectual property rights as follows:²³²

“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.”²³³

In light of the submissions by the authorities cited above, it is indeed appropriate to underline that there is no textual basis for the right to access to medicines but rather a universal right to health of which access to medicines constitutes an important subset. Because this study is biased towards using the human rights approach to solve the access problem for the SADC region, it is now appropriate to briefly explore the tenets and content of the rights-based approach and tentatively explore its possible application to the resolution of the access to medicines problem.

²²⁷ Declaration of Alma Ata 1978 available at http://www.euro.who.int/_data/assets/pdf_file/0009/113877/E93944.pdf (last visited 12/03/13), provides in Article I that *Health is a fundamental human right* [my emphasis] and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

²²⁸ See note 218 above.

²²⁹ Ibid.

²³⁰ Mann J, Gruskin S, Grodin M and Annas G (Eds), “Medicine and Public Health, Ethics and Human Rights” in Mann J *Health and Human Rights: A Reader* (1999) 439 -452.

²³¹ Heywood M “Drug Access, Patents and Global Health: ‘Chaffed and Waxed Sufficient’” (2002) 23 *Third World Quarterly* 217 – 231 at 220.

²³² t Hoen EFM “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond” (2002) 3 *Chicago Journal for International Law* 39 – 67.

²³³ Declaration of the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 , Fourth WTO Ministerial Meeting, Doha, Annex 1 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited 12/03/13)

3.4 The Rights-based Approach and its Potential Utility in Resolving the access Problem

3.4.1 Preliminary Remarks

Since I have established elsewhere in this chapter that access to medicines is an important component of the right to health, it is appropriate to prescribe the right-based approach as a possible solution to resolving the access problem. If, despite the lack of consensus over whether or not there is a right to access medicines, human rights norms are infused into access to medicines policy and legislation, access to medicines may improve.

3.4.2 What is a Rights-Based Approach?

It is asserted that ‘there is no source that neither defines human rights-based approaches nor is there a uniform approach’ in this regard.²³⁴ The definition varies depending on whether it comes from an NGO, donor government, UN Agencies and organisations.²³⁵ The definitions of human rights approaches are generally based on international human rights norms (taken from the UDHR and international human rights treaties) but concepts from other discourses are also imported. Examples of fields from which concepts have been imported are ethics,²³⁶ good governance,²³⁷ development and social justice.²³⁸

The rights-based approach²³⁹ is about claims, bringing about a ‘root cause’ approach, focusing primarily on matters of state policy and discrimination.²⁴⁰ In this approach, ‘the move from needs to rights, and from charity to duties, also implies an increased focus on accountability.’²⁴¹ In the relevant context, the promotion and protection of human rights appears to be articulated more through the notions of good governance, democratization, inclusion and participation.²⁴²

The human rights approach argues that any process of change that is being promoted through development assistance ought to be participatory, accountable and transparent with equity in

²³⁴ UNAIDS Global Reference Group on HIV/AIDS and Human Rights “Issue Paper: *What Constitutes a Rights – based Approach? Definitions, Methods, and Practices*” 4th Meeting 23 -25 August 2004.

²³⁵ Ibid.

²³⁶ For example, notions of equity.

²³⁷ Issues relating the rule of law.

²³⁸ Issues relating to inclusion.

²³⁹ For a comprehensive account of the general background reading on the ‘rights-based approach’, see Olowu D “Environmental Governance and the Accountability of non-state Actors in Africa: A Rights-Based Approach” (2007) 32 *South African Yearbook of International Law* 261 -282 and the authorities cited therein in footnote 94 at 280.

²⁴⁰ Uvin P “From the Right to Development to the Rights –Based Approach: How ‘Human Rights’ Entered Development” (2007) 17 *Development in Practice* 597 -606 602.

²⁴¹ Ibid.

²⁴² UNAIDS Global Reference Group on HIV/AIDS and Human Rights above 2.

decision-making and ‘sharing of the fruits or outcome of the process.’²⁴³ The rights-based approach remains largely a theoretical concept which is confined to mainstream development discourses.²⁴⁴ This, however, does not imply that the important concept cannot be applied to the right to health and access issues. At the moment, it would seem that human rights-based approaches are concerned with internationally ‘agreed human rights’.²⁴⁵ The evolving understanding of the rights and advocacy, such as ‘the right to access lifesaving treatment’ must be part of the rights-based framework/strategy.²⁴⁶ The contention of this study is that the rights-based approach will go a long way towards bridging the gap between patents and human rights and thus ensure more access to medicines.

The rights-based approach is underpinned by the realization that the processes by which development aims are pursued ‘should themselves respect and fulfil human rights’.²⁴⁷ If one were to consider pharmaceutical companies as having rights to intellectual property as patent holders, the granting of the patents and the exercise of the monopoly should not be pursued in a manner that does not respect and fulfil human rights, especially the right to access life-saving medicines. It needs to be reiterated, therefore, that the important aspects of the rights-based approach are that it ought to be participatory, accountable and transparent with equity in decision-making and sharing of the fruits or outcome of the process.²⁴⁸

The rights-based approach may be associated with the risk that it may amount to making ‘nice statements of intent regarding things that would be nice to achieve, or duties that we would like the world to assume one day, without setting out concrete procedures for actually achieving those rights’.²⁴⁹ It is submitted that the attitude of this study is that the rights-based approach will be appropriate and relevant if we consistently remind ourselves that access to medicines is part of the right to life, a fundamental right which WTO Members must fulfil; and in some instances,

²⁴³ Uvin above at 603.

²⁴⁴ Olowu above at 282. This view seems to concur with that held by Uvin at 597 wherein he writes that, ‘rights, human rights and rights-based are relatively recent additions to the development lexicon’.

²⁴⁵ UNAIDS Global Reference Group on HIV/AIDS and Human Rights above at 3.

²⁴⁶ Ibid.

²⁴⁷ Uvin above at 603.

²⁴⁸ Uvin above at 603.

²⁴⁹ Ibid.

the fulfilment of the right may clash with other subservient rights such as the rights of a patent holder.²⁵⁰

The rights-based approach, whether in the context of development or access to medicines as is the case in this study, advocates for the empowerment of marginalized groups, challenging oppression and exclusion, and changing power relations; a task lying outside the legal arena but falling squarely in the political realm.²⁵¹ This observation is quite apt in the present study because the rights-based approach to access to medicines is likely to work in the presence of both the legal and political will. Hence, it is suggested as a solution mainly in the specific context indicated above.

Some commentators have contrasted the ‘rights-based’ with the ‘needs-based’ approach and came to the conclusion that the needs-based approach focuses on securing additional resources for the delivery of services to particular groups while the rights-based approach calls for existing resources to be shared more equally and assist marginalized populations to assert their rights to those resources.²⁵² In the context of this study, the marginalized people would be those in the developing countries grappling with access issues to medicines. Notably, needs may be motivated by charitable intentions while rights are always based on legal obligations.²⁵³ When big pharmaceutical companies donate some needed drugs to poor countries to alleviate access problems, the motivation is needs-based rather than rights-based. A rights-based approach is likely to give priority to gross or severe types of human rights violations even if these affect only a small segment of the population.²⁵⁴

Under international law, the state is the principal duty-bearer with respect to the human rights of the people living within its jurisdiction.²⁵⁵ By stipulating an internationally agreed set of norms, backed by international law, the rights approach provides a stronger basis for citizens to make claims on their states and holding states to account for their duties to enhance the access of their

²⁵⁰ The human right to health and by extension the right to access medicines, may be fulfilled after trampling upon the pharmaceutical company’s right to its intellectual property, namely a patent through the instrumentality of a compulsory license (see Chapter five below).

²⁵¹ Uvin above at 604.

²⁵² Cornwall A and Nyamu-Musembi C “Putting the ‘Rights-Based’ Approach to Development into Perspective” (2004) 25 *Third World Quarterly* 1415 – 1437 at 1417.

²⁵³ Cornwall and Nyamu-Musembi above at 1417.

²⁵⁴ Cornwall and Nyamu-Musembi above at 1417.

²⁵⁵ Ibid.

citizens towards the realization of their rights.²⁵⁶ The most important aspect of the human rights approach is that it foregrounds the accountability of policy makers and other actors whose actions have an impact on the rights of people.²⁵⁷ Rights imply duties, and duties demand accountability.²⁵⁸

A human rights approach to health is critical in addressing the growing global health inequalities.²⁵⁹ Human rights approaches can include holding states and other parties accountable, developing policies and programmes consistent with human rights and facilitating redress for victims of violations of the right to health.²⁶⁰

In order to address conditions that create vulnerability, a human rights approach must seek to give voice to those who are vulnerable and enable them to improve their decision making scope to change their conditions of vulnerability.²⁶¹ The most common conception of the human rights approach is one where the human rights framework is used to hold government accountable.²⁶² Activities supporting accountability may be public critiques and litigation, and most others usually assume an adversarial mode.²⁶³ Therefore, a human rights approach offers a framework for pro-active development of policies and programmes so that health objectives can be operationalized in ways that are consistent with human rights.²⁶⁴ Additionally, human rights provide a much more powerfully normative set of criteria by which to judge right and wrong.²⁶⁵

From the above brief narration of the human rights approach in the context of access to medicines, it is clear that social movements can utilize the fact that governments have obligations in terms of recognized international human rights standards and pressurize the governments to prioritise access to medicines because it is a human right. If pharmaceutical

²⁵⁶ The Committee on Economic, Social and Cultural Rights made clear that such an obligation extends to the creation of enabling conditions rather than direct provisioning.

²⁵⁷ Ibid.

²⁵⁸ See Office of the UN High Commission for Human Rights, *Draft Guidelines for a Human Rights Approach to Poverty Reduction Strategies*, available at www.unhcr.ch/development/povertyfinal.html (last visited 1/03/13).

²⁵⁹ London L “What is a Human-Rights Based Approach to Health and Does It Matter?” (2008) 10 *Health and Human Rights* 65 – 88 at 65.

²⁶⁰ Ibid.

²⁶¹ London above at 68.

²⁶² London above at 70.

²⁶³ Ibid.

²⁶⁴ London L, Holtman L, Gilson L, Erasmus E, Khumalo G, Oyedele S and Ngoma B (2006) *Operationalizing Health as a Human Right: Monitoring Tools to Support Implementation of the Patients’ Rights Charter in the Health Sector* at 50.

²⁶⁵ London above at 68.

companies insist on their rights to patents and their sacrosanct nature, governments can look to international human rights law and the TRIPS flexibilities and proceed to make it possible for their citizens to enjoy the ‘benefits of scientific progress.’

Because this study is biased towards access to medicines in the context of the SADC region, it is appropriate that the pertinent African and SADC provisions on access to medicines are explored next. In the following paragraphs, therefore,²⁶⁶ I give a critical expository account of access to medicines as a human right in terms of the pertinent African and SADC regional instruments.

3.5 The Right to Health and Access to Medicine in Africa and the SADC Region

3.5.1 The Right to Health and Access to Medicines in Africa

In the African regional context, the main instrument binding sub-Saharan African countries to human rights prescriptions concerning access to medicines as part of the right to health is the African Charter on Human and Peoples’ Rights (ACHPR).²⁶⁷ The ACHPR was ratified by all 53 members of the African Union.²⁶⁸ With specific regard to health and medicines, the ACHPR provides as follows:

Every individual shall have the right to enjoy the best attainable state of physical and mental health. States Parties are obliged to take the necessary measures to protect the health of their peoples and to ensure that they receive medical attention when they are sick.²⁶⁹

Notably, the ICESCR outlines the comprehensive notion of health by describing the human right to health as the ‘right to the highest attainable standard of physical and mental health’.²⁷⁰ For the comparability of the relevant ACHPR and ICESCR Article formulations, one must consider that, according to the ACHPR,²⁷¹ international instruments can be used by the African Commission in order to interpret the Charter. Therefore, the availability of the ‘right to enjoy the best attainable state of physical and mental health’ to citizens in ACHPR Member states will be guided by the provision and interpretation of the right to health in the context of the ICESCR.

Access to medicines is necessary for the realization of the objectives spelt out in the pertinent provision of the ACHPR relating to health as pointed out above notwithstanding the fact that the

²⁶⁶ At para 3.5 below.

²⁶⁷ African Charter on Human and Peoples’ Rights (ACHPR), OAU Doc.CAB/LEG/67/3 rev. 5, 21 I.L.M 58 (1982), entered into force 21 October 1986.

²⁶⁸ Niada 1 above 705.

²⁶⁹ Per Article 16 of the ACHPR.

²⁷⁰ Article 12 of the ICESCR.

²⁷¹ In Article 60 thereof.

Charter does not make direct reference to access to medicines. In fact, the African Commission on Human and Peoples' Rights (hereafter African Commission), the Charter's treaty body,^{272, 273} has recently issued a resolution on access to medicines; which *inter alia*, recognises that 'access to needed medicines is a fundamental component of the human right to health and that state parties to the African Charter have an obligation to provide, where appropriate needed medicines or facilitate access to them'.²⁷⁴ The resolution has been widely welcomed by NGOs and other rejoinders as being timely and contemporaneous.²⁷⁵

In summary, the following key points about the resolution are worth reiterating. The human right to medicines entails three types of duties namely, to respect, protect and fulfil.²⁷⁶ While the African Commission defines the first set of duties in relation to access to medicines as 'promotion', substantively, it refers to negative actions of *respect* (emphasis added) by 'refraining' from certain actions.²⁷⁷ The resolution urges states to ensure that everyone has access to medical care while at the same time reiterating that 'access to needed medicines is a fundamental component of the right to health'; hence state parties have a mandate to promote 'the realization of the right to medicines for all'.²⁷⁸

Intellectual property is mentioned among the duties to respect access to medicines in that states are urged to refrain from 'implementing intellectual property policies that do not take full

²⁷² See Baderin MA "The African Commission on Human and Peoples' Rights and the Implementation of Economic, Social and Cultural Rights in Africa" in Baderin MA and McCorquodale R (eds) *Economic, Social and Cultural Rights in Action* (2007) at 144.

²⁷³ In terms of the ACHPR Article 45 (1), (2) and (3), the Commission's mandate is to protect, interpret, and promote the rights guaranteed under the ACHPR. Under its protective function, the African Commission receives biennial reports, can consider communications and complaints by other state parties or NGOs (per ACHPR Article 55), and can formulate recommendations (Article 59) for the implementation of the Charter. According to Baderin, thus far the African Commission has not been officially requested to interpret a Charter provision; however, it has expressed authoritative interpretation through the recommendations expressed in the exercise of its protective role.

²⁷⁴ African Commission on Human and Peoples' Rights, 2008, *Resolution on Access to Health and Needed Medicines in Africa*, OAU Doc. ACHPR/Res.141 (XXXXIII), 08 -24 November 2008, preamble para. 4. The resolution, which is available at <http://www.achpr.org/sessions/44th/resolutions/141> (last visited 04/03/13), was adopted at the ACHPR's 44th Ordinary Session held in Abuja, Federal Republic of Nigeria, from the 10th to the 24th of November 2008.

²⁷⁵ See for example the undated "Statement in Support of a Resolution on the Right to Health and Access to Medicines", signed by Patrick Eba (Aids and Human Rights Research Unit, University of Pretoria, South Africa), Sean Flynn (programme on Information Justice and Intellectual Property, American University) and Meetal Jain (International Human Rights Clinic, American University) and the "Resolution on the Right to Health and Access to Needed Medicines" reproduced from the original ACHPR resolution by the NGO Forum in Abuja in 2008.

²⁷⁶ Resolution preamble para 1.

²⁷⁷ Niada 1 above at 706.

²⁷⁸ Resolution preamble para 1.

advantage of all flexibilities in the WTO'.²⁷⁹ Entering into 'TRIPS-plus' free trade agreements is singled out as an impugned measure that is likely to defeat the access objective and state parties are discouraged from entering into such arrangements.²⁸⁰ Nevertheless, the African Commission calls on states to stimulate intellectual property in order to promote access to medicines.²⁸¹

The Resolution on Access to Health and Needed Medicines in Africa is an important African instrument which binds all the African Union member states and will in all likelihood be frequently cited in both municipal and regional courts by access advocates. The resolution makes it clear that access to medicines is a human right which state parties must respect. Having canvassed the Africa-wide position on the subject thus far, it is now appropriate to turn to the SADC position.

3.5.2 The Right to Health and Access to Medicines in the SADC Region

The most important documents in the SADC context relating to access to medicines and human rights are the SADC Protocol on Health,²⁸² SADC Pharmaceutical Business Plan²⁸³ and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.²⁸⁴ The three documents are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.²⁸⁵ The health programme has been developed taking into account the global and regional health declaration and targets.²⁸⁶

It is disheartening to write that in none of the three SADC instruments is the right to health mentioned directly, the closest the instruments come to mentioning the right to health is when they refer to the right as a fundamental principle underpinning regional integration in terms of the SADC treaty.²⁸⁷

²⁷⁹ Resolution preamble para 1.

²⁸⁰ Ibid.

²⁸¹ Ibid para 2(2).

²⁸² SADC Protocol on Health (1999), signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

²⁸³ SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat on 27 June 2007.

²⁸⁴ Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, published by the SADC Secretariat in September 2012.

²⁸⁵ See executive summary of the SADC Pharmaceutical Business Plan para 2 at 3.

²⁸⁶ Ibid.

²⁸⁷ See the 'Values and Principles' of the SADC Strategy on Pooled Procurement of Essential Medicines and Health Commodities (hereafter SADC Strategy document) 5, wherein the values of Human rights, transparency. Equity,

In the following paragraphs, I give an expository account of the content of each of the pertinent SADC instruments in the context of access to medicines and come to the conclusion that access issues are also given prominence by SADC despite the fact that they are not couched in the human rights language.

3.5.2.1 The SADC Protocol on Health

In the SADC Protocol on Health, health is not defined and neither is there express reference to access to medicines.²⁸⁸ Instead, the Protocol talks about ‘coordinating and supporting individual and collective efforts of the Member States to attain an acceptable standard of health for all their people’²⁸⁹ and to promote health care for all ‘through better access to health services’²⁹⁰ (not medicines!). The most logical implied message in this context would be to regard access to medicines as subsumed in ‘better access to health services’. The preamble to the Protocol begins by acknowledging that SADC member states are aware that a healthy population is a prerequisite for sustainable human development and increased productivity.²⁹¹ Furthermore, the preamble points out clearly that rendering coordinated and comprehensive health services in a concerted manner is a prerequisite for the improved health status of the people in the region in the 21st century and beyond.²⁹²

SADC Member States are urged to cooperate in addressing health problems and challenges facing them through effective regional collaboration and mutual support for the purpose of identifying and supporting those initiatives that have the potential of improving the health of the population within the region;²⁹³ promoting education, training and effective utilization of health personnel and facilities;²⁹⁴ foster cooperation and coordination in the area of health with international organisations and cooperating partners;²⁹⁵ develop common strategies to address the

gender, sustainable ownership, efficiency, and the principle of subsidiarity are expressly mentioned as guides. The SADC Protocol on Health does not expressly recognize individuals’ right of access to medicines but instead it bluntly observes that in its preamble that a healthy population is a prerequisite for sustainable human development and increased productivity in member states and calls for closer cooperation in the area of health.

²⁸⁸ The closest term that is defined is ‘health promotion’, defined as ‘the process of enabling people to increase control over and to improve their health’ (Article 1 of the SADC Protocol on Health).

²⁸⁹ Article 2 (b) of the Protocol on Health.

²⁹⁰ Article 2 (d) of the SADC Protocol on Health.

²⁹¹ SADC Protocol on Health, preamble para 3.

²⁹² Ibid para 6.

²⁹³ Article 3 (a). The Draft SADC Strategy may be regarded as an example of such cooperation.

²⁹⁴ Article 3 (c).

²⁹⁵ Article 3 (e).

health needs of women,²⁹⁶ children and other vulnerable groups;²⁹⁷ and to progressively achieve equivalence, harmonization and standardization in the provision of health services in the region.²⁹⁸

It is noteworthy that the SADC Protocol on Health does not refer to intellectual property rights in general terms; neither does it refer to the flexibilities provided by the WTO TRIPS Agreement. However, the only instance in which intellectual property rights are mentioned is in the context of the establishment of a regional databank of traditional medicines and attendant procedures which will ensure that the protection of medicinal plants is in accordance with the regimes and *related intellectual property rights* (emphasis added) governing genetic resources, plant varieties and biotechnology.²⁹⁹ The fact that intellectual property rights relating to pharmaceuticals specifically are not mentioned in this Protocol remains a serious omission. The reason for the seriousness of the omission is simple. Health is usually synonymous with medicines or medication, produced by pharmaceutical companies holding patents (intellectual property rights) over the medicines.

The most relevant and pertinent provision of the Protocol to this study is the one dealing with pharmaceuticals.³⁰⁰ The Protocol calls upon member States to explore and share experiences with others in the process of searching for additional financial resources to acquire medicines, technology and other resources needed by the citizens in the respective States.³⁰¹

Very specifically, the highlights of the pharmaceutical provision of the Protocol are as follows: State parties shall cooperate and assist one another in the various ways ranging from the production, procurement and distribution of affordable essential drugs;³⁰² development of an essential drugs' programme and the promotion of the rational use of drugs;³⁰³ establishing

²⁹⁶ This resonates with the provisions of the SADC Protocol on Gender and Development, wherein in Article 26 thereof, state parties are urged to have implemented, by 2015, legislative frameworks, policies, programmes and services to enhance gender sensitive appropriate and affordable health care.

²⁹⁷ Article 3 (g).

²⁹⁸ Article 3 (h). Once again, the Draft SADC Strategy on Pooled Procurement may be regarded as a good example of an attempt at standardization/harmonization.

²⁹⁹ Article 29 (f) of the SADC Protocol on Health.

³⁰⁰ See generally, Article 29 of the SADC Protocol on Health. See Further, Moyo A "The Protection and Promotion of Socio-Economic Rights in the SADC Region" (2010) 11 *ESR Review* 12 – 15 14.

³⁰¹ Moyo above at 14.

³⁰² Article 29 (b).

³⁰³ Article 29 (c).

quality assurance mechanisms in the supply and conveyance of vaccines, blood and blood products³⁰⁴; conducting research and documenting aspects of traditional medicine and its utilisation³⁰⁵ and establishing a regional databank of traditional medicines.³⁰⁶

The SADC Protocol on Trade spells out in general terms the envisaged health outcomes for the region. The Protocol recognises that close cooperation in the area of health is essential for the effective control of communicable and non-communicable diseases and for addressing common health concerns.³⁰⁷ The specifics are later laid down in more detail in later instruments, namely the Pharmaceutical Business Plan and the Draft Strategy for Pooled Procurement of Essential Medicines, discussed immediately below.

3.5.2.2 The SADC Pharmaceutical Business Plan 2007 – 2013

The business plan was launched against the background of the need to develop and implement a pharmaceutical programme in line with the SADC Protocol on Health and SADC health policy.³⁰⁸ The purpose of the programme is to enhance the capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.³⁰⁹

The Pharmaceutical business plan identifies priority areas, objectives and major activities that will be implemented both at the regional and national levels to improve access to quality and affordable essential medicines including African Traditional medicines.³¹⁰ This point is very relevant to this study and the business plan seems to be making the right ‘access to medicines noises’ which resonate with the pertinent provisions of the ICESCR and the 2008 Resolution of the African Union Commission on *Access to Health and Needed Medicines in Africa*. At least the Business plan resonates well with the pertinent access instruments to medicines instruments, despite having been passed earlier than the ACHPR resolution. The overall goal of the Business

³⁰⁴ Article 29 (d).

³⁰⁵ Article 29 (e).

³⁰⁶ Article 29 (f).

³⁰⁷ See “Introduction and Background information” to the SADC Pharmaceutical Business Plan 3.

³⁰⁸ SADC Pharmaceutical Business Plan, executive summary at 3.

³⁰⁹ Ibid.

³¹⁰ SADC Pharmaceutical Business Plan, executive summary at 4.

Plan is to ensure availability of essential medicines including traditional medicines in the region in a sustainable way.³¹¹

In order to achieve its objective of improving access to quality and affordable essential medicines, the SADC Pharmaceutical Business Plan will adopt the following strategies:³¹²

- (a) Harmonising standard treatment guidelines and essential medicine lists;
- (b) Rationalizing and maximizing the research and production capacity of the local and regional pharmaceutical industry of generic essential medicines and African traditional medicines;
- (c) Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- (d) Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need the most at affordable prices;
- (e) Establishing a regional databank of traditional medicine, medicinal plants and procedures in order to ensure their protection in accordance with the regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology;
- (f) Developing and retaining competent human resources for the pharmaceutical programme;
- (g) Developing mechanisms to respond to emergency pharmaceutical needs of the region;
and
- (h) Facilitating the trade in pharmaceuticals within the region.

³¹¹ SADC Pharmaceutical Business Plan 4. The main object is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.

³¹² See SADC Pharmaceutical Business Plan Executive summary at 4 for a list of objectives that are regarded as crucial, reproduced verbatim here in the form of bullet points.

In summary, the Pharmaceutical Business Plan emphasizes harmonization of the treatment guidelines and the essential medicines lists. Secondly, it aims to maximize research and the capacitation of the pharmaceutical industry in the region so that essential generic medicines and their traditional counterparts may be produced. Thirdly, the plan seeks harmonization in the regulatory infrastructure applicable to pharmaceuticals so that there will be a positive improvement in the supply and distribution chain of pharmaceuticals. Fourthly, and very importantly in the context of access to medicines, the Pharmaceutical business plan will strive to promote joint procurement of essential medicines in the region where necessary; and fifthly, the development of a pharmaceutical databank on traditional medicines and the respect of intellectual property rules will be one of the key objectives of the business plan. The SADC Pharmaceutical Business Plan also aims to develop and retain human resources while at the same establishing mechanisms to respond to regional pharmaceutical emergencies. Finally, the plan aims to facilitate intra-regional pharmaceutical trade.

It is important to point out that the SADC Pharmaceutical Business Plan forms part of the broad SADC health programme, which takes into account global health declarations and targets.³¹³ In the context of access to medicines that cure common epidemics in the SADC region, the business plan is very specific in that it seeks to enhance the capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.³¹⁴ The specific diseases are HIV/AIDS, tuberculosis, malaria and other communicable and non-communicable diseases.³¹⁵

With specific reference to access to medicines in the context of this study, the business plan identifies ‘outdated medicine laws and intellectual property laws which are not TRIPS compliant’ as a major weakness of SADC countries’ pharmaceutical regulatory framework.³¹⁶ To address this major weakness, the plan acknowledges that the TRIPS Agreement does contain flexibilities which allow countries to ‘import or manufacture pharmaceuticals that are still under

³¹³ SADC Pharmaceutical Business Plan, para 1.2. The global and regional health declarations and targets include *inter alia*, the millennium development goals; New Economic Partnership for Africa’s Development, Abuja Declaration on HIV/AIDS; Tuberculosis and Other Related Infectious Diseases (2001); United Nations General Assembly Special Session on HIV and AIDS (UNGASS) 2001; The Maseru Declaration on HIV and AIDS (2003); Brazzaville Commitment on Scaling-up Towards Universal Access to HIV and AIDS prevention, treatment care and support in Africa by 2010 (2006); and Lusaka Declaration on African Traditional Medicine (2001).

³¹⁴ See SADC Pharmaceutical Business Plan para 1.3.

³¹⁵ Ibid.

³¹⁶ SADC Pharmaceutical Business Plan para 2.2 (i).

patent without the consent of the patent holder'. The plan urges Member States to take advantage of this opportunity which has been exploited before by three SADC Member states.³¹⁷ The other window of opportunity that the plan urges SADC Member States to take advantage of is the fact that more than half of SADC members are least developed countries (LDCs); such economic blocks are allowed to trade in pharmaceuticals within the block without restrictions.³¹⁸ These two opportunities are specifically identified as possible effective ways of improving accessibility thereby lowering medicine prices in the region.³¹⁹

The suggested methodology for taking advantage of and coordinating the implementation of the TRIPS flexibilities to improve access to medicines within the SADC region will involve a three-pronged approach.³²⁰ Firstly, a regional assessment of intellectual property and medicines legislation in SADC countries will be conducted to determine their TRIPS compliance and adaptability.³²¹ After the regional assessment of the legal and policy regime, specialized legal resources from within and outside the SADC region will be identified to give reliable and specialized legal advice.³²² A roster of legal and other experts, who are able to offer technical assistance on TRIPS, will be maintained.³²³ Finally the SADC region will collaborate with regional development partners in order not only to be enabled to protect and take advantage of TRIPS flexibilities but also to be assisted in bilateral trade negotiations to conclude agreements that are not detrimental to public health.³²⁴

The other weakness identified by the SADC Pharmaceutical Business Plan, which weakness has a direct bearing on access issues, is the fact that the region has an acute overdependence on imported medicines, both patented and generics.³²⁵ The overdependence may be alleviated by enhancing the 'regional capacity for pharmaceutical manufacturing as well as conducting

³¹⁷ Namely Mozambique, Zambia and Zimbabwe in the context of compulsory licenses.

³¹⁸ This is provided for in paragraph 6 of the WTO decision of 30 August 2003.

³¹⁹ SADC Pharmaceutical Business Plan, para 2.3 (iv).

³²⁰ Ibid para 4.18.

³²¹ This suggestion is in line with the approach that was adopted by this study in chapter four.

³²² SADC Pharmaceutical Business Plan para 4.18 (ii).

³²³ Ibid.

³²⁴ Ibid para 4.18 (iii).

³²⁵ Ibid para 2.2 (vii). About 85% of generic ARV medicines used in the region are imported from India and 15% are manufactured in the region.

research in medicines and other pharmaceutical products including African Traditional Medicines.³²⁶

In light of the foregoing discussion, I find the SADC Pharmaceutical Business to be quite an ambitious but realistic document that correctly problematizes SADC access issues to medicines and proffers honest and plausible strategies as solutions. The Pharmaceutical Business Plan provides the priorities and focus for the SADC pharmaceutical programme.³²⁷ To further actualize some of the objectives in the SADC Pharmaceutical Business Plan, namely, the harmonization in the pharmaceutical procurement field, the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities was adopted in September 2012. In the following section, I briefly highlight the salient aspects of the strategy and contextualize them within the broad framework of access to medicines advocated by this study.

3.5.2.3 The SADC Draft Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017

The Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities (Pooled Procurement Strategy) is a response to the objective of improving ‘sustainable availability and access to affordable, quality, safe, efficacious essential medicines’, as provided for in the SADC Pharmaceutical Business plan.³²⁸ Therefore, the Pooled Procurement Strategy is an important step in the pursuit of the achievement of the objective of improving access to ‘affordable, quality, safe, and efficacious essential medicines’. The pertinent question to ask at this stage will be: How does the Pooled Procurement Strategy purport to improve access to medicines?

According to the Pooled Procurement Strategy, if harmonization can be achieved by the SADC Member States on issues such as pharmaceutical procurement, supply chain management as well as procedural issues such as quality assurance and public procurement, then access to safe, quality and efficacious medicines may be improved.³²⁹ The Pooled Procurement Strategy argues that there are positives in adopting a regional approach to the procurement of pharmaceuticals including the application of ‘good practices’ in the pharmaceutical procurement and supply

³²⁶ SADC Pharmaceutical Business Plan para 1.3.2.

³²⁷ See Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, discussed in detail in para 3.5.2.3 below 1.

³²⁸ See ‘Executive Summary’ of the Pooled Procurement Strategy para 1 V.

³²⁹ Ibid para 2.

management systems.³³⁰ One of the cited advantages of pooled procurement, also called joint procurement or procurement cooperation,³³¹ is that it can result in considerable savings made through information and work sharing by procurement agencies in the Member States.³³² If savings are made, then more funds become available for procurement. This will, in turn, increase availability of and access to essential medicines and health commodities.

The Pooled Procurement Plan envisages the establishment of an entity called the SADC Pharmaceutical Procurement Services, which will manage the implementation of the strategy relying on guidance from the relevant SADC structures for policy development, monitoring and evaluation functions, general oversight and implementation processes.³³³

In summary, the main objective of the pooled procurement strategy is to achieve regional integration³³⁴ in the procurement of essential medicines, a practice which will, in addition to fostering deeper integration, also facilitate the adoption of a uniform pharmaceutical procurement strategy, which will in the long run ensure access to essential medicines in the region. This overall objective should be applauded as a regional initiative which will work alongside the actualization of the TRIPS flexibilities, discussed in chapter four below.

The SADC Pooled Procurement Strategy identifies a number of access issues/concerns which are directly relevant to this study.³³⁵ I highlight briefly some of the issues below and contextualize them in relation to the study's objectives as spelt out in chapter one above.

Information on pharmaceutical procurement is not easily accessible in the SADC region due to different and disparate transparency levels in the private and public pharmaceutical sectors.³³⁶ The above implies that the availability of essential medicines will vary between countries of the

³³⁰ Executive Summary of the Pooled Procurement Strategy para 3.

³³¹ Pooled procurement (or joint procurement or procurement cooperation) is defined as 'the overarching term for procurement where part of all of the procurement process of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or a third party procurement entity' (see "Definition of terms") in the Pooled Procurement Strategy document viii.

³³² See 'Executive Summary' of the Pooled Procurement Strategy para 3 v.

³³³ Pooled Procurement Strategy 'Executive Summary' para 4 v.

³³⁴ The SADC common agenda includes the promotion of *sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged through regional integration* [emphasis in the Pooled Procurement Strategy original 1].

³³⁵ See generally "Situational Analysis" in the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017 3 – 9.

³³⁶ Pooled Procurement Strategy para 2.2.1 – 2.2.2 at 3.

region with serious access implications.³³⁷ In light of the above challenges, pooled procurement would be a possible solution in addressing access challenges and lack of uniformity in the relevant sectors.

As if the compilation of the Pooled Procurement Strategy data on pharmaceutical budgets and expenditure was hard to obtain, there was a further additional challenge in that most SADC Member States rely for a considerable part on donor support for the purchase of essential medicines especially in relation to HIV/AIDS, malaria and tuberculosis.³³⁸ It is submitted that while reliance on donor support is inevitable when due consideration is given to the fact that more than 50% of SADC Member States are least developing countries (LDCs),³³⁹ this continued reliance on donors will frustrate access to medicines in the region in the long run because TRIPS flexibilities will not be taken advantage of and the development of in-country pharmaceutical capacity will be arrested. Once again, with specific reference to the problem outlined briefly above, pooled procurement may be the panacea in resolving the access problem in the specific context.

The SADC Pooled Procurement Strategy also bemoans the fact that four Member States do not have a medicines regulatory authority responsible for regulating the quality of medicines in the market with five countries not actively registering medicines.³⁴⁰ Therefore, in the region, the capacity and capability of the Member States' regulatory authorities, responsible for the assessment and approval of medicines, are severely limited.³⁴¹ The global implication of the foregoing observation is that medicines allowed in one Member State will not automatically be allowed to be used in other SADC Member States. It is envisaged that once the region adopts pooled procurement as suggested in the Draft Strategy, regulatory variations and inconsistencies will be things of the past and access to medicines will be significantly enhanced.

The other pertinent observation made by the Draft Strategy is that there was no information that was provided by the countries on their use of TRIPS flexibilities in the national legislation to

³³⁷ Despite the fact that It would be simplistic to expect a uniform availability of essential medicines across the SADC, in an ideal world, the expectation would be that the basic medicines are available across the region.

³³⁸ SADC Pooled Procurement Strategy, para 2.2.4 at 4.

³³⁹ SADC Member States which are classified as LDCs are Zambia, Malawi, Angola, Mozambique, Seychelles, Swaziland, Lesotho, Democratic Republic of Congo and Tanzania.

³⁴⁰ See para 2.2.6 of the SADC Pooled Procurement Strategy at 4. The five countries, all of whom are LDCs are Angola, Lesotho, Seychelles, Democratic Republic of Congo and Swaziland.

³⁴¹ Ibid.

increase access to essential medicines.³⁴² This is a noteworthy observation in light of the pertinent provisions of the SADC Protocol on Health and the Pharmaceutical Business Plan³⁴³ as well as the objectives of this study.

On a positive note, the Draft SADC Pooled Procurement Strategy observes that despite the shortcomings identified above, national policy regulations are fairly similar in all SADC Member States. Additionally, all member states have a national medicines policy and an essential medicines list in place; and all but South Africa have a public procurement Act.³⁴⁴

From the situational analysis made in the Draft Pooled Procurement Strategy, it is clear that progress has been registered across the region towards improving access to essential medicines.³⁴⁵ However, the identified progress is hampered by limited resources, lack of standardization in the public sector procurement practices, and lack of regional pharmaceutical market intelligence.³⁴⁶ For pooled procurement to succeed in the SADC context, information and work sharing must be prioritized with the progressive move towards group contracting across Member States to reach the minimum standards of good practice.³⁴⁷ I agree with the submission and add that the achievement of such an option should be taken as a long term rather than short term goal and its full realization will depend on whether technical assistance is forthcoming from fellow WTO members and other development partners.

The common thread running through all the three SADC instruments is that access to essential medicines' cries for regional attention and the solution to the access problem lies in taking advantage of the TRIPS flexibilities in the context of pharmaceutical regional integration. It is very clear that all the three instruments are aware of the existence of the TRIPS flexibilities but as to why SADC Members are reluctant to take advantage of the flexibilities in an access to essential medicines context remains a mystery. An attempt to unravel the mystery is made in chapters four and five below.

³⁴² SADC Pooled Procurement Strategy at para 2.2.8.

³⁴³ See Article 29 of the SADC Protocol on Health and para 2.3 VI of the SADC Pharmaceutical Business Plan.

³⁴⁴ Draft SADC Pooled Procurement Strategy para 2.3.1 at 4.

³⁴⁵ Ibid para 3 at 5.

³⁴⁶ Ibid.

³⁴⁷ Ibid.

Conclusion

This chapter focused on the existing and implied conflict between intellectual property rights and human rights. It established the legal historical relationship between the two concepts and came to the inescapable conclusion that these fields need each other. Both intellectual property rights and human rights as legal fields originated and grew quite apart out of social developments which were not interrelated. However, the modern contemporary reality is that the relationship between the legal disciplines has now evolved into a problematic one. The problematic aspect is exemplified by the view that intellectual property rights and human rights are in conflict since the legal protection of private intellectual property rights is considered incompatible with community-based human rights; with human rights viewed as legal instruments that limit and restrict the enforcement of intellectual property rights. If this view is pursued to its extreme ends, then human rights must always trump intellectual property rights.

Intellectual property rights were discussed in light of patients' rights to health and access to essential medicines pitted against pharmaceutical inventors' rights to their intellectual property, namely patents. The chapter advocates that if inventors have any right to their intellectual property, then such rights must be subordinated to patients' rights to health and by extension, the right to access essential medicines. The right to health is a fundamental right identified in the UDHR, the Declaration of Alma Ata; UN General Assembly documents, African and other regional instruments and the SADC region; hence it must trump intellectual property rights.

This chapter looked at the rights-based approach as a possible solution to the access to medicines problem, which can be resolved in the SADC context by taking into account the provisions of the SADC Protocol on Health, the SADC Pharmaceutical Business Plan and the Draft SADC Strategy on Pooled Procurement, instruments which shout loudly for the utilization of the TRIPS flexibilities against the backdrop of regional integration. The SADC Pooled Procurement Strategy, which calls for a common regional pharmaceutical procurement legal and policy framework, is a unique proposition for the resolution of the access problem to essential medicines. It should be celebrated as a legal and policy tool in the right direction; which may be used in conjunction with other solutions proffered by the WTO TRIPS Agreement, other regional instruments and international human rights law. The call made by the three SADC instruments resonates quite well with the pertinent provisions of the *Resolution on Access to Health and*

Needed Medicines in Africa, issued on 28 November 2008 by the African Commission on Human and Peoples' Rights. If the relevant TRIPS flexibilities, discussed in chapter four below, are carefully studied and contextualized to the SADC region, the access to essential medicines problem may partially be solved.

CHAPTER FOUR

AN OVERVIEW OF WTO TRIPS FLEXIBILITIES AVAILABLE FOR USE BY SADC MEMBER STATES

4. Introduction

The previous chapter established that despite the right to access medicines seemingly not having an express textual basis in most legal instruments perused, using the rights-based approach to confront the problem of access to medicines may be a viable solution. The source of rights in this particular context would be constitutional provisions in individual SADC Member states' constitutions entrenching the right to health. However, providing for the right to health in a constitution would not be an effective tool on its own in the absence of legislative provisions that domesticate TRIPS' provisions relating to overriding patents in specific instances. While the TRIPS Agreement¹ enjoins WTO Members to protect patents in their respective territories, the Agreement does have provisions catering for derogation from patents in specific contexts in order to facilitate access to medicines. The permissible derogations are now characterised as TRIPS flexibilities and are outlined in this chapter and contextualized to the SADC regional situation.

Overall, this chapter shows that the use of TRIPS flexibilities such as compulsory licences, parallel imports, the paragraph six system, government non-commercial use, research and *bolar* exceptions and limits on data protection among others, can promote access to medicines in the SADC countries.² Since the TRIPS Agreement generally requires member states to increase intellectual property protection, for example, that patents be protected for 20 years, SADC Member states are not excepted from this obligation.³ However, at the time of adopting the Doha

¹ The TRIPS Agreement was adopted as part of the final Act of the Uruguay Round of Multilateral Trade Negotiations in Marrakech, in Morocco on 15 April 1994. For a full text of the Agreement see WTO *The Legal Texts the Results of the Uruguay Round of Multilateral Trade Negotiations* (1999) 321-353.

² See also chapter 5 below for an overview picture of the use and implementation of TRIPS flexibilities in selected SADC Member states.

³ Osewe PL, Nkrumah YK and Sackey EK *Improving Access to HIV/AIDS Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities* (2008) at 11 correctly point out that in terms of the transitional arrangements, developed countries were expected to have been fully compliant with TRIPS by January 1996 while developing countries would have to do so five years later in the year 2000 and least developed countries (LDCs) in 2006. With specific reference to pharmaceutical products, developing countries were expected to recognize and

Declaration, the WTO membership also recognized that for many of them, it remained difficult to make effective use of these flexibilities as a public health policy tool.⁴ For example, paragraph 6 (six) of the Doha Declaration on TRIPS and Public Health⁵ acknowledged that while developing countries had the right to issue compulsory licences, they nevertheless faced difficulties in making effective use of this policy due to the lack of or insufficient manufacturing capacity.⁶ This is not the only constraint that developing countries including SADC member states face at the international level in their efforts to use TRIPS flexibilities.⁷ Other challenges that have been identified include: lack of technical expertise to effectively implement TRIPS flexibilities; insufficient technical and infrastructural capacities for medicines' regulations; bilateral and other pressures not to use the TRIPS flexibilities for public health purposes; difficulties in regulating anti-competitive practices and abuse of patents rights.⁸ This study does acknowledge the existence of the above mentioned challenges and discusses some of them in their proper SADC context in the subsequent chapters.

The above policy flexibilities embodied in the TRIPS must be used effectively by developing countries in general and the SADC countries in particular to protect and promote public health despite the attendant challenges.

In addition to the TRIPS flexibilities, there are other flexibilities that SADC Member states may use. The flexibilities include those developed and adopted by the SADC Member states' trading partners such as the United States, the European Communities (EC) and Canada. Individual SADC member states may elect to use the latter flexibilities.⁹ These flexibilities are, however, beyond the scope of the present study.

protect patents in this sector by 2005 while LDCs do not have to do so until 2016. LDCs in SADC are Angola, DRC, Lesotho, Madagascar, Malawi, Mozambique, Tanzania and Zambia.

⁴ Musungu SF, Villanueva S and Blasetti R *Utilising TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* (2004) 2.

⁵ World Trade Organisation, Ministerial Declaration on the TRIPS Agreement and Public Health WT/MIN (01)/DEC/2, 41 I.L.M 755 (2001) [hereafter Doha Declaration], available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited 07/09/2013).

⁶ Paragraph 6 provides inter alia that:

“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical Sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”.

⁷ Musungu, Villanueva and Blasetti above note at 3.

⁸ Ibid.

⁹ For a scholarly note on the EU and Canadian flexibilities and their implications in the developing country context, see generally, Sibanda O.S “Comparative analysis of access to patented HIV/AIDS pharmaceutical medicines

After outlining each of the TRIPS flexibilities, contextual reference is made to the SADC region through examples or specific legislative provisions in the SADC member's laws. This then sets the background for the contextualisation of the actual use of the flexibilities in selected SADC Member states, reserved for discussion and analysis in Chapter Five.

4.1 Preliminary Remarks on WTO TRIPS Flexibilities Generally

It must be stated right from the onset that before the public health TRIPS flexibilities introduced after the Doha Declaration in 2001 and the subsequent August 2003 decision, the TRIPS Agreement did provide for exceptions to patentability.¹⁰ These exceptions form the core of what has generally come to be characterized in access to medicines parlance as 'TRIPS flexibilities'.

The TRIPS Agreement, which is binding on all member states of the WTO, obliges all members to provide for patent protection for inventions, whether products or processes, in all fields of technology, including pharmaceuticals.¹¹ In the context of this study, it is important to note that currently all the SADC members except Seychelles¹² are members of the WTO and, therefore, have to incorporate the TRIPS Agreement in their national legislation.¹³ This position is confirmed by the SADC Protocol on Trade which aptly provides that:

Member states shall adopt policies and implement measures within the Community for the protection of intellectual property rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property rights.¹⁴

through the Canadian and EU TRIPS flexibilities measures: are they efficacious or overly burdensome and ineffective measures?" (2012) 15 *Potchefstroom Electronic Law Journal* 521 – 569.

¹⁰ See Arts 30 and 31 of TRIPS. Article 30 provides for exceptions to rights conferred in general terms by providing for limited exceptions when patents may be overridden provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account interests of third parties. On the other hand, Article 31 provides for 'other use without authorization of the right holder' in the context of issuing compulsory licenses and government use orders.

¹¹ Article 27 (1) of TRIPS.

¹² At the time of writing, Seychelles was still in accession talks with the WTO, and will formally be required to comply with TRIPS upon acquiring formal membership. Seychelles applied for accession to the WTO on 31 May 1995 [WTO "Accession Seychelles" at http://www.wto.org/english/thewto_e/acc_e/a1_seychelles_e.htm], (last visited 10/09/2013)].

¹³ As previously indicated in note 3 above, TRIPS requires that all developing countries, other than those designated as LDCs, must have complied with the minimum standards of intellectual property protection by 1 January 2000 (see Arts. 65(1) and 65(2) of TRIPS). LDCs were initially given until 1 January 2005 to comply, but the period was subsequently extended to December 2013, before being recently extended to 1 July 2021 [see "The Least developed get eight years more leeway to Protect Intellectual Property" at http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm (last visited 03/10/2013)]. However, with reference to pharmaceuticals and agricultural products, the due date for compliance by LDCs, which was extended by the Doha Declaration to 2016 (see Art 66 (1) of TRIPS), has not changed.

¹⁴ Article 24 of the SADC Protocol on Trade, 1996.

Before the advent of the TRIPS Agreement, a number of developing countries did not recognize or protect pharmaceutical patents, and those countries that did limited patent terms to less than 20 years and this enabled the generic market not only to develop but also to thrive.¹⁵ The TRIPS Agreement aims to “contribute to the promotion of technological innovation” as well as aid “the transfer and dissemination of technology”.¹⁶ This balance has, however, been difficult to achieve due to competing interests of the pharmaceutical companies and the developing countries in desperate need of affordable drugs.¹⁷

The basic nature of the TRIPS Agreement, which seeks to ensure a balance between the rights of intellectual property rights (IPR) holders, on the one hand, and consumers on the other, is buttressed by the principles of the TRIPS.¹⁸ The relevant Article allows WTO Members, in formulating or amending their intellectual property (IP)-related laws and regulations, to adopt measures necessary to protect public health and promote the public interest in sectors vital to their socio-economic and technological development.¹⁹ Therefore, social objectives allow for exceptions to the patent holder’s rights when it is necessary to protect public health.²⁰ Members of the WTO may make an exception to patents during certain circumstances, one of these being a national emergency.²¹ The implication here is that the provision allows WTO Members to draft their laws in a manner that would maximally protect their citizens’ rights to health. This maximal protection could take the form of a compulsory licence or a provision allowing for government use in the case of public health emergency.²²

However, the exception may only be used “provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner”.²³ If the envisaged prejudice does materialize, then other

¹⁵ Pfumrodze J “The WTO TRIPS Agreement and Access to Medicines in Southern Africa” (2011) 13 *Botswana Law Journal* 87 at 89.

¹⁶ Article 7 of TRIPS.

¹⁷ Cotter C “The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries” (2008) 5 *Loyola University Chicago International Law Review* 177 at 181.

¹⁸ The principles of TRIPS are encapsulated in Article 8.

¹⁹ Osewe, Nkrumah and Sackey above at 9.

²⁰ Article 8 of TRIPS.

²¹ Shoell S “Why Can’t the Poor Access Life-Saving Medicines? An Exploration of Solving the Patent Issue” (2002) 4 *Minnesota Intellectual Property Review* 151 at 160.

²² See para 4.2 below.

²³ Shoell above at 160.

Members may enforce their IP protection through resorting to the WTO dispute settlement mechanism.²⁴

While the TRIPS Agreement enjoins Members to provide patent protection in all fields of technology,²⁵ whether for processes or products, there are, however, provisions in the same Agreement for exceptions from patentability.²⁶ In general, the TRIPS Agreement requires Members to increase patent protection, which shall be extended to 20 years from the filing date.²⁷ It will be recalled that despite some notable pharmaceutical manufacturing capacity in the SADC region,²⁸ SADC Member states are all net importers of patented medicines and this is likely to make medicines more costly and adversely affect access to medicines (as lower priced generics are no longer allowed).²⁹

The TRIPS Agreement also confers extensive rights on the patent holder, including exclusive marketing rights for the entire patent duration.³⁰ Another TRIPS-imposed obligation which has serious implications for access to medicines is the requirement that member states protect undisclosed data against unfair commercial use.³¹

The net effect of the permissible flexibilities in interpreting the provisions of the TRIPS Agreement and the specified limitations to the obligations under the Agreement form the basis of what are often referred to as the ‘TRIPS Flexibilities’ discussed in detail from 4.2 below. In the same vein, the Doha Declaration reiterates that the TRIPS Agreement can and should be interpreted in a manner that supports the members’ right to protect public health specifically by

²⁴ Shoell above at 160.

²⁵ Article 27 (1) of TRIPS.

²⁶ See for instance Article 31 of TRIPS, providing for compulsory licenses.

²⁷ Article 33 of TRIPS.

²⁸ For a bird’s eye view of pharmaceutical manufacturing capacity in the Africa and the SADC region, see specifically SEATINI, CEHURD, TARSC “Overcoming Barriers to Medicines Production through South-South Cooperation in Africa” (2013) 34 *EQUINET Policy Brief* 1-2.

²⁹ However, generic production through a compulsory license on any one of the grounds listed in Article 31 of TRIPS may still be possible.

³⁰ See article 28 of TRIPS. However, this is subject to Article 30, which limits rights of patentees to exclusively exploit benefits arising out of patents.

³¹ Article 39 (3) of TRIPS.

ensuring access to medicines for all.³² The same Declaration also clarifies the permissible interpretation of certain provisions of the TRIPS Agreement.³³

The flexibilities may, therefore, be viewed as the balancing criteria which the developing countries were able to achieve in order to address their specific concerns over patents and access to medicines within the WTO.³⁴ It is, however, prudent that any analysis of the usefulness of the flexibilities in protecting public health must take into account the ability of the developing country member states of the WTO to implement them.³⁵ This is the major reason why this study was embarked upon in the first place – to explore the extent of the use of the flexibilities by the SADC Member states and thence make recommendations that factor in current legal policy and other challenges.

The thesis of this study is that, barring obvious challenges, TRIPS flexibilities do allow member states to mitigate the negative impact of the TRIPS Agreement on matters of national importance such as access to medicines.³⁶ In the context of this study and indeed in the SADC region, in addition to general TRIPS flexibilities,³⁷ the main flexibilities which may be benefitted from by the SADC countries can better be understood if read together with the TRIPS provisions relating to technical cooperation, temporary derogations for the developing countries and LDCs, the Doha Declaration and the August 2003 Decision, later incorporated *mutatis mutandis*, as the TRIPS amendment of December 2005.³⁸

The following section renders an expository account of the available TRIPS flexibilities, starting with the Doha Declaration and the subsequent August 2003 Decision which has now become a

³² Para 4 of the Doha Declaration.

³³ See para 5 of the Doha Declaration. These include the right to grant compulsory licenses, the freedom to determine the grounds upon which such licenses may be granted; the right to determine what constitutes a national emergency and circumstances of extreme urgency and the freedom of Member states to choose which regime of exhaustion of IPRs they wish to establish.

³⁴ Osewe, Nkrumah and Sackey above at 10.

³⁵ Ibid.

³⁶ Other matters of national importance may be national security and economic development spurred by intellectual property and innovation in certain high technology areas.

³⁷ Such as, among others, compulsory licensing, government use, parallel imports, research exceptions and limits on data exclusivity.

³⁸ See Kingah SS, Smis S and Soderbaum F “How Countries of the Southern African Development Community (SADC) Can use the World Trade Organization and the European Community Flexibilities for Better Access to Affordable HIV/AIDS Medicines” (2008) *Monitoring Regional Integration in Southern Africa Yearbook* 14.

permanent amendment of the TRIPS Agreement.³⁹ Technical cooperation and temporal derogations for poor countries under TRIPS are discussed next, followed by an exposition of the general TRIPS flexibilities, including parallel importation and compulsory licensing.

The use of the above outlined flexibilities and others that are discussed in subsequent paragraphs was affirmed and confirmed by the Doha Declaration in 2001 and subsequently by the August 2003 Decision, which has become a permanent amendment to the TRIPS Agreement. It is, therefore, appropriate now to turn to the provisions of the Doha Declaration and the August 2003 Decision.

4.2 Public Health, the Doha Declaration⁴⁰ and the August 2003 Decision

4.2.1 Background to the Doha Declaration and the August 2003 Decision

The Doha Declaration on TRIPS and Public Health may be regarded as an important step towards making the TRIPS Agreement more developmentally friendly.⁴¹ The Declaration was the outcome of the WTO Ministerial meeting which was held in the United Arab Emirates in November 2001.⁴² 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.⁴³ The Declaration was initiated by the African group within the TRIPS Council.⁴⁴ The African group and other third world countries wanted to ensure that the Ministerial Conference in Qatar became an opportunity to demonstrate the

³⁹ According to the WTO website http://www.wto.org/english/news_e/pres05_e/pr426_e.htm (last visited 09/09/2013), WTO members on 6 December 2005 approved changes to the TRIPS Agreement making permanent a decision on Patents and Public Health originally adopted in 2003. The permanent amendment is set to formally take full effect once two thirds of the WTO members have ratified it. At the time of writing, only 73 WTO members out of more than 159 members, including seven African countries (Zambia being the only SADC member to have ratified) had ratified the amendment to TRIPS. WTO members have up to the end of December 2013 to ratify, and there is a strong possibility, that the period for ratification, which has been extended three times thus far, may be extended again!

⁴⁰ For scholarly accounts of the legal and other implications of the Declaration on access to medicines in the developing world, see Abbott F.M “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *The American Journal of International Law* 317 – 358 and Attaran A “Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution” (2003) 17 *Emory International Law Review* 744 – 778.

⁴¹ Elbeshbishi AN “TRIPS and Public Health: What Should African Countries Do?” (2007) *ATPC Work in Progress* no.49 at 3.

⁴² Ministerial conference, Fourth Session, Doha 9-14 November 2001, adopted on 14 November 2001.

⁴³ Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, adopted on 14 November 2001 (the Doha Declaration).

⁴⁴ Kingah, Smis and Soderbaum above at 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.

members' commitment and contribution in preventing further deaths and saving lives through facilitating easier access to medicines at affordable prices.⁴⁵ The gist of the African group's proposal was that the TRIPS Agreement should not prevent members from taking measures to protect public health.⁴⁶ 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.⁴⁷ The Declaration also explicitly recognises the flexibility within TRIPS to grant compulsory licences and the rights of the members to determine the grounds for the granting of such licences.⁴⁸ The passage of the Declaration was considered a major victory for the developing nations.⁴⁹ The Declaration also extended the deadline for developing countries to comply with the TRIPS' provisions relating to pharmaceutical patents until 2016.⁵⁰

Very importantly, the Declaration noted that members will reserve the right to determine what constitutes national emergency or a case of extreme urgency⁵¹ with the understanding that diseases such as HIV/AIDS, tuberculosis, malaria and other epidemics may come under such a narrow category.⁵²

In summary, the Declaration is important in that it gave the 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 exception from patentability and providing for the early working (bolar exceptions) of patents.⁵³

⁴⁵ Kingah, Smis and Soderbaum above at 16

⁴⁶ Ibid.

⁴⁷ Doha Declaration, para 4.

⁴⁸ Doha Declaration, para 5 (b).

⁴⁹ Watson AG "International Intellectual Property Rights: Do TRIPS Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?" (2009) 32 *Boston College International & Comparative Law* 143 at 146.

⁵⁰ Ibid.

⁵¹ For critical perspectives on alternatives to determining and defining national emergency, see generally Manne above at 349-379.

⁵² Doha Declaration, para 5 (c).

⁵³ Mabika A and Makombe P "Claiming our Space: Using the Flexibilities in the TRIPS Agreement to Protect Access to Medicines" (2006) 16 *SEATINI Policy Series* 1 at 1.

However, there was a problem which the Doha Declaration identified and proposed a solution therefore.⁵⁴ 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.⁵⁵ The implications of this Article for access to medicines are likely to be dire for developing countries with limited or no pharmaceutical manufacturing capacity. Countries that have the capacity to manufacture generics, through the issuance of compulsory licences, such as India and Brazil, can only do so for the overall predominant supply of the domestic market. Exports of such generics to countries in dire need would be very much limited.⁵⁶

The above mentioned problems, commonly known as ‘the paragraph six 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 the 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.⁵⁷

The solution to the problem came in August 2003 in the form of a Decision of the General Council to implement paragraph 6 of the Doha Declaration.⁵⁸ 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.⁵⁹ Canada was the first country to issue a compulsory licence⁶⁰ under the

⁵⁴ See paragraph 6 of the Declaration.

⁵⁵ 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.

⁵⁶ See generally, Scherer FM and Watal J “Post-TRIPS Options for Access to Patented Medicines in Developing Countries” in Maskus K (ed) *The WTO, Intellectual Property Rights and the Knowledge Economy* (2004) 355-381.

⁵⁷ Generally provided for in Article 31 of the TRIPS Agreement.

⁵⁸ 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, at para 2, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last 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.

⁵⁹ 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.

⁶⁰ On compulsory licenses, see para 4. 3.3 below.

system for the production and export of generic AIDS medicine to Rwanda.⁶¹ The licence was issued in October 2007.

4.2.2 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.⁶² The Declaration did recognize the gravity of public health problems afflicting developing countries especially problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.⁶³ The Declaration also did acknowledge that the TRIPS Agreement was part of the wider national and international action to address the public health problem.⁶⁴ 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.⁶⁵ Therefore, WTO members were equally cognizant of the importance of maintaining the balance of interests in the IP system.⁶⁶

The pith and marrow of the Declaration, which has often been cited as one of the most important and potentially revolutionary WTO provision 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* (my emphasis).⁶⁷

The above cited provision was further buttressed by the reaffirmation of the 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.⁶⁸

⁶¹ See Cotter C "The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries" (2008) 5 *Loyola University Chicago International Law Review* 177-189.

⁶² Doha Declaration at para 1.

⁶³ Doha Declaration para 1. The specific diseases mentioned herein are not a closed list. The specified diseases affect most SADC member states and are quite relevant in the context of this study.

⁶⁴ Ibid at para 2.

⁶⁵ Ibid para 3.

⁶⁶ Kingah, Smis and Soderbaum above at 17.

⁶⁷ Doha Declaration at para 4. See on a related note Ferguson IF "The WTO, Intellectual Property and the Access to Medicines Controversy" (2007) *CRS Report for Congress* at 2.

⁶⁸ Doha Declaration para 4. The specific flexibilities are discussed from paragraph 4.3 below.

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.⁶⁹

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.⁷⁰

Very importantly for access to medicines, the Declaration affirms each member's right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.⁷¹

The Declaration gives each WTO member the right to determine what constitutes national emergency or other circumstances of extreme urgency and reiterates that public health crises are not limited to those identified in paragraph one.⁷² Therefore, the Declaration made it very clear that situations of 'national emergency' or of 'extreme urgency' are not limited to short-term crises.⁷³ 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.⁷⁴ This legal position is different from the one obtaining under the general exceptions of Article XX of GATT 1994 and Article XIV of the GATS.⁷⁵ The reversal of the burden of proof is likely to be favourable to the plight of developing countries and SADC members as 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.

⁶⁹ See generally, para 5 of the Doha Declaration.

⁷⁰ 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.

⁷¹ Doha Declaration para 5 (b). Compulsory licenses, which are provided for in Article 31 of TRIPS, will be discussed in detail in para 4.3 below and their use or potential use by SADC member states will be discussed in chapter five below.

⁷² Doha Declaration para 5 (c). On the subject of interpretive alternatives to "national emergency", see Manne C above at 369 – 378.

⁷³ Van den Bossche P *The Law and Policy of the World Trade Organisation: Text, cases and Materials* (2008) at 790.

⁷⁴ Ibid.

⁷⁵ See further on this point, Correa C.M "The TRIPS Agreement and Developing Countries" in Macrory PFJ, Appleton AE and Plummer MG (eds) *The World Trade Organisation: Legal, Economic and Political Analysis* (2005) at 441.

Further, in the context of TRIPS flexibilities generally and this study in particular, the Declaration acknowledges that the effect of the provisions of the TRIPS Agreement are relevant to the exhaustion of intellectual property rights by leaving each member free to establish its own regime for such exhaustion⁷⁶ without challenge, subject to the Most-Favoured Nation (MFN)⁷⁷ and national treatment⁷⁸ provisions of the TRIPS Agreement.⁷⁹

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 Agreement⁸⁰ will not be easy to implement for WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector.⁸¹ It is common cause that this lack of manufacturing capacity abounds in developing and least developing WTO members. The Council for TRIPS was, therefore, asked to come up with a solution to the problem posed by paragraph six and 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.⁸² Paragraph six is widely considered as a positive development for developing countries and the successful use of compulsory licenses will hinge on it.

The last paragraph of the Doha Declaration deals with two important issues for developing countries – the commitment of the developed countries’ members to provide incentives to their enterprises and institutions to encourage technology transfer to LDCs⁸³ and the exemption of LDCs from protecting pharmaceutical patents until 2016.⁸⁴

Writing in early 2003, Samantha Shoel correctly opined that the Declaration was not legally binding since it was neither an amendment nor a modification.⁸⁵ This submission is, however, no longer legally valid with specific reference to the plight of countries without manufacturing

⁷⁶ In this study, the meaning and implications of exhaustion regimes are discussed in para 4.3 below under parallel importation.

⁷⁷ The most-favoured nation treatment in the context of TRIPS is provided for in Article 4 of TRIPS. For detailed discussion of the MFN and national treatment provisions, see chapter two above.

⁷⁸ The TRIPS Agreement provides for national treatment in Article 3 thereof.

⁷⁹ Doha Declaration para 5 (d).

⁸⁰ See generally Article 31 of TRIPS.

⁸¹ Doha Declaration paragraph 6.

⁸² See 4.2.3 below.

⁸³ The obligation arises pursuant to Article 66 (2) of TRIPS.

⁸⁴ The exemption is so important that it is discussed in this chapter as a TRIPS flexibility. The 2016 exemption of pharmaceuticals from patentability for LDCs should be read together with the recent 2021 exemption relating to TRIPS Agreement generally.

⁸⁵ Shoel above at 175.

capabilities to use compulsory licensing. This submission is based on the fact that on 6 December 2005, WTO members agreed to incorporate the 2003 Decision as an amendment and Annex to TRIPS.⁸⁶ It is now appropriate to turn to a discussion of the salient provision of the Decision.

4.2.3 Important aspects of the Paragraph 6 Decision (now Article 31bis of TRIPS)

As has previously been recorded, the August 2003 Decision was passed in order to remedy the nagging problem in the TRIPS Agreement⁸⁷ which requires that compulsory licences be used ‘predominantly’ for a member’s supply of the domestic market. Because WTO members have agreed to incorporate the 2003 Decision into the TRIPS Agreement permanently, my discussion of the detailed aspects of the Decision is based on the text that is intended to permanently amend TRIPS.⁸⁸ The amendment⁸⁹ has thus far been ratified by only 73 members out of a possible 159, including the United States and the European Union.⁹⁰ Therefore, the two-thirds threshold will be reached if 106 countries ratify the amendment. African countries in particular, are conspicuous by their reluctance to officially accept the amendment.⁹¹

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 Agreement⁹² 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.⁹³ According to the Gamble, the relevant Article was introduced to address the limitations and

⁸⁶ Furgusson above at 3.

⁸⁷ This problem is to be found in Article 31(f) of TRIPS.

⁸⁸ The permanent amendment will come into force when two-thirds of WTO members ratify 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 has been extended again and ratification is now expected to happen by 31 December 2013 (see note 89 below).

⁸⁹ The amendment is captured as Article 31 *bis* of the TRIPS Agreement.

⁹⁰ See WTO “Members Accepting Amendment of the TRIPS Agreement” at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 03/10/2013). The EU ratified the amendment as a block (28 countries in all).

⁹¹ Only 8 out of 40 African WTO members have ratified Article 31 *bis* of TRIPS (see note 89 above).

⁹² 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, Wager and Watal (2012) above at 360 – 366.

confusion surrounding TRIPS Article 31(f),⁹⁴ which had hitherto allowed compulsory licences 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 force⁹⁵ upon being appropriately ratified,⁹⁶ the TRIPS shall accordingly be amended by inserting Article 31 *bis* after Article 31 and the Annex to the TRIPS Agreement after Article 73.⁹⁷ 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 the other members of the WTO.⁹⁸

The essence of Article 31 *bis* is captured in the first paragraph of the Annex to the Protocol Amending the TRIPS Agreement⁹⁹ which explicitly suspends the obligations of an exporting member under Article 31(f) of TRIPS for the granting of a compulsory licence as long as such a licence is necessary for the production of pharmaceutical products to be exported to eligible importing members according to set conditions.¹⁰⁰ 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*.¹⁰¹ 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.¹⁰²

The conditions have been cited as impediments to access to medicines despite the positive aspects of Article 31 *bis*.¹⁰³ In order to use the system as an eligible importing member, notification must be made to the Council for TRIPS covering the following issues: Firstly, the

⁹³ See Taubman, Wager and Watal above at 360 – 361 for a full text of the Protocol Amending the TRIPS Agreement.

⁹⁴ Gumbel M “Is Article 31*bis* Enough? The Need To Promote Economies Of Scale In The International Compulsory Licensing System” (2008) 22 *Temple International & Comparative Law Journal* 161 at 170.

⁹⁵ The Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

⁹⁶ The Initial date for such ratification was 1 December 2007.

⁹⁷ See paragraph 1 of the Protocol Amending the TRIPS Agreement.

⁹⁸ 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*.

⁹⁹ Article 31 *bis* paragraph 1.

¹⁰⁰ The conditions are spelt out in paragraph 2 of the Annex to the TRIPS Agreement.

¹⁰¹ See paragraph (b) of the Annex to the TRIPS Agreement.

¹⁰² Annex to the TRIPS Agreement, paragraph (c).

¹⁰³ See for instance Palombi L “The Role of Patent Law in Regulating and Restricting Access to Medicines” (2009) 6 *Scripted* 394 at 404 wherein he correctly submits that the conditions may amount ‘disincentives for the right kind of drugs’.

importing member must, in the notification, specify the names and expected quantities of the product needed¹⁰⁴ and secondly, confirm that the member has insufficient or no manufacturing capacities in the pharmaceutical sector for the relevant product (s) in question.¹⁰⁵ This last requirement will not apply if the importing member is an LDC.¹⁰⁶ Thirdly, if the product is patented in its territory, and the eligible importing member has granted or intends to grant a compulsory licence in accordance with Article 31 of TRIPS and 31 *bis*, this must be confirmed.¹⁰⁷

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, the amounts to be manufactured are limited to those required by the importing member that has notified the Council for TRIPS of its need.¹⁰⁸ 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 licence issued by an eligible exporting member is that products produced under such a licence 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.¹⁰⁹ Thirdly, before the products are shipped to the importing country, the licensee must post on the website (WTO or own website) information relating to the quantities being supplied to each destination and the distinguishing features of the products.¹¹⁰

The last general condition relating to the exporting member is that it must notify the Council for TRIPS of the granting of the licence including the conditions attached to it.¹¹¹ The information provided shall include the name and address of the licensee, the product (s) for which the licence

¹⁰⁴ Paragraph 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.

¹⁰⁵ Paragraph 2 (a) (ii) of the Annex to the TRIPS Agreement.

¹⁰⁶ Ibid.

¹⁰⁷ Paragraph 2(a) (iii) of the Annex to the TRIPS Agreement.

¹⁰⁸ Paragraph 2(b) (i) of Annex to The TRIPS Agreement.

¹⁰⁹ Paragraph 2(b) (ii) of the Annex to the TRIPS Agreement.

¹¹⁰ Paragraph 2(b) (iii) of the Annex to the TRIPS Agreement.

¹¹¹ The information will be published on the WTO website.

has been granted, the quantities for which the licence has been granted, the countries to which the products are destined and the duration of the licence.¹¹²

Other important considerations which fit very well into the scope of using compulsory licences 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 measures¹¹³ to ensure that there is no trade diversion through re-exportation of products imported through the system.¹¹⁴ Additionally, members are required to have in place effective legal means to prevent importation into, and sale in, their territories of the products produced under the system.¹¹⁵ 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 are enhanced.¹¹⁶ Finally, the Council for TRIPS shall review annually the functioning of the system with the view of ensuring its effective operation and report annually to the General Council of the WTO.¹¹⁷

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

A compulsory licence 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 to that member taking into account the economic value to the importing member of the authorized use.¹¹⁸ However, in a context quite relevant to LDCs and the SADC region, if the compulsory licence is granted for the same products in the eligible importing member, then the obligation to pay adequate compensation does not arise.¹¹⁹ However, I submit that the above cited provision is problematic and does not augur well for access to

¹¹² Paragraph 2(b) (iii) of the Annex to the TRIPS Agreement.

¹¹³ 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.

¹¹⁴ Paragraph 3 of the Annex to the TRIPS Agreement.

¹¹⁵ Paragraph 4 of the Annex to the TRIPS Agreement.

¹¹⁶ Paragraph 6 of the Annex to the TRIPS Agreement.

¹¹⁷ Paragraph 7 of the Annex to the TRIPS Agreement.

¹¹⁸ Article 31 *bis* para 2.

¹¹⁹ Ibid.

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 the 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 the local production of pharmaceuticals.¹²⁰ Very briefly, this paragraph provides that Article 31(f) will not apply if a compulsory licence is issued by 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.¹²¹ 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.¹²² It is recommended that the SADC countries take advantage of this flexibility and consider a regional compulsory licence or regional pharmaceutical manufacture of targeted medicines.¹²³ 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.¹²⁴

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.¹²⁵ 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 are without prejudice to the rights obligations, and flexibilities that members have under the general provisions of TRIPS. It is now appropriate, therefore, to turn our discussion of the available flexibilities to TRIPS flexibilities generally.

¹²⁰ Article 31 *bis* para 3. The provisions of this paragraph are discussed in detail in chapter seven below and establishing regional manufacturing capacity in the SADC area is proposed as a viable access solution.

¹²¹ Article 31 *bis* para 3.

¹²² Paragraph 5 of the Annex to the TRIPS Agreement.

¹²³ See on a closely related note, chapter seven below.

¹²⁴ This issue is specifically acknowledged in paragraph 5 of the Annex to the TRIPS Agreement.

¹²⁵ Article 31 *bis*, paragraph 4.

4.3 Public Health and General TRIPS Flexibilities in Detail

4.3.1 Technical Cooperation and Temporal Derogations for Poor Countries under TRIPS

The main provisions of TRIPS, which may be viewed as sympathetic to the needs of developing countries including SADC member states refer to technical cooperation¹²⁶ and transitional provisions.¹²⁷

The TRIPS Agreement requires developed countries' members to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of the developing and the least-developed countries' members.¹²⁸ Such cooperation shall include, and will not be limited to the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as the prevention of the abuse of such rights.¹²⁹ Additionally, the prevention of abuse of IPRs also includes the provision of support by the developed countries regarding the establishment or reinforcement of domestic offices or agencies relevant to TRIPS matters, including the training of personnel.¹³⁰

Therefore, SADC member states may ask their developed countries' counterparts to comply with the obligation imposed by Article 67 so that access to medicines for the poor may be realized. This is so notwithstanding the traditionally polarized positions of the developed and the developing countries relating to the rationale and utility of IP.¹³¹ Some developing countries still view IP as publicly good while developing countries view intellectual property as encompassing the same rights as physical property.¹³²

The SADC could conceive the request for technical assistance as a block or individual countries may ask for assistance severally. The preparation of the laws to be compliant with TRIPS may be one example of such technical assistance. SADC members would in this specific context be

¹²⁶ Article 67 of TRIPS, this should be read together with the provisions of Article 66 (2) of TRIPS, which imposes on developed members the obligation to transfer technology to LDCs and developing countries. See on a related note, 4.3.1 below.

¹²⁷ Article 65 of TRIPS. See para 4.2.2 below for an elucidation on the relevant applicable transitional periods.

¹²⁸ Article 67 of TRIPS.

¹²⁹ Ibid.

¹³⁰ Ibid.

¹³¹ Manne C "Pharmaceutical Patent Protection and TRIPS: The Countries that Cried Wolf and Why Defining 'National Emergency' Will Save them from themselves" (2010) 42 *George Washington International Law Review* 349 at 357.

¹³² See Pulmano RA "In Search of Compliance with TRIPS against Counterfeiting in the Philippines: When is Enough Enough? (1999) 12 *Transnational Law* 241 at 252.

urged to restrict themselves only to the incorporation of the minimum required under TRIPS into their legislation.

The other form of assistance that is relevant to access to medicines may be to assist the SADC member states, jointly or severally, to domesticate TRIPS flexibilities such as compulsory licences. This would be in accord with one of Article 67's major objectives which is to prevent the abuse of intellectual property rights by pharmaceutical companies. The only reservation that may be expressed about Article 67 is that while developed WTO members have an obligation to provide technical assistance, such assistance can only be rendered on request and on mutually agreed terms and conditions.¹³³ The implication for access to medicines therefore will be that the assistance may be desperately needed but the developing countries and the LDCs may not have the technical capacity to conceive their own requests for assistance. To their detriment, LDCs may be arm-twisted by the developed countries into accepting assistance which may not immediately be in their best interests – such as providing for pharmaceutical patents.¹³⁴

The WTO and the World Intellectual Property Organisation (WIPO) have thus far been cooperating in disseminating information in the field of IP to some third world countries.¹³⁵ Information on the technical cooperation and training activities of the WTO Secretariat can be found on the Technical Cooperation and Training page.¹³⁶ It should be noted that many of the general technical cooperation activities of the WTO Secretariat also cover intellectual property.¹³⁷

The WIPO Intellectual Property Technical Assistance Database (IP-TAD) contains information on technical assistance activities undertaken by the Organization where one or more of the beneficiary countries were either developing or the least developed countries or countries in transition.¹³⁸ Such form of assistance has been on-going.

¹³³ Article 67 of TRIPS.

¹³⁴ LDCs are now exempt from providing for pharmaceutical patents in their domestic legislation until 2021.

¹³⁵ Kingah, Smis and Soderbaum above at 16.

¹³⁶ See WTO “Technical Cooperation in the TRIPS Area” at https://www.wto.org/english/tratop_e/trips_e/intel9_e.htm (last visited 10/09/2013).

¹³⁷ Ibid.

¹³⁸ For a complete picture of the extent of the technical assistance thus far, see WIPO “Technical Assistance Database” at <http://www.wipo.int/tad/en/> (last visited 10/09/2013).

Some developed countries have been consistent in supporting the developing countries and the LDCs to put into place the necessary infrastructure needed to bolster the protection of IPRs. Countries such as Canada, Norway and some EC members have provided reports to the WTO Secretariat on their activities in this regard.

Despite technical assistance and cooperation having consistently not been cited as one of the major TRIPS flexibilities in most of the access literature perused,¹³⁹ it is submitted that it ought to be regarded as such since implementing it may result in improved access to medicines. Secondly, technical assistance is provided for and built into the TRIPS Agreement in order to help developing and least developing WTO members to comply with TRIPS and by implication, benefit from its provisions. This, therefore, makes the provision relating to the granting of technical assistance to a TRIPS' flexibility when viewed in this context. SADC countries should and can take advantage of the technical assistance provisions of TRIPS to specifically ask for assistance in areas that will ensure access to medicines, such as adapting patent laws to incorporate the minimal TRIPS flexibilities.

4.3.2 Transition Periods

Closely related to the provisions relating to technical assistance in the TRIPS Agreement are those provisions talking to temporary derogations from complying with TRIPS through transition periods. The periods generally allow WTO members to comply with TRIPS in a staggered manner; with the developed countries being expected to comply first, followed by the developing countries while the LDCs would be the last ones to be fully compliant.¹⁴⁰

It will be prudent to point out from the onset that the preamble to the TRIPS Agreement states that members recognize the special needs of their least-developed counterparts in respect of the

¹³⁹ Most authorities, notably Musungu SF and Oh S "The Use of TRIPS Flexibilities by Developing Countries: Can they Promote Access to Medicines?" (2005) 20 *CIPiH Study Paper 4C* at iv – vii do not include technical assistance provisions as aspects of the flexibilities. The commonly mentioned flexibilities are transition periods, compulsory licenses, public non-commercial use, parallel importation, exemptions from patentability, limits on data protection, bolar exception, use of competition law and limits on data protection.

¹⁴⁰ At the time of writing, LDCs were initially exempt from complying with TRIPS provisions relating to pharmaceutical and agricultural patents until 2016, there was a heightened expectation among academics and access activists that this period was likely to be extended, and it has since been extended to 2012 for other IPRs except pharmaceuticals, which continue to be subject to the 2016 deadline.

maximum flexibility in the domestic implementation of law and regulations in order to enable them to make a sound and viable technological base.¹⁴¹

In addition, the TRIPS Agreement states that the LDCs will have ten years to implement general TRIPS provisions.¹⁴² However, the TRIPS Agreement does expressly state that the ten-year period may be extended by the Council for TRIPS if the request is made by an LDC member.¹⁴³ Such an extension was granted and the LDCs were, therefore, expected to fully implement their TRIPS obligations in 2013 (and 2016 for pharmaceutical products) and not in 2005 as originally envisaged.

The developing countries were expected to have complied with the TRIPS Agreement by the year 2000,¹⁴⁴ but this was subsequently extended to 2005. While this staggered implementation of the TRIPS provisions may be lauded as having been sympathetic to the economic conditions and developmental challenges obtaining in the developing countries and the LDCs, whether they are good for access to medicines depends on how they have been taken advantage of. It is quite ironic that by the end of 2013, almost 18 years after the TRIPS Agreement was concluded, no single SADC member had taken advantage of this flexibility for its development.

This flexibility has tremendous potential for enhancing access to medicines in the SADC region. This fact notwithstanding, it appears that African countries in general and the SADC members in particular are not taking optimal advantage of the opportunity. More than half of the SADC members are LDCs and the 2016 initial deadline, together with its recent extension for pharmaceutical compliance with TRIPS must be understood as being mainly for the benefit of SADC, with more than 50% of its membership being made up of LDCs.

SADC LDC members should use technical assistance from WIPO, WTO and regional IP bodies such as ARIPO and OAPI to amend their domestic IP laws to take into account the transitional provisions by specifically excluding patent applications for pharmaceuticals. It has been argued that while one is mindful of the fact that LDCs will eventually have to implement TRIPS in any

¹⁴¹ See sixth recital of the Preamble to the TRIPS Agreement.

¹⁴² Article 66 (1) of TRIPS. There is however a proviso that the application of Articles 3 (national treatment), 4 (most favoured nation treatment) and 5 (multilateral agreements on acquisition or maintenance of protection) are to be immediate. The expected deadline was 2005.

¹⁴³ Art. 66 (1) of TRIPS.

¹⁴⁴ Art. 65 (1) of TRIPS.

event, it may be futile to surmise what will eventually come to pass.¹⁴⁵ Such a view sounds a bit too pessimistic if not cynical when one considers how Brazil and India grew their generic¹⁴⁶ pharmaceutical industries.¹⁴⁷ LDCs could negotiate with generic manufactures and even governments of the countries with superior pharmaceutical manufacturing capacity to set up manufacturing plants in LDCs which are not expected to grant pharmaceutical patents until 2016. It is heartening to report that Brazil is setting up a pharmaceutical plant in Mozambique, an LDC to manufacture HIV/AIDS drugs.

To show that LDCs in the SADC region have not taken advantage of their LDC statuses, Malawi may be used as an example of how not to take advantage of this flexibility.¹⁴⁸

In implementing its antiretroviral therapy (ART) programme, the government of Malawi purported to rely on the Doha Declaration. The government sought to use the 2016 extension in order to procure the fixed dose combination drug Triomune, produced by Cipla, an Indian generic company.¹⁴⁹ However, two components of the drug combination had been patented in Malawi¹⁵⁰ before the Doha Declaration, while no changes had in the meantime been made to the Malawian patent law to override or cancel these patents. The implication here is that while Malawi was generally expected not to recognize the patents involved in the drug combination in terms of the relevant transitional provision, technically, it could not take advantage of the transitional provision because its legislation provides for pharmaceutical patents way ahead of the 2016 deadline. Fortunately, the products were subsequently supplied to Malawi, despite the palpable potential violation of its domestic patent laws, because the patentee did not object.¹⁵¹

In closing, the transition periods are important both positively and negatively. On a negative note, the expiry of the 2005 deadline has had serious implications for the future supply and

¹⁴⁵ Robbani G “Trade-Related Aspects of Intellectual Property Rights and Least Developed Countries” (2005) 8 *Journal of World Intellectual Property* 565 at 568.

¹⁴⁶ According to Baker B.K *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilise TRIPS Flexibilities in non-producing Countries* (2004) at 59, a generic is an equivalent version of an on-or off-patent medicine and generic companies are drug companies that manufacture generic medicines.

¹⁴⁷ See chapter 6 below.

¹⁴⁸ The narrative in this paragraph draws largely from Osewe, Nkrumah and Sackey above at 14-15.

¹⁴⁹ Osewe, Nkrumah and Sackey above at 14.

¹⁵⁰ It is noteworthy to record that in terms of the applicable TRIPS transitional provision, Malawi, an LDC WTO member, has no obligation to recognise patents in pharmaceutical patents until at least 2016.

¹⁵¹ Osewe, Nkrumah and Sackey above at 14.

availability of generic versions of patented medicine,¹⁵² the bulk of which has traditionally been imported by SADC members from India. The implication is that India and Brazil will no longer be able to produce generic versions of drugs patented after the deadline and this will in turn impact on the prices and affordability for SADC countries.¹⁵³ Although this impact is not expected immediately, it is foreseeable that this will affect the generic drug industry in the producing countries and also in those that are dependent on the generic drug and active ingredients from the producing countries.¹⁵⁴

The transitional period relating to LDCs remains important and relevant until 2016, and may be beyond. From a public health perspective, the extension is of significant importance to the LDCs. The extension is an important acknowledgement of the possible negative implications of patent protection for public health.¹⁵⁵ As shown in the Malawian example above, there is a need for SADC countries to take advantage of this flexibility relating to the LDCs by implementing it in their domestic legislations. As for the uncertainty relating to patents already granted, it is recommended that the LDCs prospectively suspend the operation of their patent, test data and market exclusivity schemes with respect to medicines until 2016, and if an extension to the transition period is granted, until that new date.¹⁵⁶

While it is not the intention of this study to encourage the invasion of patent rights with impunity in the LDCs with no patent laws, at the minimum, the absence of a patent will ensure that patents rights do not become an obstacle to the supply of generic medicines.¹⁵⁷ However, this study is alive to the fact that the absence of patent protection may or may not encourage the establishment and growth of the local pharmaceutical industry. Eastern and Southern African (SADC) LDCs can, therefore, take advantage of this flexibility by simply not protecting patents on pharmaceuticals that are deemed essential for public health up to 1 January 2016.¹⁵⁸

¹⁵² Musungu S.F and Oh C (2005) above at v.

¹⁵³ Ibid.

¹⁵⁴ Ibid.

¹⁵⁵ Ibid.

¹⁵⁶ Ibid. See chapter 7 below.

¹⁵⁷ See chapter 7 below.

¹⁵⁸ Munyukwi E and Machemedze R “Implementing the TRIPS Flexibilities by the East and Southern African Countries: Status of Patent Law Reforms by 2010” (2010) 80 *EQUINET Discussion Paper* at 9.

4.3.3 Compulsory licenses

It is important as a preliminary remark to clearly state that 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 expressly refer to compulsory licences.¹⁵⁹ The most relevant provisions of the TRIPS Agreement which are relevant to compulsory licences are Articles 7,¹⁶⁰ 8,¹⁶¹ 31¹⁶² and 40;¹⁶³ while Article 5 of the Paris Convention is also very relevant.¹⁶⁴

According to Baker, 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.¹⁶⁵ 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.¹⁶⁶ The issuance of a compulsory licence is subject to a number of other conditions in addition to the remuneration requirement,¹⁶⁷ and additionally, a member state may have its own peculiar conditions prescribed in domestic law.¹⁶⁸

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 above:¹⁶⁹

- (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’;¹⁷⁰

¹⁵⁹ 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).

¹⁶⁰ Objectives.

¹⁶¹ Principles.

¹⁶² Other use without authorization of the right holder.

¹⁶³ Control of anti-competitive practices in contractual licenses.

¹⁶⁴ 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’.

¹⁶⁵ Baker above 14.

¹⁶⁶ Article 31(h) of TRIPS.

¹⁶⁷ See for instance TRIPS Article 31 (a) – (l).

¹⁶⁸ 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.

¹⁶⁹ The following list draws largely from Abbott F.M and Van Puymbroeck R.V “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* at 7.

(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.’¹⁷¹

(c) the use authorized by the compulsory license must be ‘predominantly for the supply of the domestic market’¹⁷² and

(d) adequate remuneration must be paid to the right holder.¹⁷³

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.¹⁷⁴ 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.¹⁷⁵ 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.¹⁷⁶ 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.¹⁷⁷ In the context of this study, compulsory licences may be granted to address public health emergencies by ensuring access to cheaper drugs.¹⁷⁸ It is possible that the granting

¹⁷⁰ Article 31 (b).

¹⁷¹ Article 31(b).

¹⁷² Article 31 (f).

¹⁷³ Article 31 (h).

¹⁷⁴ Article 31(k) of TRIPS.

¹⁷⁵ Abbott and Puymbroeck above at 7.

¹⁷⁶ Reichmann J.H Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options (2009) *Pharmaceutical Regulations* 247 – 263.

¹⁷⁷ Taubman, Wager and Watal above at 109.

¹⁷⁸ Correa CM *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2007) at 313.

of one or more of such licences will force process down, thus furthering consumer welfare.¹⁷⁹ Because compulsory licences must be non-exclusive, this means that licences to use a patent may be given to more than one company.¹⁸⁰

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).¹⁸¹ 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.¹⁸² 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.¹⁸³ With generalized compulsory licences, these expenditures would be unnecessary and thus increase the welfare benefits.¹⁸⁴ 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.¹⁸⁵

It is noteworthy that although the TRIPS Agreement gives several grounds¹⁸⁶ meriting the grant of compulsory licences, when read together with the pertinent provision of the Doha Declaration,¹⁸⁷ there is no limit in any way on the capacity of governments to grant compulsory licences or undertake government use.¹⁸⁸ The absence of restrictions on the purposes for which compulsory licenses may be granted is quite a significant achievement for the developing countries and is now considered “as a major policy instrument in attenuating the adverse effects

¹⁷⁹ Correa above at 313.

¹⁸⁰ Ibid.

¹⁸¹ Ibid.

¹⁸² See for example a study conducted by Schreiner, cited in Correa at 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.

¹⁸³ Tandon P “Optimal Patents with Compulsory Licensing” (1982) 90 *Journal of Political Economy* at 485.

¹⁸⁴ Ibid.

¹⁸⁵ At least this seems to have been the net result in the Zimbabwean context in 2002 (see chapter five below) 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.

¹⁸⁶ 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.

¹⁸⁷ 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.

¹⁸⁸ Correa above at 314.

of strong patent protection”.¹⁸⁹ 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.¹⁹⁰ Therefore, SADC members may include other grounds for compulsory licences and clearly spell out in simple language, 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.

Domestic legislation of most countries in Africa,¹⁹¹ and in the SADC region,¹⁹² has provided 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).¹⁹³ 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.¹⁹⁴

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, but the effort failed because active pharmaceutical ingredients were expensive, thus rendering local production economically unviable.¹⁹⁵ 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.

The other problem that has been identified with specific reference to the potential viability of compulsory licences as an access tool in the SADC region relates to the requirement to pay

¹⁸⁹ Watal J *Intellectual Property Rights in the WTO and Developing Countries* (2001) at 380 – 381.

¹⁹⁰ Watal above at 381.

¹⁹¹ 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).

¹⁹² For example, Botswana (sections 34 and 35 of the Industrial Property Act of 2010), South Africa (section 56 of the Patents Act 57 of 1978), Zimbabwe (section 35 of Patents Act (Chapter 26:03) of 1972 as amended) and section 9 of Zambian Patents Act [chapter 400] of 1996.

¹⁹³ For the specifics, see Love J.P “Recent examples of the use of compulsory licenses on patents” (2007) *Knowledge Ecology International* at 15 – 18.

¹⁹⁴ Love above at 16 – 17.

¹⁹⁵ Osewe, Nkrumah and Sackey above at 17.

adequate compensation.¹⁹⁶ Legislation in most SADC countries lacks clear provision for the determination of the level of ‘adequate remuneration’ to be paid once a compulsory licence has been issued.¹⁹⁷ Additionally, there are no specific provisions in the countries’ laws allowing a waiver of the payment of royalties by the importing country, as sanctioned by the 2003 Decision.¹⁹⁸

It will, therefore, be important to clarify in national laws the different circumstances when an importing country would be exempted from the payment royalties;¹⁹⁹ this is based on the fact that most countries in the SADC region, except South Africa, lack pharmaceutical production capacity.

Compulsory licences as a TRIPS flexibility offer unique advantages for WTO members especially the developing countries and the LDCs. 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.²⁰⁰ However, despite the advantages, compulsory licences will be problematic to use in the SADC context because their use will be limited to small quantities of imports to deal with the specific problem. Secondly, due to the lack of pharmaceutical manufacturing capacity, SADC countries are likely to use the licences as importers, thus retarding the development of domestic manufacturing capacity.²⁰¹

However, despite the above highlighted reservations, compulsory licences and parallel imports remain important TRIPS flexibilities for the SADC in the context of access to medicines under the Doha Declaration and the 2003 Decision. This study, therefore, largely based its search for access solutions on the use of these two flexibilities.²⁰²

¹⁹⁶ Osewe, Nkrumah and Sackey above at 17.

¹⁹⁷ Ibid.

¹⁹⁸ It will be recalled that in terms of the Decision, when a medicine imported from a country in which it not patented, the importing country must pay compensation in the form of a royalty. On the other hand, if the medicine is patented in both the importing and exporting country, the payment of compensation by the importing country is waived (see paragraphs 2 and 3 of the Decision).

¹⁹⁹ Osewe, Nkrumah and Sackey above at 17.

²⁰⁰ Ogendi P.O *Access to Essential Medicine and the Utilisation of Compulsory Licensing and Parallel Importation in Kenya and South Africa* (2013), LLM Dissertation submitted to Faculty of Law, University of Nairobi.

²⁰¹ Ibid.

²⁰² See chapters 5 – 7 below.

4.3.4 Parallel Importation

Because compulsory licences are based on a complex procedure prescribed by the TRIPS Agreement and in some instances may only be judicially sanctioned, SADC members will be reluctant to rely on them as an access to medicines tool. Additionally, unless the member is an LDC, which does not have patent legislation on its statute books, if a compulsory licence is to be utilized, issues of the payment of ‘adequate’ remuneration to the patent holders will arise.

The foregoing remarks then call for an alternative flexibility which is less complex to implement and for which the payment of remuneration to the patent holder does not arise. Parallel importation squarely fits the description of such an alternative.

Parallel importation, just like compulsory licensing, is not directly mentioned in the TRIPS Agreement but arises in the context of the international exhaustion of rights.²⁰³ The TRIPS Agreement disclaims any limitation on the members’ freedom to regulate international exhaustion of rights in intellectual property rights.²⁰⁴ International exhaustion of intellectual property rights will make it possible for a patented product to be legally imported into a country after the product has been legitimately put on the market in a foreign market.²⁰⁵

The relevant TRIPS provision (Article 6) leaves the determination of when exhaustion may be deemed to have occurred to each individual member to decide.²⁰⁶ Exhaustion may be applied at the national level,²⁰⁷ regional level²⁰⁸ and international level.²⁰⁹ International exhaustion is important for developing countries which will be free to import cheap drugs from wherever they have been placed by the patent holder, without breaching any obligations under the TRIPS Agreement.²¹⁰ The TRIPS and the Declaration, therefore, allow members to choose the

²⁰³ Correa above at 78.

²⁰⁴ See Article 6 of TRIPS which provides that for the purposes of dispute settlement under the Agreement, and subject to the principles of national treatment and the most favoured nation, nothing in that Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

²⁰⁵ Correa above at 78.

²⁰⁶ Correa above at 79.

²⁰⁷ In this case, rights will be deemed exhausted domestically and their commercialization in foreign countries is not deemed to have exhausted the patentee’s rights.

²⁰⁸ In this instance exhaustion is deemed to have occurred if commercialization took place in a country member of a regional agreement e.g. SADC, EU, East African Community (EAC) or Economic Community of West African States (ECOWAS).

²⁰⁹ In this case, parallel imports will be allowed from any country.

²¹⁰ This is confirmed by paragraph 5 (d) of the Doha Declaration, which affirms members’ autonomy in determining the exhaustion regime applicable to each one of them.

exhaustion regime suitable for their individual circumstances and be in a position to import patented products without the authorization of the title-holder, using a practice generally known as ‘parallel importation’.

Parallel importation may aptly be defined as “the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent”.²¹¹ Therefore, parallel importation may be beneficial to developing countries that will be able to import patented products from countries where they are sold at lower prices than those at which they are sold in the importing country.²¹²

One reason why patented products may be cheaply available in other countries could be differential pricing,²¹³ explored as a possible solution to the SADC access problem in Chapter seven below. One writer has characterized differential pricing, which is now seriously considered as a solution to the high drug prices occasioned by the existence of patents, as an ‘imperfect solution’.²¹⁴ The reality of parallel importation is that governments will be allowed to import, without the right holder’s consent, patented products into their territories from other countries where such products have been placed on the market at a lower price.²¹⁵ It does not matter whether or not the products have been placed on the market with or without the right holder’s consent.

To convincingly illustrate the advantages and access to medicines’ potential in respect of parallel importation as a TRIPS flexibility Mabika and Makombe²¹⁶ used the price of the drug Amoxil in 1999 and the table shown on the next page is an attestation to this effect.

²¹¹ Khor above at 3.

²¹² Osewe, Nkrumah and Sackey at 20.

²¹³ For a general note on the differential pricing for pharmaceuticals, see Danzon P.M and Towse A “Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents” (2003) 3 *International Journal of Health Care Finance and Economics* 183 – 205.

²¹⁴ Saddiqi A “Patents and Pharmaceutical Drugs: The Need for Change” (2005) *Intellectual Property Law* 1 – 9.

²¹⁵ Mabika and Makombe above at 2.

²¹⁶ Ibid.

US\$ price of Amoxil

Pakistan	\$8
Canada	\$14
Italy	\$16
New Zealand	\$22
Philippines	\$29
Malaysia	\$36
Indonesia	\$40
Germany	\$60

(Source: Mabika A and Makombe P (2006:2)

From the table above, it is axiomatic that the drug is the cheapest in Pakistan and most expensive in Germany. Germany can import the drug from wherever it is cheap, notably Pakistan and Italy without resort to the right holder. This of course will depend on what exhaustion regime Germany subscribes to. The rationale for parallel importation is the promotion of ‘pricing equity by allowing importation of patented products marketed more cheaply in another country’.²¹⁷

Applied to the SADC countries, parallel imports may be useful in procuring cheap medicines from other countries where the product has been placed on the market at a cheaper price. Sometimes right holders can place their products cheaply in certain markets due to prior negotiations or a desire to establish a foothold and business presence in the specific country. This will be possible if the SADC member’s legislation provides for parallel importation. It is important to highlight that LDCs with no intellectual property laws whatsoever, can chose to resort to parallel import without any hindrance whatsoever; at least until 2016 with respect to pharmaceuticals and until 2021 with regard to the other IP forms. It is heartening to note that in the SADC region, all members except Angola, Botswana Democratic Republic of Congo, Lesotho, Malawi, Mozambique and Zambia provide for parallel imports in their domestic laws.²¹⁸ To maximally take advantage of parallel importation, SADC members must move away from national and regional exhaustion and include international exhaustion regimes in their

²¹⁷ Baker above at 22.

²¹⁸ Makombe and Mabika above at 3.

domestic legislation. On the African continent, Ghana, Kenya, South Africa and Zimbabwe are good examples of countries that provide for the international exhaustion of rights.²¹⁹ However, with respect to South Africa, parallel importation is not provided for in the Patents Act but in the Medicines and Related Substances Control Amendment Act.²²⁰ Parallel importation is provided for in Article 15C of the Act.²²¹

It is appropriate to end this discussion of parallel importation as a TRIPS' flexibility by referring to the inherent challenges. The major challenge as outlined in the foregoing paragraph is that most SADC members have not adapted their domestic laws to allow for the international exhaustion of rights as mandated by TRIPS and the Doha Declaration. This problem becomes acute when one factors in the reality that about 50% of SADC members are considered developing nations which have to align their laws with the TRIPS Agreement. The deficiency in the laws leaves SADC members unable to shop around for cheaper drugs in other markets through parallel importation. Considering the disease burden in the region, incorporating an international exhaustion regime into domestic laws could go a long way towards fulfilling SADC citizens' right to health, and by the extension access to medicines.

4.3.5 The Research and Early Working or Bolar Exception

The TRIPS Agreement specifies exclusive rights²²² that a patentee is entitled to and additionally, outlines general bases for exceptions to such exclusive rights.²²³ The general rule of law is that exceptions to the patent rights must be limited;²²⁴ not unreasonably conflict with the normal exploitation of the patent;²²⁵ and not unreasonably prejudice the legitimate interests of the patent holder,²²⁶ taking into account the legitimate interests of third parties.²²⁷ Apart from the above broad outline, Article 30 of TRIPS does not define the scope or nature of the permissible exceptions.²²⁸ This leaves WTO members with a lot of interpretive freedom. Consequently,

²¹⁹ Osewe, Nkrumah and Sackey above at 20.

²²⁰ Act 90 of 1997, published in Government Gazette No. 18505 of 12 December 1997.

²²¹ See specifically Du Plessis E "The TRIPS Agreement and South African Legislation: The Case of the Parallel Importation of Medicines" (1999) 4 *Law, Democracy and Development* 62 – 65.

²²² These rights, which include the patentee's right to exclude a third party from making, using, offering for sale or importing the patented products, are enumerated in Article 28 of TRIPS.

²²³ See Article 30 of TRIPS.

²²⁴ *Ibid.*

²²⁵ *Ibid.*

²²⁶ *Ibid.*

²²⁷ *Ibid.*

²²⁸ Musungu and Oh (2005) above at vi.

exceptions crafted to achieve objectives related to the transfer of technology; the prevention of abuse of intellectual property rights; as well as the protection of public health is justifiable and desirable.²²⁹

It is conceivable that the testing and establishment of the bioequivalence²³⁰ of a generic version of a drug before the expiry of the patent may be done in pursuit of research and experimentation.²³¹ The research and experimental use exception is aimed at ensuring that scientific research generating new knowledge is fostered and not impeded by patents.²³² This exception is longstanding and is justifiable on the basis that one of the main aims of patent laws is to facilitate the dissemination of knowledge, promote innovation and facilitate the advancement of science.²³³ This exception, which is in actual fact a TRIPS flexibility, is likely to be useful in spurring pharmaceutical technological progress when pharmaceutical companies and research institutes experiment with a patented medical invention in order to improve it or evaluate it to establish if it works.²³⁴ There is a lot for SADC countries to gain if they include the research exception in their individual patent laws because the flexibility is sanctioned by the TRIPS Agreement.²³⁵

The early working or *bolar* exception may be regarded as one of the desirable ones that is acutely relevant to access to medicines for SADC countries. The exception is a useful mechanism for facilitating the production and accelerated introduction of generic drugs when patents expire. The existence of this exception, which allows members to permit generic medicine manufacturers to undertake and complete the task of obtaining regulatory approval

²²⁹ Ibid.

²³⁰ Bioequivalence in medical terminology means the measurement of blood or plasma concentrations of two drugs (or of a combined drug against the component drugs administered simultaneously) over time to characterize the rate and extent of the drug absorption; if measured bio-availability of the two drugs is comparable, bio-equivalence demonstrates interchangeability in terms of expected safety and efficacy (Baker above at 59).

²³¹ See Taubman A, Wager H and Watal J (eds) *A Handbook on the WTO TRIPS Agreement* (2012) at 109.

²³² Musungu, Villanueva and Blasetti above at 17.

²³³ Ibid.

²³⁴ Ibid.

²³⁵ At least this is the interpretive result that one is likely to get when the broad objectives of Article 30 of TRIPS are contextually applied to developing countries and LDCs.

from national regulatory authorities for generic versions before original patents expire, was confirmed by the WTO in a panel ruling pitting Canada against the European Union.²³⁶

This exception is important because it ensures that generic versions of the patented product are available on the market immediately or within a reasonable time after the expiry of the patent.²³⁷ It has been reported that the actual implementation of this exception differs from country to country. In Zimbabwe for instance, early working of an invention is allowed as early as six months before the expiry of the patent.²³⁸ In Kenya, something similar to the Zimbabwean situation obtains with the net result being that the life of the patent is not extended.²³⁹ In the United States, on the other hand, the relevant legislation introduced this exception while allowing patent holders an extended period of protection.²⁴⁰

Because the bolar exception is important for technology transfer and local manufacturing, it is advisable that SADC countries include it clearly and unambiguously in national laws. Although African countries and SADC members have limited capacity for the production of pharmaceuticals, there is demonstrated effort in countries such as Ghana, Kenya, South Africa, Zimbabwe and Nigeria.²⁴¹ In the SADC region, noticeable pharmaceutical manufacturing capacity exists in South Africa, the DRC, Zimbabwe, Tanzania and Zambia in that order.²⁴² Other SADC countries with some pharmaceutical manufacturing capacity are Malawi, Mauritius, Mozambique, Namibia, Seychelles and Swaziland.²⁴³ The incorporation of the early working system into national laws, as has been done in South Africa²⁴⁴ and Zimbabwe²⁴⁵ is, therefore,

²³⁶ See Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R 17 March 2000, available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited 07/10/2013)

²³⁷ Musungu, Villanueva and Blasetti above at 17.

²³⁸ See section 24 (3) of Zimbabwe's Patents Act of 1996 as amended in 2002.

²³⁹ Section 21(3) of the Kenyan Industrial Property Act, published in Kenya Gazette Supplement No. 60 (Act No.3) of 3 August 2001.

²⁴⁰ United States Drug Price Competition and Patent Restoration Act of 1984, informally known as the Hatch-Waxman Amendment [Public Law 98-417 – September 24 1984], was the first US law to encourage the manufacture of generic drugs in the United States, it also established a system for the registration of generics. The full text of the legislation was accessed at <http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf> (last visited 07/10/2013).

²⁴¹ See in this specific regard SEATINI, CEHURD, TARSC "Overcoming Barriers to Medicines Through South-South Cooperation in Africa" (2013) 34 *Policy Series* at 1.

²⁴² Ibid.

²⁴³ Ibid.

²⁴⁴ Amendments to the Patents Act of 1978 in 2002 introduced bolar provisions.

²⁴⁵ See note 80 above.

worth emulating as a crucial step towards the eventual production and distribution of essential medicines in the region.²⁴⁶

Even where countries are not likely to be producers of pharmaceuticals, the UK Commission on Intellectual Property has recommended that developing countries incorporate a bolar-type exception within their domestic laws, in order to make it possible for generic products of a foreign company to gain regulatory approval and to enter the market soon after the expiry of the patent.²⁴⁷

4.3.6 Public non-Commercial Use of Patents (government use)

Just like in other instances when patents may be overridden in a legally sanctioned manner,²⁴⁸ government's use of patents, while taking into account the interests of the society and third parties, has not been considered to be unreasonably prejudicial to the interests of patent right holders.²⁴⁹

The right of the state to use a patent without the consent of the patent holder for public health purposes is considered to be an important public health safeguard by many countries.²⁵⁰ Although the TRIPS Agreement sets out the conditions governing both government use and compulsory licences, one important difference is that government's use of patents may be 'fast tracked' because of the waiver of the requirement for prior negotiations with patent holders.²⁵¹ Although the term 'government' is not defined in the TRIPS Agreement, the use is limited to public rather than private non-commercial use.²⁵² "Public commercial purposes" is also not defined in the TRIPS Agreement, hence this leaves developing and SADC countries with ample policy space to interpret the concept.²⁵³ The major distinction between government-use

²⁴⁶ Osewe, Nkrumah and Sackey at 22.

²⁴⁷ Musungu and Oh (2005) above at vi.

²⁴⁸ See Article 30 of TRIPS. Specific instances include research and experimentation, early working of a patent, prior use of a patented invention and temporary use on vessels, aircraft or land vehicles temporarily or accidentally entering the waters, airspace or land [this exception is expressed as an explicit obligation in Article 5ter of the Paris Convention].

²⁴⁹ Taubman, Wager and Watal above at 109.

²⁵⁰ See for example section 34 of Zimbabwe's Patents Act 26:03 of 2002 and section 78 of the South African Patents Act 57 of 1978 provide for government use of patented inventions.

²⁵¹ See generally, Article 31 of TRIPS and specifically 30 (b) which exempts government non-commercial use from the obligation to negotiate for a voluntary license with the patent holder.

²⁵² Pfumrodze above at 92.

²⁵³ The implication therefore is that *public non-commercial purposes* (emphasis added) could mean diverse things to different countries.

provisions and compulsory licences lies primarily in the nature or purpose of the use of the patent.²⁵⁴ In the case of government's use, it would be limited to "public non-commercial purposes" while compulsory licences would also cover private and commercial use.²⁵⁵

Therefore, in the thematic context of this study, the purchase of anti-retroviral drugs for distribution through public hospitals without commercial profit would fall under the scope of this flexibility.²⁵⁶ It has been recommended that those developing countries with no legislation on government use of patents should incorporate this flexibility into their domestic legislation.²⁵⁷ Additionally, it has further been recommended that the incorporated provisions must be no less broad than those currently applicable in the United States and United Kingdom (UK) legislation.²⁵⁸

4.3.7 Exemptions from Patentability

The general rule on patentable subject matter under the TRIPS Agreement is that, subject to exceptions set out therein, patents shall be available for all inventions, whether products or processes, in all fields of technology, provided that they are new and involve an inventive step and are capable of industrial application.²⁵⁹

However, an invention is not defined in the TRIPS Agreement and this leaves WTO members with the flexibility to define the scope of the concept of invention under their national laws.²⁶⁰ This flexibility may have both good and bad implications for access to medicines. On a positive note, the absence of a definition may make it possible for WTO members to exclude new uses of drugs from patentability under national laws.²⁶¹ However, on a negative note, WTO members may take advantage of the absence of a definition and use it to frustrate access to medicines by granting patents to new and sometimes minimally improved uses of drugs. Standards should,

²⁵⁴ Musungu and Oh (2005) above at 20.

²⁵⁵ Ibid.

²⁵⁶ Ibid. It is submitted that even if the government uses agents such as private hospitals and NGOs to distribute the medicines, as long as the distribution is to the public in the absence of any commercial advantages to the government, then this will still be covered by Article 30 (b).

²⁵⁷ Musungu and Oh (2005) above at v.

²⁵⁸ Ibid.

²⁵⁹ Article 27 (1) of the TRIPS Agreement.

²⁶⁰ In a similar vein, section 25 of the South African Patents Act 57 of 1978 specifies the requirements for patentability in similar terms like the TRIPS Agreement, but on the aspect of industrial application (utility), the law says the patent must be useful in *trade, industry and agriculture* (emphasis added). The South African Patents Act does not define an invention.

²⁶¹ Musungu, Villanueva and Blasetti above at 15.

therefore, be set to avoid the granting of patents for “evergreen” or “me-too drugs” that extend patent duration without an improvement to the drugs’ efficacy.²⁶²

The proponents of new use patents justify them on the basis that the discovery of a new use may require the same level of investment like what obtained with the first patent.²⁶³ According to Musungu, Villanueva and Blasetti,²⁶⁴ the forms of innovation in the pharmaceutical industry for which patents may be claimed varies from breakthrough discoveries to minor modifications of existing medications. The authors cite examples from a recent study that was conducted by the National Institute of Healthcare Management Research and Educational Foundation which showed that in the United States, the market with the largest number of pharmaceutical patents, in the 12 year period from 1989 to 2000, of the 1035 new drugs approved by the Federal Regulatory Agency, only 35 per cent of them contained a new active ingredient.²⁶⁵ From the cited report, during the 12 year period, only 15 per cent of the medicines were highly innovative drugs.²⁶⁶ The logical conclusion based on the study, therefore, is that the bulk of new medicines are modified versions of older drugs, which ironically cost more than the original ones on which they are based.

To raise the standards in the SADC region, patent examiners have to be trained to interpret patentability requirements strictly before granting pharmaceutical patents.²⁶⁷ On a related note, India has raised the criteria for patentability so as to prevent evergreen patents from being registered.²⁶⁸ In the specific Indian context, applicants are made to establish to a high degree of certainty that the medication for which an application for a patent has been made is *more effective than* (emphasis added) those already used for the same condition.²⁶⁹ Avenues should be provided for patent opposition proceedings during the patent application process because the

²⁶² Adusei P “Exploiting Patent Regulatory Flexibilities to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa” (2011) 14 Journal of World Intellectual Property 1-20 at 12.

²⁶³ Musungu, Villanueva and Blasetti above at 15.

²⁶⁴ Ibid.

²⁶⁵ Musungu, Villanueva and Blasetti above at 15 citing from the National Institute of Health Care Research Management Research and Educational Foundation (NIHCM) (2002) report at 3.

²⁶⁶ That is to say, drugs which contain new active ingredients and at the same time provide significant clinical improvement.

²⁶⁷ Musungu, Villanueva and Blasetti above at 15.

²⁶⁸ See section 3(d) of the Indian Patent (amendment) Act 2005.

²⁶⁹ Angell M The Truth about Drug Companies: How they Deceive and what to Do about it (2004) at 75 New York: Random House.

court process is tedious and likely to be expensive.²⁷⁰ In India for instance, the relevant law²⁷¹ allows members of the public to bring evidence which may lead to patent rejection to the attention of the patent controller.²⁷² The existence of this remedial measure made it possible for the Indian Network of People living with HIV/AIDS and the Manipur Network of Positive People to successfully oppose GSK's patent application for zidovudine and lamivudine in 2006 on the basis that the patent claim in the specific instance was not for a new invention.²⁷³

South Africa, a SADC member with one of the highest HIV/AIDS infection rates in the world, does not have provisions in its patent laws dealing with pre-grant opposition to patents as a condition precedent for the granting of a patent.²⁷⁴ Such an omission does not augur well for access to medicines and deserves a legal administrative rethink. Therefore, patent offices must push for high standards of disclosure in order to discourage the filing of bogus patent applications meant to serve a gate-keeping function thus deterring the entry of generics on the market.²⁷⁵ Patent Offices in the SADC region may, therefore, consider dealing with this problem by requesting technical assistance to amend their laws so that patent examination becomes mandatory.²⁷⁶

In closing, the implication of this flexibility for SADC members is that the TRIPS Agreement does not prevent them from denying the patentability of new uses of drugs for lack of novelty, the involvement of an inventive step and lack of industrial applicability.²⁷⁷ Developing countries and SADC member states would be within their rights if they exclude new uses of known products including diagnostic, therapeutic and surgical methods from patentability.²⁷⁸

²⁷⁰ Adusei above at 12.

²⁷¹ Section 3(d) of the Indian Patent (amendment) Act 2005.

²⁷² Adusei above at 12.

²⁷³ Adusei above at 13.

²⁷⁴ The patent office, based in Pretoria only examines patents for formal compliance with the provisions of the law and the attendant regulations since it is technically unable to assess the scientific propriety of novelty and inventive step requirements (see specifically section 34 of the South African Patents Act 57 of 1978).

²⁷⁵ See on a related note Drahos P *The Global Governance of Knowledge: Patent Offices and their Clients* (2010) at 37 – 38.

²⁷⁶ See Articles 66(2) and 67 of the TRIPS Agreement.

²⁷⁷ See generally Correa C.M *Intellectual Property Rights and Developing Countries: The TRIPS Agreement and Policy Options* (2000).

²⁷⁸ Pfumrodze above at 94. Additionally, see specifically, Article 27 (3) of TRIPS.

4.3.8 Limitations on Data Protection

The TRIPS Agreement allows each WTO member to determine how to protect test data in the public interest.²⁷⁹ The pertinent provision reads as follows:

Members, when requiring as a condition of approving the marketing of pharmaceutical or agricultural products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that such data are protected against unfair commercial use.²⁸⁰

The most important aspects of the provision that may be emphasized for ease of comprehension may be summed up as follows: Firstly, the provision relates to data relating to new chemical processes which are aimed at the production of new chemical products.

Secondly, the origination of the data must involve a considerable effort.²⁸¹

Thirdly, the data must be protected from *unfair commercial use* (my emphasis), and nothing more.

It appears that two possible defences against a charge of disclosure of the data do exist.²⁸² Firstly, a member can admit that the data was indeed disclosed, to the chagrin of the complainant but such disclosure was done to safeguard and protect public health. Secondly, data may have been disclosed because non-disclosure thereof has been rendered superfluous by the fact that concrete steps have been taken to protect the data against unfair commercial use.

Therefore, there is no textual basis for a submission that pharmaceutical test data must be protected against disclosure all the time (data exclusivity).²⁸³ The protection must only address the possibility of unfair commercial use of the test data. Interpreting Article 39 (3) of TRIPS as demanding data exclusivity rather than data protection against unfair commercial use has the

²⁷⁹ TRIPS Article 39 (3).

²⁸⁰ Ibid.

²⁸¹ The real nature of such effort is not defined but it is submitted that processes that require a lot of man hours to work on and considerable human and capital investment will easily fall into this category.

²⁸² This inference is easily drawn from the second sentence of TRIPS Article 39 (3).

²⁸³ At least this submission concurs with Osewe, Nkrumah and Sackey above at 21.

potential of blocking access to generic versions of new medicines.²⁸⁴ Since the WTO does not require “data exclusivity”, a generic producer, which is given permission, for example, under a compulsory licence to sell or produce a generic version of a patented drug, can make use of that data when it seeks safety approval from the drug regulatory authority.²⁸⁵ In so far as generic competition lowers prices and increases availability and access to essential medicines, it is in the public interest to limit the extent of test data protection.²⁸⁶

The data refers to test data which is submitted to drug regulatory authorities to demonstrate the safety and quality of products.²⁸⁷ During the subsistence of the test data protection, drug regulatory authorities are not allowed to rely on the originator’s test data to approve other registrations during the entire period of data protection.²⁸⁸ Most countries in Africa do not have specific provisions with respect to data protection and where such provisions exist the authorities protect the data against disclosure to a third party for “unfair commercial use”.²⁸⁹

In some developed jurisdictions, such as the United States and the European Union, the pertinent regulations provide for exclusive use of the test data by the originator company for a limited period of time.²⁹⁰

It is, therefore, recommended that SADC member states clearly stipulate in their domestic laws the extent of data protection that accords with the TRIPS Agreement so that drug regulatory authorities can effectively register generic medicines. From a public health policy standpoint, it is vital that policies that ensure competition, such as limitations on data protection be adopted in order to ensure a timely entrance of generic medicines to ameliorate the access enigma to medicines. SADC members are not exempt from this important requirement.

4.3.9 Exceptions based in Competition Law

The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer of technology, in addition to a balance in the enjoyment of the benefits accruing

²⁸⁴ Osewe, Nkrumah and Sackey at 21.

²⁸⁵ Khor M *Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences* (2007) at 20.

²⁸⁶ Musungu, Villanueva and Blasetti above at 19.

²⁸⁷ Pfumrodze above at 94.

²⁸⁸ Ibid.

²⁸⁹ Osewe, Nkrumah and Sackey at 21.

²⁹⁰ Musungu, Villanueva and Blasetti at 19.

to the users and producers of technology.²⁹¹ The most relevant principle upon which the balance may be achieved is one allowing members to adopt appropriate measures to prevent the abuse of intellectual property rights by rights holders or their resorting to practices that unreasonably restrain trade or adversely affect international transfer of technology.²⁹²

Members are not obliged to apply the provisions of Article 31(b)²⁹³ and (f)²⁹⁴ of the TRIPS Agreement if intellectual property rights are abused in the context of anti-competitive behaviour.²⁹⁵ Patents may, therefore, be overridden and compulsory licences issued if it can be proved that the right holder is engaged in anti-competitive conduct, such as abusing dominance in a market by charging excessively high prices for pharmaceuticals. In this case, the need to correct anti-competitive behaviour may be taken into account in determining the amount of remuneration as compensation.²⁹⁶ This remedy may be resorted to after going through a judicial or administrative process,²⁹⁷ which a member seeking to rely on such a remedy must have in place. Article 31 (k) of the TRIPS Agreement is, therefore, a flexibility which SADC member states may use if their domestic legal regime provides for the redress of anti-competitive behaviour.

Additionally, the TRIPS Agreement does acknowledge that some licensing practices or conditions pertaining to intellectual property rights may restrain competition and impede the transfer of technology,²⁹⁸ thus compelling an affected member to enter into consultations with its trading partner in order to stem the abuse of intellectual property rights.²⁹⁹ Examples of contractual practices that may restrain competition are the use of terms such as exclusive grant back clauses which are clauses that preclude challenges to the validity of the patent and coercive

²⁹¹ Musungu, Villanueva and Blasetti at 19.

²⁹² See Article 8 (2) of TRIPS.

²⁹³ This Article requires that the member must first negotiate for a voluntary license before resorting to compulsory one and that secondly, if the situation amount to a national emergency, such negotiations will not be necessary.

²⁹⁴ This Article, which has been waived by the 2003 Ministerial Decision with respect to countries with limited or no pharmaceutical manufacturing capacity, specifies that compulsory licenses must be granted for the predominant supply of the domestic market.

²⁹⁵ See Article 31(k) of TRIPS.

²⁹⁶ Ibid.

²⁹⁷ Ibid.

²⁹⁸ Article 40 (1) of TRIPS.

²⁹⁹ Article 40 (3) of TRIPS.

packaging.³⁰⁰ Such practices must be prohibited in order to improve competition and reduce the concentration of market power in one country or specific geographical region.

WTO members are, therefore, allowed within the purview of the TRIPS Agreement to pass domestic legislation specifying the specific licensing practices or conditions that may constitute an abuse of intellectual property rights with adverse effects on competition in the relevant market.³⁰¹ Such domestic legislation has extra-jurisdictional application.³⁰² The reason for such a submission on extraterritoriality is that the pertinent provision refers to a request for consultation directed at a WTO member by a fellow member on the basis that anti-competitive conduct complained of violates a provision in the complaining state's domestic legislation.³⁰³ Anti-competitive practices or conditions adversely affecting trade and the dissemination of technology and the use of competitions law can be an effective mechanism to check medicine pricing abuses on the markets.³⁰⁴ However, for competition law and policy to work favourably for the access cause to medicines, the two must be viewed as complementary to other TRIPS flexibilities, specifically those highlighted by the Doha Declaration.³⁰⁵

Competition law and policy have been used as a tool to improve access to medicines in the SADC region. In South Africa this is best exemplified by two cases whose finalization by the relevant authorities was eye-opening for the region.³⁰⁶ Taking a cue from South Africa, SADC member states that do not have competition legislation³⁰⁷ and institutions to check anti-competitive practices need such regulatory frameworks. The enforcement of the competition law and policy are likely to succeed in an environment with robust civil society activity and NGOs that keep government on its feet. In the context of South Africa, the actions of the Treatment

³⁰⁰ Article 40 (2) of TRIPS.

³⁰¹ Article 40 (2) of TRIPS.

³⁰² Article 40 (3).

³⁰³ Ibid.

³⁰⁴ Adusei above at 12.

³⁰⁵ See generally para 4.3 below.

³⁰⁶ The two cases are *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim and Treatment Action Campaign v Bristol-Myers Squibb*. For an in-depth analysis of the cases in the context of access to medicines and the ramifications for Sub-Saharan Africa and the region, see Avafia T, Berger J and Hartzenberg T *The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries* (2006) at 36-50.

³⁰⁷ Sakata N "Are Southern African Competition Law Regimes Geared up for Effective Cooperation in Competition Law Enforcement?" (2011) *South African Competition Commission* 11-12 available at <http://www.compcom.co.za/assets/Uploads/events/Fifth-Annual-Conference/African-Regional-cooperation-PaperFinal-27-Sept-11-.pdf> (accessed 17/09/2013) highlights the fact that all SADC member states except the Democratic Republic of Congo, Lesotho, Angola and Mozambique have competition legislation and policies.

Campaign and other groups forced the pharmaceutical companies to agree to voluntary settlements.³⁰⁸

Conclusion

The most relevant TRIPS flexibilities for the developing countries, especially the SADC members include transition periods, compulsory licenses, public non-commercial use of patents, parallel importation, exceptions from patentability and limits on data protection, *bolar* exception and use of competition law. Although the SADC Protocol on Trade enjoins all SADC members to implement TRIPS flexibilities in their legislation, it must be recalled that LDCs do not have to worry about such an obligation until 2016 for pharmaceuticals³⁰⁹ and 2021 for all other IP forms.

This chapter has identified the above flexibilities and contextualized the relevance of each to the SADC region, with examples drawn from SADC members' legislation where applicable. The overall picture is that the inclusion of these flexibilities in individual SADC members' legislation is not systematic but random. In addition, where a flexibility such as compulsory licensing is included in a country's legislation, the provisions thereof are complex or the grounds for the use of the flexibility are narrowly spelt out.

The Doha Declaration on TRIPS and Public Health together with the August 2003 waiver and the subsequent introduction of Article 31 *bis* of TRIPS are very crucial developments which remain potentially useful arsenal for the developing countries and the LDCs to use in their access war. While the Doha Declaration has received significant praise for its bold statements on access to medicine and providing interpretive clarity, it did not solve all the problems associated with the protection of intellectual property rights and the burgeoning health problems.³¹⁰ This chapter gave a detailed exposition of the pertinent provisions of the Doha Declaration and Article 31 *bis* and came to the conclusion that the legal developments will yield positive results for access to medicines. The most important aspect of the legal developments is the provision for an

³⁰⁸ Adusei above at 12. Specifically, the pharmaceutical companies GSK and BI granted voluntary licenses to both private and public sector marketers in return for royalties below 5%.

³⁰⁹ However, it ironic, as noted by Dountio J "Access to Medicines in Africa: Where there is a Will there is a Way" (2012) 1 *Bridges Africa Review* 1 – 4, that Articles 1-10 of the Bangui Agreement, which forms the legal basis for the establishment of the African Intellectual Property Organisation (OAPI), provides patent protection in all fields of technology for its members despite 12 out of 63 members being LDCs. This implies that the Bangui Agreements is very bad for access to medicines because it shuts the door for LDCs to take advantage of existing favourable transitional periods.

³¹⁰ T' Hoen EFM "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond" (2003) *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges* 39 – 67.

exemption of regional agreements in which 50% of the members are LDCs from complying with the restrictive procedure applicable to compulsory licences in terms of Article 31 of TRIPS.³¹¹ The SADC, the EAC and ECOWAS would all satisfy this 50% LDCs membership requirement. This provision is explored in detail later in this study and is proposed as a major part of the solution to the access to medicines problem in the SADC region.

This chapter also established that in order to be able to take maximum advantage of the flexibilities, SADC members must legislate for the various forms of intellectual property rights including patents. Apart from the TRIPS flexibilities, the TRIPS Agreement itself does have provisions which SADC members may take advantage of in order to and improve access to medicines. These provisions include but are not limited to abuse of patent rights, limits on new use patents, the use of transitional periods and provisions obliging developed countries to offer technical assistance to developing countries and LDCs. These provisions of the TRIPS Agreement play a complementary role to the TRIPS flexibilities narrated above.

Having outlined, narrated and contextualised the salient contents of the TRIPS flexibilities, albeit briefly, in the SADC region, it is now appropriate to focus on the actual implementation of the flexibilities in selected SADC countries. The next chapter, therefore, deals with the specifics of the actual implementation of the TRIPS flexibilities in the selected SADC members emphasising parallel imports and compulsory licensing.

³¹¹ Paragraph 6 of the August 2003 Decision, now paragraph 3 of Article 31 *bis* of TRIPS.

CHAPTER FIVE

THE ACTUAL USE OF TRIPS FLEXIBILITIES IN SELECT SADC COUNTRIES

5. Introduction

Because the exposition of TRIPS flexibilities in Chapter Four above did not go into a very detailed discussion of the actual implementation of the flexibilities in individual countries' IP policy and legislation, it is appropriate that the curiosity aroused by the narrative in Chapter Four be satiated with a detailed exposition in this chapter.

This chapter focuses on three major themes. Firstly, it outlines the SADC legal policy regime on the implementation of TRIPS flexibilities as provided for in the Treaty and accompanying Protocols. Secondly, the chapter gives an overview picture of the extent of the domestication of TRIPS flexibilities in SADC members' laws and IP Policy instruments. Lastly, the chapter closes with a detailed exposition and analysis of case studies on the use of TRIPS flexibilities in select SADC countries namely, Botswana, Zimbabwe and South Africa and extracts useful lessons for the region from the case studies.

Botswana, a developing middle-income SADC member, recently completed reviewing her patent law in order to take full advantage of TRIPS flexibilities by drafting a new Industrial Property Act and accompanying Regulations. Despite some flaws in the new law which this study will expose, Botswana is included here as an example of best practice in the SADC region.

Zimbabwe, which is a developing country, is chosen as a case study here not for the introduction of the recent IP law reform. On the contrary, its inclusion has been prompted by the fact that it was the first SADC member to issue a government compulsory licence for the manufacture of a combination of patented HIV/AIDS drugs post the Doha Declaration. Zimbabwe's use of TRIPS flexibilities is, therefore, sketched out before focusing on how it made use of a government use order to effectively issue a compulsory licence in 2002.

In retrospect, the access debate to medicines was sparked by South Africa's Medicines and Related Substances Control Amendment Act of 1997, which led to acrimonious litigation in the High Court in Pretoria in 1998 before the matter was settled out of court. Using the 1998

pharmaceutical dispute as a point of departure, the South African case study first outlines South Africa's use of TRIPS flexibilities before briefly discussing its use of competition law to access medicines. Additionally, because South Africa recently published a Draft IP Policy,¹ the salient aspects of the Draft IP Policy are also briefly discussed.

From the case studies, the chapter distils thematic lessons for other SADC member states and anticipates the future direction of regional SADC IP law reform aimed at improving access to medicines. It is hoped that the thematic lessons will complement those to be extracted from other developing country jurisdictions, such as India, Thailand and Kenya, discussed later in Chapter Six below.

5.1 The Use of TRIPS Flexibilities: Brief Overview of Pertinent SADC Instruments

In brief, the Southern African Development Community (SADC) was preceded by the Southern African Development Coordination Conference (SADCC) formed in Lusaka, Zambia on 1 April 1980. This came after the adoption of the Lusaka Declaration² by nine founding member states.³

The Declaration and Treaty of the SADC, which has replaced the Coordinating conference was signed at the summit of the heads of state or government on July 17, 1992, in Windhoek, Namibia.⁴ SADC was transformed “to promote sustainable and equitable economic growth and socioeconomic development”.⁵ A major aspect of SADC's socioeconomic agenda has been health and health-related issues, especially in light of the high disease burden imposed by the

¹ The public health provisions of the Policy have had a chilling effect on multinational pharmaceutical companies which were recently reported in the South African media as having gone on a spirited campaign against the implementation of the policy. See specifically *Mail & Guardian*, January 17 to 23 2014, “This is Genocide: Health Minister outraged by US-Funded big pharma conspiracy to Combat SA's new plan to make drugs cheaper” at 2-3.

² The declaration was titled “Southern Africa: Towards Economic liberation”. See African Union “SADC Profile” at <http://www.au.int/en/recs/sadc> (last visited 19/11/2013) for a full text of the Lusaka Declaration.

³ *The Official SADC Trade Industry and Investment Review* (1997), Gaborone: Southern African Marketing Company (Pty) Ltd. The nine founding members were Angola, Botswana, Lesotho, Malawi, Mozambique, Swaziland, Tanzania, Zambia and Zimbabwe.

⁴ Current member states of the SADC are Angola, Malawi, Namibia, Mauritius, Botswana, Lesotho, South Africa, Seychelles, Democratic Republic of Congo, Madagascar (currently suspended for political reasons), Tanzania, Swaziland, Zambia and Zimbabwe. Previously, each member state had the responsibility to coordinate a sector or sectors on behalf of others. Angola coordinated energy, Botswana livestock production and animal disease control, Lesotho environment and land management, Malawi forestry and wildlife, Mauritius tourism, Mozambique transport and communications, Namibia marine fisheries and resources, South Africa finance and investment, Swaziland human resources development, Tanzania industry and trade, Zambia mining and Zimbabwe food, agriculture and natural resources.

⁵ Musungu SF “Pharmaceutical Patents, TRIPS Flexibilities and Access to Medicines in Southern Africa Development Community (SADC)” (2012) *Report for a SADC Member States Consultation* at 4.

high prevalence of both communicable diseases such as HIV/AIDS, tuberculosis and malaria and non-communicable diseases such as diabetes, hypertension and cancer.⁶

The most important instruments in the SADC context of access to medicines are the SADC Protocol on Health,⁷ complemented by the Implementation Plan for the SADC Protocol on Health,⁸ SADC Pharmaceutical Business Plan⁹ and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.¹⁰ The above instruments are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.¹¹ The health programme has been developed taking into account global and regional health declaration and targets.¹²

The most basic instrument relating to health matters in the SADC region is the Health Sector Policy Framework Document (Policy Framework Document), developed by SADC Health Ministers in Grand Bie, Mauritius.¹³ In terms of the policy framework, regional cooperation is crucial for addressing health problems of the region.¹⁴ One of the main objectives of the policy relevant to this study was to “harmonise legislation and practice regarding pharmaceuticals, including their registration, procurement, and quality assurance”.¹⁵ With specific reference to pharmaceuticals, the policy identified the following issues as crucial: maximizing the production capacity of local and regional firms in producing affordable generic essential drugs; promoting

⁶ Executive summary of the Implementation Plan for the SADC Protocol on Health at 3.

⁷ SADC Protocol on Health (1999), signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

⁸ The Implementation Plan provides an overall framework for effecting the provisions of the SADC Protocol on Health and is available at

http://www.sadc.int/index.php?cID=1&bID=1283&arHandle=Sidebar&ccm_token=1383736029:41bfb778708ee17dc30b95e83826bc93&btask=pass thru&method=signmeup (last visited 06/11/2013).

⁹ SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat on 27 June 2007.

¹⁰ Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, published by the SADC Secretariat in September 2012.

¹¹ See executive summary of the SADC Pharmaceutical Business Plan para 2 at 3.

¹² Ibid.

¹³ The policy document was approved by the SADC Council of Ministers in September 2000 and published by the SADC Health Sector Coordinating Unit, then administered by the Republic of South Africa, which provided the Secretariat to coordinate activities.

¹⁴ Policy Framework Document at 4.

¹⁵ Ibid at 5. This is likely to have led to the adoption of the Strategy on Pooled Procurement of Essential medicines.

joint procurement of therapeutically beneficial medicines and responding to pharmaceutical needs of regional health programmes.¹⁶

The main objectives,¹⁷ priorities,¹⁸ strategies¹⁹ and indicators of success²⁰ of the Policy Framework Document are echoed in the SADC Protocol on Health, Pharmaceutical Business Plan and the strategy on Pooled Procurement.²¹

The SADC Protocol on Health²² may be regarded as the first SADC health instrument to directly refer to TRIPS flexibilities in the context of health matters because it enjoins member states to adopt policies and implement measures within the Community for the protection of intellectual property rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.²³ Pharmaceuticals are very crucial in terms of the Health Protocol and are dealt with in a separate Article.²⁴ The Protocol calls on state parties to cooperate and help each other in registering pharmaceuticals,²⁵ distributing affordable essential drugs,²⁶ promoting the rational use of drugs,²⁷ quality assuring the supply and conveyance of vaccines²⁸ and researching and documenting traditional medicine and its utilization.²⁹

The adoption of policies and measures for the protection of intellectual property rights in line with the TRIPS Agreement is further repeated in the SADC Pharmaceutical Business Plan of 2007.³⁰ In its situation analysis of pharmaceuticals in the SADC region, the Pharmaceutical Business Plan acknowledges that all countries in SADC are members of the WTO, and this makes them automatic signatories to the TRIPS Agreement.³¹ Secondly, the Pharmaceutical

¹⁶ Policy Framework Document at 98.

¹⁷ Ibid at 98.

¹⁸ Ibid.

¹⁹ Ibid at 99.

²⁰ Ibid.

²¹ See the paragraphs following immediately below.

²² SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

²³ Article 24 of the SADC Protocol on Trade, 1996.

²⁴ See generally, Article 29 of the SADC Protocol on Health.

²⁵ SADC Protocol on Health, Article 29(a).

²⁶ Ibid at Article 29 (b).

²⁷ Article 29(c).

²⁸ Article 29(d).

²⁹ Article 29(e).

³⁰ The Plan covers the period 2007 – 2013.

³¹ See para 2.1 subparagraph vi of the Pharmaceutical Business Plan. This statement is inaccurate because Seychelles is still in accession talks with the WTO hence it is not yet a member of the WTO.

Business Plan cites “outdated medicine laws and intellectual property laws which are not TRIPS compliant”³² as a major weakness that cuts across most SADC countries. Citing prior use of TRIPS flexibilities in favour of access to medicines in Zambia, Zimbabwe and Mozambique, the Pharmaceutical Business Plan encourages SADC members to take full advantage of the flexibilities including the opportunity presented by the August 2003 paragraph 6 Decision which took the form of a waiver.³³

Finally, the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities, taking its cue from the Pharmaceutical Business Plan, restates the important step towards the achievement of the objective of improving “sustainable availability and access to affordable, quality, safe, efficacious essential medicines”.³⁴

The Pooled Procurement Strategy argues that there are positives in adopting a regional approach to the procurement of pharmaceuticals including the application of ‘good practices’ in the pharmaceutical procurement and supply management systems.³⁵ One of the often cited advantages of pooled procurement, also called joint procurement or procurement cooperation,³⁶ is that it can result in considerable savings made through information and work sharing by procurement agencies in member States.³⁷

Therefore, the Strategy on Pooled Procurement will prioritize the movement of essential medicines and health commodities in the region by bringing together issues of trade (such as customs procedures and tariffs) relevant legislation, procurement, finance and investment in the pharmaceutical sector.³⁸ While the Pharmaceutical Business Plan is about harmonization of pharmaceutical regulation and law reform in sympathy with TRIPS, the Strategy on Pooled Procurement targets a seamless movement of essential medicines within SADC. The Strategy will in all likelihood enhance economies of scale and enable SADC members to consider and

³² Para 2.2 (i) of the SADC Pharmaceutical Business Plan.

³³ See para 2.3 (vi).

³⁴ See para 1 of the executive summary of the SADC Strategy on Pooled Procurement of Essential Medicines and Health Commodities at v. This objective was first highlighted in the SADC Pharmaceutical Business Plan in 2007.

³⁵ Ibid para 3.

³⁶ Pooled procurement (or joint procurement or procurement cooperation) is defined as ‘the overarching term for procurement where part of all of the procurement process of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or a third party procurement entity’ (see “Definition of terms”) in the Pooled Procurement Strategy document viii.

³⁷ See ‘Executive Summary’ of the Pooled Procurement Strategy para 3 v.

³⁸ SADC Strategy on Pooled Procurement at 2.

possibly establish a regional manufacturing plant within the region as permitted by the August 2003 waiver.

After rendering an expository account, albeit briefly, of the SADC legal and policy instruments aimed at enhancing access to medicines in the region, it is now appropriate to turn to an exposition of individual countries' patent laws and how they deal with pharmaceutical patents.

5.2 Availability of Patents for Pharmaceuticals and New use Patents in SADC

In this specific context, there are two issues to take note of. The first one is that all SADC members have provisions in their laws allowing for the granting of pharmaceutical patents.³⁹ A sizable number of SADC members allow patents for new uses of known medicines,⁴⁰ mostly through legislation that allows for the granting of patents generally without express reference to the prohibition of new uses of known substances. Only three countries, namely, Malawi,⁴¹ Namibia⁴² and Zambia,⁴³ have provisions in their relevant legislation specifically prohibiting the patenting of new use forms of substances in the pharmaceutical context.⁴⁴

The second issue is that while more than 50% of the SADC members are LDCs, which are not obliged to comply with TRIPS requirements for the patenting of pharmaceuticals, virtually all of the SADC LDCs permit pharmaceutical patents.⁴⁵ The sad reality here is that SADC LDCs have not taken advantage of the opportunity provided to them by the extension of the transition period given to them by the TRIPS Council.⁴⁶

The situation narrated in the two foregoing paragraphs is summarised in the tabular form below.

³⁹ This may be by virtue of specific provisions in the pertinent patents legislation or membership of the Patent Cooperation Treaty and the ARIPO Harare Protocol.

⁴⁰ Musungu above note 4 at 8.

⁴¹ Section 18 of Malawi's Patents Act, Chapter 49:02 excludes the patenting of inventions 'capable of being used as food or medicine' which are 'a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients'.

⁴² Sections 17 (1) (j) – (k) and 17 (2) of the Industrial Property Act of 2012 exclude the patenting of new uses of patents.

⁴³ The Zambian Patents Act, last amended in 1987, generally does not exclude new uses except in cases where the invention is capable of being used as food or medicine in the similar prohibitory context as provided for in Malawian law [see section 18(1)(c) of the Zambian Patents Act].

⁴⁴ Musungu above note 4 at 8.

⁴⁵ Ibid.

⁴⁶ The pertinent decision of the TRIPS Council was passed on 27 June 2002 as contained in WTO document IP/C/25.

5.2.1 Summary of SADC IP Laws and Pharmaceutical patents Protection

	Country	Domestic Legislation/s	Patents available for Pharmaceutical Products?	Exclusion of new use/second use Patents	Pre and post-grant Patent Opposition?
1.	Angola*	Industrial Property Law No.3/92 of February 28, 1992	No	No	No
2.	Botswana	Industrial Property Act no.8 of 2010	Yes	No specific exclusion. However due to ARIPO membership, Botswana may grant patents for such use.	Yes, in sections 21 – 22 of the Industrial Property Act 2010.
3.	Democratic Republic of Congo*	Law No. 82-01 of 1982	Yes	Yes- inventions relating to medicine will only be patented if the subject matter is a product, substance or compound presented for the first time as constituting a medicine.	No
4.	Lesotho*	The Industrial Property Order (IPO), as amended in 1997	Yes	No. But membership in ARIPO implies that Lesotho grants	No

* Denotes Least Developing Country (LDC) status with no current legal obligation to grant pharmaceutical patents until 2016; and other forms of IP, not until 2021.

				patents for such use.	
5.	Madagascar *	Ordonnance No. 89-019 instituant un regime pour la protection de la propriete industrielle en Republique democratique de Madagascar, de juillet 1989 (Titre I) (Art 3 a 54) (JO D' aout 1989)	Yes-after 1996	No	No
6.	Malawi*	Patents Act, 1992, Draft IP Policy currently under consideration	Yes	Yes – but Inventions ‘capable of being used as food or medicine’ which are ‘a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients’ are excluded on a discretionary basis.	Yes for pre-grant opposition (see s 22) and no for post-grant opposition
7.	Mauritius	The Patents, Industrial Designs, and Trademark Act No. 25	Yes	No	No

		of 2002			
8.	Mozambique*	Industrial Property Code: Decree No.4/2006	Yes	No	No
9.	Namibia	Patents, Designs, Trade Marks and Copyright Act 9 of 1916, as amended in South in April 1978 (only the portions of this Act relating to patents and designs remain in force in Namibia).	Yes	No	No
10.	Seychelles	Patents Act Chapter 156 of 1991	Yes	No	Pre-grant opposition (see s11 of Act) but no for post-grant opposition.
11.	South Africa	Patents Act of 1978 as variously amended in 1997, 2002 and 2005; the Medicines and Related Substances Control Act as amended, Draft IP Policy published in Sept. 2013 currently	Yes	No	No

		under consideration			
12.	Swaziland	Patent, Utility Models and Industrial Designs Act No.6 of 1997	Yes	No	No
13.	Tanzania*(excluding Zanzibar, with a separate Patent Law)	Patent Act 1987 as amended by Acts No.s 13 and 18 of 1991	Yes	No	No
14	Zambia*	Patents Act, last amended in 1987, draft Patents Bill passed in 2012	Yes	Generally no exclusion. However inventions which are 'capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients' are excluded from patentability.	No
15	Zimbabwe	Patents Act, 1978 as last amended in 2002	Yes	Generally no exclusion. However, where an application claims as an invention a substance	Section 17 provides for pre-grant opposition while post-grant opposition is not provided for.

				capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients or that it claims as an invention a process producing such a substance by mere admixture, a patent for such will not be allowed [s32 (a) read together with s13 (1) (c) of the Patents Act].	
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Source: Adapted from Musungu S.F (2007:16 – 20) and updated by the researcher.

5.3 An Overview of the use of TRIPS Flexibilities in SADC Member States' Laws

Preliminary Remarks

All SADC members, except Seychelles, are members of the WTO and subject to available exceptions, will have to comply with the provisions of the TRIPS Agreement.⁴⁷ In addition to TRIPS, many SADC members are also parties to other regional and international IP treaties such as those administered under the auspices of the World Intellectual Property Organization (WIPO).⁴⁸ Since the adoptions of TRIPS in 1994, many SADC countries have reviewed their IP laws or updated them in order to be TRIPS compliant.⁴⁹

5.3.1 The actual Use of Selected TRIPS Flexibilities in SADC Members States

In the context of access to medicines post the Doha Declaration, a number of SADC countries have taken various efforts to domesticate TRIPS flexibilities in the context of access to medicines.⁵⁰ The most common flexibilities that have featured in the SADC IP legislative reform agenda have been parallel imports; redefining patentable subject matter; exceptions to patents based on research and experimental use; regulatory (bolar) exceptions; compulsory licences; government use of patents; and limitations on test data.⁵¹

On the issue of patentable subject matter,⁵² it has been previously stated that only three countries, namely, Malawi, Namibia and Zambia have provisions in their relevant legislations specifically prohibiting the patenting of new use forms of substances in the pharmaceutical context.⁵³

Since patents may only be granted for inventions that are novel and involve an inventive step and are capable of industrial application,⁵⁴ the impression thus created is that new uses of known substances are unlikely to be patentable. Additionally, the three criteria are not defined, leaving SADC members with ample legal and policy space to interpret their meanings. Member states

⁴⁷ Notable exceptions will be those relating to exemptions from pharmaceutical patents for LDCs until 2016 and in all other fields, until 2021.

⁴⁸ These would include the Paris Convention for the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty (PCT) as well as the Harare Protocol on Patents and Designs (Harare Protocol) under ARIPO.

⁴⁹ For example, South Africa purported to do this through the Patents Amendment Act 58 of 2002 while Zimbabwe introduced amendments in the form of the Patents Amendment Act 9 of 2002.

⁵⁰ Musungu above note 4 at 6.

⁵¹ See Musungu above at 6 – 8.

⁵² The nature of patentable subject matter is clearly spelt out in Article 27 of TRIPS.

⁵³ See 5.2 above.

⁵⁴ Article 27 of TRIPS.

can then interpret the meanings of the three criteria in such a manner that it will not be easy to grant weak patents. This will make more medicines to be available in generic form in a competitive market, and this is likely to have a positive impact on prices by lowering them and improving access to medicines. Many SADC member states' IP laws are, therefore, inadequate in the specific regard because they promote ever greening of pharmaceutical patents.⁵⁵ Ever greening does not augur well for access to medicines and SADC members are urged to amend their laws to signal their non-tolerance of new-use patents.

Parallel importation will enable SADC members to shop around for cheaper drugs in the region and beyond. In terms of the TRIPS Agreement issues relating to parallel imports may be addressed exclusively by the member in the context of the exhaustion of rights.⁵⁶ Exhaustion of rights refers to the point at which the IP right holder “loses legal control over a protected [sic] product by virtue of selling or otherwise releasing it onto the channels of commerce”.⁵⁷ In the context of access to medicines, using parallel importation allows procurement agencies and third party importers to source medicines from other countries where the prices are lower than in the SADC member's domestic market.⁵⁸

With reference to SADC members' IP laws, Angola, the Democratic Republic of Congo, Malawi, Swaziland and Zambia have no explicit provisions on parallel imports. The implication is that the specified countries will not be able to take advantage of the pertinent flexibility permitting parallel imports in order to procure cheaper drugs after comparative shopping. Botswana,⁵⁹ Madagascar,⁶⁰ Mauritius,⁶¹ Mozambique,⁶² Namibia,⁶³ South Africa,⁶⁴ Tanzania⁶⁵

⁵⁵ At least South Africa has reacted to this criticism by coming up with a Draft IP Policy that seeks to limit the patentability of new uses of known substances including pharmaceuticals.

⁵⁶ Article 6 of TRIPS.

⁵⁷ Musungu note 4 above at 7

⁵⁸ Ibid. For an exhaustive discussion of the exhaustion doctrine from a different context from access to medicines, see the US topical case of *Bowman v. Monsanto Co. et al* case No. 11-796, argued February 19, 2013 and decided by the Supreme Court of the United States on 13 May 2013, available at http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf (last visited 15/11/2013).

⁵⁹ Section 25 (a) of the Industrial Property Act of 2010.

⁶⁰ Article 30 (2) of Ordonnance No.89-019 of 1989.

⁶¹ Section 21 (4) (a) of the Patents, Industrial Designs, and Trademark Act No. 25 of 2002.

⁶² Article 68 (b) of the Industrial Property Code: Decree No. 4/2006.

⁶³ Section 43 (1) (a) of the Industrial Property Act No.1 of 2012.

⁶⁴ Section 45(2) of the Patents Act 57 of 1978.

⁶⁵ Section 38 (2) of the Patents Act of 1987 as amended in 1991.

and Zimbabwe,⁶⁶ on the other hand, have explicit IP legislative provisions relating to the exhaustion of patent rights.⁶⁷ However, in Madagascar, Mozambique and Tanzania, the exhaustion regime is national, hence it prohibits parallel imports. Such a state of affairs is unfortunate. The other five SADC members (Botswana, Mauritius, Namibia, South Africa⁶⁸ and Zimbabwe) apply an international exhaustion regime for parallel imports. This is a positive development for access to medicines since the domestication of parallel importation provisions will remain a potential tool for use by each country when the need arises.

The TRIPS flexibility based on research and experimental uses of patents is very important for technological transfer and innovation. Under this exception, researchers are allowed to use patented inventions for research in order to test their chemical compositions and understand the underlying structure of the inventions. Patents should not hinder research and the advancement of knowledge. In the pharmaceutical context, this exception may be used by researchers to improve the effectiveness of drugs or produce medical products suited for the local environment. In terms of the relevant TRIPS provision, the research exception can be used to foster both commercial and non-commercial activities.⁶⁹

A number of SADC members have provisions in their laws allowing for the research exception. Botswana,⁷⁰ the DRC,⁷¹ Lesotho,⁷² Madagascar,⁷³ Mauritius,⁷⁴ Mozambique,⁷⁵ Namibia,⁷⁶ Swaziland⁷⁷ and Tanzania⁷⁸ provide for research exception, either directly or indirectly. An example of an indirect provision on research is that obtaining in Madagascar, whose relevant law provides that patent rights will be available only for industrial and commercial purposes.⁷⁹

⁶⁶ Section 24A of the Patents Amendment Act of 1978 as amended in 2002 and 2005.

⁶⁷ It must be noted that the relevant provisions are not specific to pharmaceuticals but apply to inventions in other fields of technology generally.

⁶⁸ South is peculiar in that the Patents Act (section 45) contemplates national exhaustion while on the other hand, the Medicines and Related Substances Control Amendment Act (section 15(c)) provides for an international exhaustion regime.

⁶⁹ See TRIPS Article 30.

⁷⁰ Section 25(c) of the Industrial Property Act 2010.

⁷¹ Article 49 of the Law No. 82-01 of 1982.

⁷² The Industrial Property Order (IPO) as amended in 1997 exempts Acts done for scientific research.

⁷³ Article 30 of Oddonance No. 89-019.

⁷⁴ Section 21(4) (d) of the Patents, Industrial Designs, and Trademarks Act No. 25 of 2002.

⁷⁵ Article 68(a) of the Industrial Property Code Decree No.4/2006.

⁷⁶ Sections 43(1) (c) and 43(1) (d) of the Industrial Property Act No.1 of 2012.

⁷⁷ The law provides that patents rights shall only extend to acts done for Industrial or commercial purposes.

⁷⁸ Section 62 of the Patents Act 1987.

⁷⁹ See note 70 above.

Mauritius' laws, on the other hand, directly provide for the research exception by explicitly stating that acts done for scientific research and experimental purposes qualify as an exception to patents.⁸⁰

Closely linked to research and experimentation exception is the regulatory early working (bolar) exception which some of the SADC members seem to be much aware of and have incorporated in their respective domestic laws. As previously explained in Chapter Four above, this exception allows generic companies to make use of patented inventions whose terms are about to come to an end so that generic drugs may be introduced as soon as the patent lapses upon expiry of the 20 year period. The existence of this exception, which allows members to permit generic medicine manufacturers to undertake and complete the task of obtaining regulatory approval from national regulatory authorities for generic versions before original patents expire, was confirmed by the WTO in a panel ruling pitting Canada against the European Union.⁸¹

Despite the importance of the early working exception in the pharmaceutical sector, only three SADC members have domesticated the exception in their laws. The specific members are Botswana,⁸² Namibia⁸³ and Zimbabwe.⁸⁴ Other SADC members do not have clear provisions on the exception and do not bother mentioning it at all in their pertinent laws.

Compulsory licences and government's use of exceptions are important tools which may be employed to access medicines and they have a lot of potential to be effectively used by SADC members. WTO rules are very liberal as they do not limit the grounds for the granting of compulsory licences, neither are there limitations on the scope of diseases.⁸⁵ Additionally, there is no requirement that compulsory licences be limited to cases involving health and pharmaceutical problems only.⁸⁶

⁸⁰ See note 71 above.

⁸¹ See *Panel Report, Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R 17 March 2000, available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited 04/11/2013).

⁸² Section 25(h) of the Industrial Property Act 2010.

⁸³ Section 43(2) of the Industrial Property Act No.1 of 2012.

⁸⁴ Section of the Patents Amendment Act of 1978 amended in 2002.

⁸⁵ Love J “Recent examples of the Use of Compulsory Licenses on Patents” (2007) 2 *Knowledge Ecology International* at 2.

⁸⁶ *Ibid.*

Generally speaking, a compulsory licence will be resorted to if the patentee unreasonably refuses to grant the applicant a voluntary licence.⁸⁷ Additionally, the issuance of a compulsory licence must be accompanied by the payment of adequate compensation.⁸⁸ However, in cases of public emergency or extreme urgency, the obligation to negotiate with the patent holder first may be waived, for obvious reasons.⁸⁹

A Compulsory licence may also be issued to remedy anti-competitive conduct on the part of the patentee.⁹⁰ The TRIPS Agreement also sanctions government non-commercial use of inventions in certain circumstances.⁹¹

All SADC members provide for compulsory licences and government use in their legislative provisions. Therefore, as legal access tools to medicines, compulsory licensing and government use are the most widely available in SADC members' laws. However, the big question as to what extent SADC members have used the two flexibilities to improve access to medicines for their citizens remains unanswered. The picture is not very positive because all other members with the exception of Zimbabwe, Mozambique and Zambia, which have issued either a compulsory licence or a government use order, have not put the flexibilities to the practical test of actual use.⁹²

Compulsory licences must also be viewed in the context of the 30th of August 2003 Decision and Article 31 *bis* amendment to the TRIPS Agreement. The Decision and Article 31 *bis* have key elements (about six of them) that members may incorporate into national legislation.⁹³ To incorporate the relevant laws, SADC members will have to amend their specific laws on

⁸⁷ TRIPS Article 31(a).

⁸⁸ TRIPS Article 31(h).

⁸⁹ The assumption is that in a situation of emergency or extreme urgency, there is likely to be no time to negotiate first, the negotiation may be attended to after the emergency has been dealt with.

⁹⁰ Article 31 (k) of TRIPS.

⁹¹ See TRIPS Article 31 introductory part and 31 (b).

⁹² See para 2.3 (iv) of the *SADC Pharmaceutical Business Plan 2007-2013* at 12.

⁹³ The important elements would include definitions; grounds for issuing compulsory licenses; modification of compulsory licensing provisions implementing Article 31 (f) of TRIPS; modification of compulsory licensing provisions implementing Article 31 (h) of TRIPS; rules for re-export of products imported under Article 31 *bis*; and provisions on notifications (Musungu note 4 above at 9).

compulsory licences, and to date, it is disheartening to report that no single SADC member except Botswana⁹⁴ has taken the initiative to incorporate the pertinent provisions.

The above observation is important in this study because one of the study's recommendations⁹⁵ is that SADC members must take advantage of economies of scale and consider regional production of generic drugs in light of the permissible nature of Article 31 *bis* towards regional production and pooled procurement. However, to take advantage of Article 31 *bis*, members must ratify the amendment protocol⁹⁶ and domesticate it in their laws. Taking advantage of Article 31 *bis* is very relevant to the objective of facilitating pharmaceutical trade in the SADC region including pooled procurement,⁹⁷ and member states are urged to domesticate the provision in their relevant laws as this can only be in their best interests.

Finally, with specific reference to test data, the TRIPS Agreement allows members to protect data relating to new chemical processes from unfair commercial use.⁹⁸ If there is a blanket protection of test data against all forms of use including non-commercial use, this will in all likelihood frustrate access to medicines. The situation obtaining in the SADC region relating to test data is unclear. Mauritius, for example, has a data exclusivity approach (a pejorative approach from an access to medicines perspective), which prevents the regulatory authority from using test data for licensing generic drugs for at least five years subject to the Minister's discretion.⁹⁹ South Africa, on the other hand, has general confidentiality provisions in the common law, Medicines and Related Substances Control Act¹⁰⁰ and the Fertilizers, Farm feeds, Agricultural Remedies and Stock Remedies Act.¹⁰¹ SADC members are urged to legislate for data protection rather than data exclusivity as is the case with Mauritius.

From the above exposition and discussion, it is clear that most SADC countries provide for pharmaceutical patents even though the majority of them, characterized as LDCs, are not obliged

⁹⁴ Botswana has in fact domesticated Article 31 *bis* in Article 31 (3) of the Industrial Property Act of 2010 by providing as follows:

"The exploitation of the patented invention under subsection (1) shall be for the supply of the domestic market in Botswana only, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement (my emphasis) applies".

⁹⁵ See Chapter Seven below.

⁹⁶ Thus far, only Mauritius and Zambia have ratified the amendment Protocol but are yet to domesticate it to bring the TRIPS amendment into effect.

⁹⁷ Musungu note 4 above at 9.

⁹⁸ Article 39.3 of TRIPS.

⁹⁹ See section 9 of the Protection Against Unfair Practices Act 2002.

¹⁰⁰ Act 101 of 1965.

¹⁰¹ Act 36 of 1947.

to do so in terms of TRIPS. The most widely domestically legislated TRIPS flexibilities are compulsory licences and government use. However, the two flexibilities have had little practical application in individual SADC countries due to reasons, such as lack of political will (non-IP reasons) than IP ones.

Some SADC members have good laws incorporating the flexibilities while others have incorporated TRIPS provisions to an insufficient extent. Some members have made use of TRIPS flexibilities in favour of access to medicines in a manner that should be brought to the attention of other members as a lesson on how to take advantage of the specific flexibilities.

In the following sections of this chapter, I isolate three SADC members and delve into specific aspects of their relevant legislation in order to highlight useful lessons other members may learn from the experience of the members under focus. Botswana is chosen as a model on legislative reform which is sympathetic to access to medicines while Zimbabwe provides a useful example of how to effectively use government use orders to boost local pharmaceutical manufacturing capacity and earn World Health Organisation (WHO) generic manufacturing facility approval. Finally, the South African example highlights the effective use of compulsory licences in the context of competition law.

5.4 Domesticating TRIPS Flexibilities: The Case of Botswana

In the context of the law of patents, it is important to record that Botswana is a party to the following international/regional agreements: Berne Convention;¹⁰² Harare Protocol (of ARIPO);¹⁰³ Lusaka Agreement (ARIPO);¹⁰⁴ Paris Convention;¹⁰⁵ Patent Cooperation Treaty;¹⁰⁶ and the WTO/TRIPS Agreement.¹⁰⁷

The current Patent law of Botswana is encapsulated in the Industrial Property Act (the Act),¹⁰⁸ which was assented to by the president on 26 April 2010 and came into operation on 31 August

¹⁰² Since 15 April 1998.

¹⁰³ Since 1985.

¹⁰⁴ Since 1985.

¹⁰⁵ Since 15 April 1998.

¹⁰⁶ Since 30 October 2003.

¹⁰⁷ Since 31 May 1995.

¹⁰⁸ Act No.8 of 2010.

2012.¹⁰⁹ The Act as a very recent law is expected to be very compliant with TRIPS and incorporate most of the relevant flexibilities. This, however, is not necessarily the case as the expository account below shows.

The legislation provides for the patentability of *new* inventions involving an *inventive step* and capable of *industrial application*. Further, such inventions may relate to both products and processes.¹¹⁰ The Act differentiates between an invention and a patent in its interpretation section and defines an invention as an idea of an inventor which in practice may be used as a solution to a specified problem.¹¹¹ On the other hand, a patent simply means the document issued to protect the invention under the Act.¹¹² Patents may be granted for 20 years¹¹³ from the date of filing an application.¹¹⁴ The Act provides for general exclusions from patentability such as methods of treatment of the human or animal body, therapeutic equipment and diagnostics.¹¹⁵ Also excluded from patentability are inventions the exploitation of which is necessary to protect public order or morality, including the protection of human or animal health, plant life or to avoid prejudice to the environment.¹¹⁶ New uses of patents are not specifically excluded in the Act and one may, therefore, conclude that the legislation is unfortunately silent on this aspect.

From an access to medicines perspective, the delimitation of patentable subject matter and exclusions does not raise any major concerns; the law is robust enough in the specific regard to prevent the patenting of undeserving patents.

It is noteworthy that the Act provides for pre-grant opposition¹¹⁷ to patents and the examination of patents for technical quality.¹¹⁸ Once a patent application has been published in the patents

¹⁰⁹ See Industrial Property Act (date of commencement) Order 2012, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=277945 (last accessed 06/11/2013).

¹¹⁰ Section 8(1) – 8(2).

¹¹¹ Section 2 of the Act.

¹¹² Ibid.

¹¹³ Section 28(1) of the Act.

¹¹⁴ Section 20 of the Act provides that the filing date is the date of application.

¹¹⁵ Section 8 (1) (a) of the Act. This is based on Article 27 (3) of TRIPS.

¹¹⁶ Section 8 (1) (b) of the Act.

¹¹⁷ See section 21 of the Act

¹¹⁸ See section 22 of the Act.

journal,¹¹⁹ members of the public, including those with the technical know-how of the field to which the patent relates, may oppose that grant of the patent on a number of listed grounds.¹²⁰

On a related positive note for access to medicines, the Registrar of Patents is enjoined to cause a patent to be examined for compliance with the requirements of the Act.¹²¹ If this provision of the Act is read in isolation, one is left with the disappointing impression that the examination contemplated therein relates to formal compliance with the Act. However, a further reading of the Act in the following subsection makes it clear that a formal technical examination, which may be outsourced to persons or institutions (such as universities) appointed by the registrar, is contemplated.¹²² The requirement that the Minister may in certain circumstances through regulations, prescribe the categories of inventions in respect of which an examination shall not cover the requirements of novelty and inventive step is retrogressive. The net effect of this provision is to condone weak patents and introduce ever greening via the back door.

Coming to TRIPS flexibilities that may yield positive results for access to medicines, it is gladly noted that the Industrial Property Act incorporates almost all the important flexibilities.¹²³

On the exhaustion of patent rights and the use of parallel importation, Botswana adopts the international exhaustion of rights regime which allows parallel imports.¹²⁴ Very specifically, the pertinent provision regards acts in respect of articles that have been put on the market in Botswana or abroad by the patentee or another person acting with the patentee's consent as exceptions to rights conferred by a patent.¹²⁵ The implied message here is that Botswana is permitted by its law to import cheap medicines from international and regional markets as long as the product has been placed on such markets by the patentee himself or by someone acting on

¹¹⁹ Section 21 (a) of the Act.

¹²⁰ Section 21 (5) (a) – (c). One of the grounds relevant to access to medicines may be that the invention does not meet the requirements of patentability as specified in the Act.

¹²¹ Section 22(1) of the Act.

¹²² Section 22(2) provides that the Minister may exempt some inventions from enquiries/examinations relating to novelty and inventive step. This creates the impression (correctly so) that examinations will under normal circumstances where Ministerial intervention is not contemplated, cover technical issues relating to novelty and inventive step.

¹²³ As will be elaborated upon in ensuing paragraphs, the Act provides for parallel imports, research exceptions to patentability, early working (bolar exceptions), private non-commercial use of patents, compulsory licenses as some aspects of Article 31 *bis* of TRIPS.

¹²⁴ Section 25 of the Act.

¹²⁵ Section 25(1) (a) of the Act.

behalf of the patentee with his or her permission. In lay terms, the provision allows for comparative shopping which is likely to yield positive access to medicines results for Botswana's poor citizens in need of affordable essential medicines.

Patents may also be used for research purposes¹²⁶ by non-right holders as long as the acts done are for experimental purposes relating to the subject matter of the invention as well as acts done solely for academic, scientific research and educational and teaching purposes.¹²⁷ Acts done for private non-commercial purposes are also allowed as exceptions to the rights conferred.¹²⁸ Private non-commercial players in the context of access to medicines may be civil society organisations, churches, foundations and donors like the Bill and Melinda Gates Foundation or NGOs such as Doctors without Borders. The provision for private non-commercial use as an exception to patent rights is a welcome inclusion and a first for the SADC region.

The bolar and regulatory exceptions are implicated in the provision dealing with acts done in respect of the patented invention for purposes of compliance with regulatory marketing approval procedures for pharmaceutical, veterinary, agrochemical or other products subjected to such procedures.¹²⁹ These procedures are correctly characterized as permissible exceptions to patentability.

Finally, the Act has very extensive provisions on compulsory licences. Broadly speaking, compulsory licences may be issued for: public interest or for competition,¹³⁰ importing patented products in the context of TRIPS Article 31 bis,¹³¹ to remedy a failure to exploit the patent¹³² and to deal with dependent patents.¹³³

Public interest grounds for the issuance of compulsory licences include national security, nutrition, health, development and other vital sectors of the Botswana national economy.¹³⁴ In any of the above instances, the Minister may, without the patentee's consent but after hearing

¹²⁶ Section 25 (1) (c).

¹²⁷ Section 25 (1) (j).

¹²⁸ Section 25 (1) (j).

¹²⁹ Section 25 (f) of the Act.

¹³⁰ See generally, section 31 of the Act.

¹³¹ Section 32 of the Act.

¹³² Section 33 of the Act.

¹³³ Section 34 of the Act.

¹³⁴ Section 31 (1) (a) of the Act.

him/her, authorize a government agency or another person to exploit the patent subject to the payment of adequate remuneration to the patentee.¹³⁵ If the compulsory licence is issued in response to anti-competitive practices,¹³⁶ the determination/calculation of the remuneration will have to take into account the economic value of the exploitation of the patent.¹³⁷ It is also important to take note of the fact that in terms of Botswana's patent law, in cases of national emergency or circumstances of extreme urgency (which is not defined), there is no need for the applicant for a compulsory licence to have requested a voluntary licence on reasonable terms first.¹³⁸

It is very interesting that Botswana has made a modest attempt at domesticating the August 2003 Decision and the waiver thereto, now encapsulated in Article 31 *bis*, which Botswana is yet to ratify. To show that the drafters of the patent law were aware of the existence and importance of Article 31 *bis*, when compulsory licences are issued in the public interest,¹³⁹ the "exploitation of the patented invention....shall be for the supply of the domestic market in Botswana only, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement applies".¹⁴⁰ Additionally, the government of Botswana may issue a compulsory licence to a third party to import patented products such as *pharmaceutical generic drugs* (my emphasis) from any legitimate source without the approval of the patentee for public interest or in situations of a failure to supply the market.¹⁴¹ In this context, the importation of the product shall be solely for the public non-commercial use within Botswana, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement applies.¹⁴² Therefore, the whole section 32 of the Industrial Property Act of Botswana domesticates the provisions of Article 31 *bis* and this should be welcomed by access activists and regarded as a valuable lesson for fellow SADC members.

On a negative note, the major weakness of the Industrial Property Act is the provision dealing with offences and penalties.¹⁴³

¹³⁵ Section 31(1) of the Act.

¹³⁶ Section 31(1) (b).

¹³⁷ Section 31(2) of the Act.

¹³⁸ Section 31 (10) of the Act.

¹³⁹ Under section 31 (1) (a).

¹⁴⁰ Section 31 (3).

¹⁴¹ Section 32 (1) (a)-(b).

¹⁴² Article 32 (2).

¹⁴³ Generally provided for in section 134 of the Act.

The Act proscribes acts of intentionally or wilfully performing any act which constitutes an infringement as defined in the Act.¹⁴⁴ Additionally, any person who “commits an offence shall be sentenced, on conviction, to a fine of not less than P2 000 but not more than P5 000, or to imprisonment for a term of not less than six months but not more than two years, or to both”.¹⁴⁵ To add to the chilling effect of the provision, if a person commits an offense or unlawful conduct for which no penalty has been specified, that person shall be sentenced to a fine of between P2 000 and P5 000, or to imprisonment for at least six months but not more than two years, or to both.¹⁴⁶

Criminalizing patent infringement, whether wilful or not, does not augur well for access to medicines. The criminalization will in all likelihood have a chilling effect which will stifle and kill the spirit of research into new drugs based on existing patented ones (generics). The provision criminalizing patent infringement is TRIPS-plus and uncommon and discourages innovation and flexible procurement of drugs due to the fear of criminal law. The provision is, however, sanctioned by the TRIPS agreement in cases of ‘wilful infringement on a commercial scale’¹⁴⁷ and therefore, the criminalization of patent infringement does have a textual basis in the TRIPS Agreement. While the legislation provides for exceptions to patent rights based on research and regulatory (bolar) exceptions as outlined elsewhere in this chapter, these provisions will be rendered useless by the penalty provisions criminalizing patent infringement. If the Botswana parliament is considering amending the Industrial Property Act, section 134 is a proper candidate for amendment. Section 134 is bad law from an access to medicines perspective and fellow SADC members are discouraged from following Botswana in this specific respect.

5.4.1 What Can Other SADC Members Learn From Botswana?

Fellow SADC members can learn from both the good and bad aspects of Botswana’s Industrial Property Act and then position themselves accordingly.

¹⁴⁴ Section 134 (6). This will cover infringing the rights conferred by patents as outlined in section 24 subject to exceptions to the rights conferred as outlined in section 25. Additionally, with reference to other IP forms, the penalty provisions will cover the rights of an owner of a registered design (section 53) and acts that amount to infringement of such rights (section 55); and the rights of owners of registered geographical indications and their infringement [section 111(3)].

¹⁴⁵ Section 134 (6) of the Act.

¹⁴⁶ Section 134 (7) of the Act.

¹⁴⁷ Article 61 of TRIPS.

On a positive note, Botswana's Industrial Property Act and the Regulations¹⁴⁸ domesticate almost all TRIPS flexibilities that matter. The specific flexibilities are compulsory licences, the adoption of an international exhaustion regime that permits parallel imports, provisions allowing pre-and post-grant opposition to patents, patent examinations (both formal and technical) and a list of exclusions from patentability such as diagnostics, therapeutic equipment and methods of treatment. Botswana did take the initiative of evaluating its laws in light of the TRIPS flexibilities at a workshop which was held in Gaborone from 25 -27 March 2013 and compiled a list of the flexibilities¹⁴⁹ together with an honest evaluation of the country's prospects.

The recommendations from the workshop are reiterated here as lessons for other SADC countries due to their relevance and practical nature.

According to the government of Botswana, the new law (encapsulated in the Act and the Regulations) is good in many respects.¹⁵⁰ The provisions on exclusions from patentability, the patentability criteria, patent opposition, compulsory licences, and the use of competition law border measures and the criminalization of patent infringement are cited and self-critiqued.¹⁵¹

The exclusions from patentability¹⁵² provisions of Botswana's Industrial Property Act are based on the text of the TRIPS Agreement,¹⁵³ which excludes new uses of known substances.¹⁵⁴ However, the Industrial Property Act is not explicit enough to prevent ever greening.¹⁵⁵ The Registrar of patents will, therefore, have to develop practical guidelines to ensure that patents are examined when applications for additional patents on the same subject matter are submitted.¹⁵⁶ This will limit ever greening. It has been reported elsewhere that many SADC members provide for exclusions from patentability in their laws. SADC members can, therefore, learn from Botswana's omission by including guidelines that ensure the exclusion of evergreen patents.

¹⁴⁸ The promulgation of the Industrial Property Act Regulations 2012 was done through Statutory Instrument 70 of 2012.

¹⁴⁹ See Republic of Botswana "The Implementation of Trade Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities in the National Intellectual Property Legislation for Strengthening Access to Medicines in Botswana" (2013) *UNDP-SARPAM-Botswana Government Workshop Publication* at 10-11.

¹⁵⁰ Government of Botswana "The Implementation of TRIPS Flexibilities in National IP Legislation for Strengthening access to Medicines in Botswana" (2013) *Action Brief* at 1-32.

¹⁵¹ Ibid.

¹⁵² See section 9 of the Industrial Property Act.

¹⁵³ Specifically Articles 27 (2) and 27 (3) of TRIPS.

¹⁵⁴ Government of Botswana above at 13.

¹⁵⁵ Ibid.

¹⁵⁶ Ibid.

The second lesson that SADC members can learn from Botswana's experience and self-evaluation is on the subject of patentability criteria and what amounts to a patent.¹⁵⁷ In its self-evaluation, Botswana observes quite correctly that while her laws provide for acceptable patentability criteria,¹⁵⁸ it may not be possible to examine some patents for compliance with the requirements for patentability because of the Ministerial exclusion,¹⁵⁹ which has been characterized earlier as militating against access to medicines.¹⁶⁰ Once again, fellow SADC members may learn from Botswana that the exclusion of certain patents from fulfilling technical requirements relating to novelty and an inventive step through a Ministerial decree is undesirable and counterproductive for strict patentability criteria for patent examination. Such an approach does not limit frivolous patents and ever greening, hence it should be avoided.¹⁶¹ While SADC members are encouraged to introduce patent examinations in their legal systems, technical and financial capacitation of the office of the patent examiner will be required.¹⁶² This again is an important lesson for fellow SADC members intending to reform their patent laws in that specific regard.

While Botswana's law provides for pre-and post-grant patent opposition,¹⁶³ the Regulations do not have provisions detailing the procedure to be adopted when these forms of opposition are to be used.¹⁶⁴ As matters stand, the law on this aspect (pre-and post-grant opposition) is a paper tiger and will not be possible to enforce in the absence of guiding Regulations. Pre- and post-grant patent opposition measures should be done in a fast, accessible and cost-efficient manner¹⁶⁵ in order to maximize on the use of TRIPS flexibilities for the benefit of access to medicines. The lesson for fellow SADC members here is that they should not just incorporate TRIPS flexibilities in their legislations for incorporation's sake, rather, the law must be given 'the teeth with which to bite' in a practical context so that statute books are not populated with paper laws. Some SADC members, especially LDCs, have passed IP laws prematurely and the

¹⁵⁷ For clarity on what amounts to a patent and the applicable patentability criteria, see Articles 1 and 27.1 of the TRIPS Agreement.

¹⁵⁸ See section 8 of the Industrial Property Act.

¹⁵⁹ Section 22 (2) of the Act.

¹⁶⁰ See 5.4 above at sixth paragraph.

¹⁶¹ Government of Botswana above at 13.

¹⁶² Republic of Botswana above at 11.

¹⁶³ See generally section 22 of the Act.

¹⁶⁴ Government of Botswana at 13.

¹⁶⁵ Ibid at 14.

laws have tied their hands when it comes to accessing cheap generics. This premature promulgation of the law may be due to pressure imposed by international organisations like WIPO, trading partners, the donor community and even ill-informed knee jerk reactions to international developments.¹⁶⁶ SADC members should resist these forms of pressure and legislate in the interest of the people rather than other stakeholders such as those mentioned above. This takes us to the next point which is closely related to this one and is identified by Botswana's evaluation report as requiring immediate attention.

The self-evaluation report notes with concern that while one of the major recommendations of the workshop¹⁶⁷ was that the country should not negotiate TRIPS flexibilities away in free trade agreement negotiations, it is quite ironic, if not paradoxical that Botswana is a party to the European Free Trade Area (EFTA) negotiations in her capacity as a member of the Southern African Customs Union (SACU).¹⁶⁸ The Agreement commits SACU members and EFTA countries to continue trade liberalization including harmonization in IP matters.¹⁶⁹ If Botswana were to sign the EFTA-SACU agreement, then this would reverse the gains made under the Industrial Property Act because EFTA countries apply IPR laws with TRIPS-plus commitments.¹⁷⁰ This matter should be brought to the attention of fellow SADC members as a lesson on how not to negotiate in Free Trade Agreements. South Africa, like Botswana, has made its position clear and will in future not sign TRIPS-plus Free Trade Agreements;¹⁷¹ the country has taken this commitment further by pledging to discourage other African countries from signing such agreements.¹⁷²

Compulsory licences and government use orders are well provided for in the Industrial Property Act¹⁷³ and this should be lauded as a positive development. The grounds for the granting of compulsory licences are broad enough to capture almost all the eventualities, such as public

¹⁶⁶ A classic example of this is the fact that many SADC members have rushed to negotiate and sign Economic Partnership Agreements with the United States and the European Communities sometimes to the detriment of their citizens merely because it is the trendy thing to do.

¹⁶⁷ See Republic of Botswana above at 4.

¹⁶⁸ Government of Botswana at 19.

¹⁶⁹ Ibid.

¹⁷⁰ Ibid.

¹⁷¹ See Draft National Intellectual Property Policy 2013: Invitation to the Public to comment on the National Policy on Intellectual Property 2013, published in Government Gazette number 36816 on 4 September 2013 at 9.

¹⁷² Ibid.

¹⁷³ See specifically sections 25, 30, 31 and 32 of the Act.

health issues, non-working of patents, anti-competitive behaviour, dependent patents, and abuse of patent rights and situations of national emergency or extreme urgency. Very importantly, the Act makes provision for the granting of compulsory licences in the context of the August 2003 Decision and the waiver, now captured under Article 31 *bis* of the TRIPS Agreement. The expanded grounds for the granting of compulsory licences and the domestication of the provisions of Article 31 *bis* into the Industrial Property Act provide eye-opening lessons for SADC members. SADC members are urged to elaborate on and expand the grounds for the granting of compulsory licences. Very importantly, they are urged to domesticate Article 31 *bis* of TRIPS and accede to it using the formal WTO process.

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

Finally, the TRIPS Agreement provides for the use of competition law by WTO members to remedy anti-competitive practices.¹⁷⁴ In the case study involving South Africa below, this TRIPS flexibility is explored in its proper context.¹⁷⁵ While Botswana's Industrial Property Act provides for compulsory licences to combat abuse of patents,¹⁷⁶ the Competition Act¹⁷⁷ unfortunately creates blanket exclusion against the application of any of its provisions to IPR issues. While this exclusion does not in any way imply that anti-competitive conduct in patents will go unpunished,¹⁷⁸ it is expected that the Competition Act ought to be the primary piece of legislation that can address such issues. Botswana's position is, therefore, clumsy and anomalous and should be remedied through an appropriate amendment of the relevant law.

¹⁷⁴ Articles 8.2, 31(k) and 40 of TRIPS.

¹⁷⁵ See 5.6 below.

¹⁷⁶ Article 31 (1) (b) of the Industrial Property Act.

¹⁷⁷ Botswana Competition Act of 2009.

¹⁷⁸ At least the impugned conduct may be dealt with through section 31 (1) (a) and 31 (11) of the Industrial Property Act.

All SADC member states except the Democratic Republic of Congo, Lesotho, Angola and Mozambique who have competition legislation and policies, are encouraged to learn from Botswana's omission and not exclude competition legislation from applicability in IPR matters.

While the above expository account of Botswana's law highlighted both positive and negative lessons for other SADC members, Botswana's praiseworthy legislation has never been tested practically in an access to medicines context. It is now appropriate to turn our discussion to an examination of how selected TRIPS flexibilities (the use of a government compulsory license in Zimbabwe and competition law in South Africa) were applied in practice in the SADC region.

5.5 Government Issued Compulsory Licenses as an Access Tool: The Case of Zimbabwe

In terms of Zimbabwe's Patents Act (the Patents Act),¹⁷⁹ an invention is defined in a circumlocutory way as follows:

“ ‘invention’ means any new and useful art, whether producing a physical effect or not, or process, machine, manufacture or composition of matter which is not obvious or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.”¹⁸⁰

From the definition above, it is clear that the law allows for both process and product patents and new uses of patented products (...“or any new use and useful improvement thereof...”) and includes *an alleged invention* (my emphasis). While new use patents are not prohibited in terms of the definition, their patentability is qualified by the fact that such new uses must not be obvious and must be capable of application in trade and industry. This qualification is likely to prevent ever greening especially if it is coupled with an examination system.¹⁸¹ Diagnostic, therapeutic and surgical methods for the treatment of humans and animals are excluded from patentability alongside biological processes and plants and animals.¹⁸² Additionally, the Registrar of Patents may refuse certain patents in some circumstances, namely, an alleged invention that: claims something as an invention contrary to well established natural laws,¹⁸³ is not patentable in terms of the exclusions in sections 2A,¹⁸⁴ endangers public order or public safety,¹⁸⁵ encourages

¹⁷⁹ Patents Act 26:03 of 1972, last amended in 2002.

¹⁸⁰ Section 2 (1) of the Patents Act.

¹⁸¹ Section 11 of the Patents Act provides for an examination system.

¹⁸² Section 2A of the Patents Act.

¹⁸³ Section 13 (1) (a) of the Patents Act.

¹⁸⁴ Section 13 (1) (b) of the Patents Act.

¹⁸⁵ Section 31 (a) (b1) (i) of the Patents Act.

offensive, immoral or anti-social behaviour,¹⁸⁶ endangers human, animal or plant life or health¹⁸⁷ or promotes serious prejudice to the environment.¹⁸⁸

From the above exclusions from patentability, the ones that are relevant for access to medicines are those relating to the endangering of human, animal and plant health and those pertaining to section 2A. Very importantly, aside from the definition and exclusions, a patent may be refused if “it claims as an invention a substance capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients...”.¹⁸⁹ This provision is important for access to medicines because although the law allows the patenting of new uses of known substances, such new uses are expressly prohibited if they relate to food or medical products that are mixtures rather than compounds. The prohibition of these mixtures is a very potent tool against evergreen food and medical patents.

A patent, which means letters patent for an invention granted for Zimbabwe under section twenty-one,¹⁹⁰ is granted to an inventor for 20 years from the date of lodgement of the application for a patent¹⁹¹ and is binding against the state and individuals.¹⁹²

The Zimbabwean system provides for the formal examination of patent applications by an examiner¹⁹³ in order to establish compliance with the provisions of the Act¹⁹⁴ and to check if there is congruence between the final specification, the provisional specification and the Patent Cooperation Treaty specification.¹⁹⁵ An examination does not warrant the validity of a patent, hence no legal action thereto may be pursued against the Minister, Registrar or the patent examiner.¹⁹⁶ The provision for an examination system will go a long way towards eliminating weak and evergreen patents and for this reason it favours access to medicines.

¹⁸⁶ Section 31 (a) (b1) (ii) of the Patents Act.

¹⁸⁷ Section 31 (a) (b1) (ii) of the Patents Act.

¹⁸⁸ Section 31 (a) (b1) (iv) of the Patents Act.

¹⁸⁹ Section 13 (1) (c) of the Patents Act.

¹⁹⁰ See section 2(1) of the Patents Act.

¹⁹¹ Section 25 of the Patents Act.

¹⁹² Section 24(1) of the Patents Act.

¹⁹³ Section 11 (1) of the Patents Act.

¹⁹⁴ Section 11 (1) (a).

¹⁹⁵ Section 11 (1) (b).

¹⁹⁶ Section 11 (2) of the Patents Act.

The granting of a patent may be opposed within 3 months of the publication of a complete specification in the patents' journal but before it is accepted in terms of section 16.¹⁹⁷ Any interested person including the state may oppose the granting of a patent and the application for opposition may be submitted to the Registrar who will deal with it after hearing the patentee.¹⁹⁸

There are 14 listed grounds that may be raised to oppose the granting of a patent but not all of them are relevant for access to medicines. The ones I regard as relevant for access to medicines are those relating to inventions that are not useful;¹⁹⁹ inventions that are obvious and involve no inventive step having regard to the state of the art;²⁰⁰ and those brought to the attention of Registrar through an application form containing a material misrepresentation.²⁰¹ Inventions that are not useful or do not involve an inventive step do not qualify as inventions because they do not satisfy the requirements for patentability as delimited in section 2 of the Act. Allowing such inventions would be counterproductive and deceitful. The same goes for inventions that contain a material misrepresentation and claiming the state of the art as an invention would in all likelihood amount to a material misrepresentation.

Zimbabwean patent law, just like its Botswana counterpart incorporates most of the well-known but least used TRIPS flexibilities such as the international exhaustion²⁰² and parallel imports,²⁰³ *bolar*-type exceptions,²⁰⁴ compulsory licences,²⁰⁵ anti-competitive provisions and government use of patents including use during a state of emergency.

Because the intention of this section is to show how Zimbabwe managed to make use of compulsory licences effectively, it is appropriate that compulsory licences in the Zimbabwean context be dealt with separately from all the other flexibilities.

¹⁹⁷ Section 17 of the Patents Act.

¹⁹⁸ Section 17 (1) of the Patents Act.

¹⁹⁹ Section 17 (1) (c).

²⁰⁰ Section 17 (1) (d).

²⁰¹ Section 17 (1) (i).

²⁰² Section 24 (6) of the Patents Act.

²⁰³ Section 24A introduced into the Patents Act by Act 9 of 2002.

²⁰⁴ Section 24B, also introduced into the Patents Act by Act 9 of 2002.

²⁰⁵ Sections 30, 31, 32, 34 and 35 of the Patents Act.

5.5.1 Compulsory Licenses under Zimbabwean Patent Law²⁰⁶

In terms of the relevant Zimbabwean law, compulsory licences are provided for in sections 30-35 of the Patents Act. The various instance that may trigger the application for a compulsory licence may be based on anyone of the following grounds: to deal with dependent patents;²⁰⁷ to curb patent abuse and non-use of patents;²⁰⁸ to deal with inventions relating to food, medicine or other commodities;²⁰⁹ to deal with the use of patented inventions for the service of the state;²¹⁰ and to deal with government use of patents during periods of emergency.²¹¹

The provisions dealing with dependent patents, which are patents the working of which will be impossible without infringing an existing patented invention,²¹² are not discussed in any detail here because they do not raise any serious access questions relating to medicines. In the context of dependent patents, once a voluntary licence has been unreasonably denied, the fairest remedial action would be to grant a compulsory licence.²¹³

In terms of the provisions dealing with compulsory licences for abuse and the non-working of patents, the following issues are worth highlighting. In the first instance, a compulsory licence may be sought and granted in a situation where six months after the applicant sought a voluntary licence from the patentee on the grounds that “the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied”,²¹⁴ but the voluntary licence has been unreasonably refused by the patentee. Indicators of the non-satisfaction of the ‘reasonable requirements of the public...’ include the following: non-working on a commercial scale of the invention in Zimbabwe where the capability for such working exists and there is no satisfactory reason for such non-working;²¹⁵ if the local working of the invention is prevented by

²⁰⁶ For a cursory overview of the Zimbabwean legislation dealing with compulsory licenses, see generally Sacco S.F. *A Comparative Study of the Implementation in Zimbabwe and South Africa of the International Law Rules that Allow Compulsory Licensing and Parallel Importation for HIV/AIDS Drugs* (2004) 30-32, Masters Dissertation submitted in partial fulfillment of the Requirements of the Degree LLM in Human Rights and Democratisation at the University of Pretoria.

²⁰⁷ Section 30A of the Act.

²⁰⁸ Section 31 of the Act.

²⁰⁹ Section 32 of the Act.

²¹⁰ Section 34 of the Act.

²¹¹ Section 35 of the Act.

²¹² Section 30A of the Patents Act.

²¹³ Section 30A of the Patents Act.

²¹⁴ Section 31 (1) of the Act.

²¹⁵ Section 31 (6) (a).

importation of the product at the behest of the patentee or his nominees;²¹⁶ if the demand for the patented article in Zimbabwe is not being met to an adequate extent and on reasonable terms;²¹⁷ if the trade or industry of Zimbabwe or any other person is being prejudiced and it is in the public interest that a compulsory licence be issued;²¹⁸ and if the trade or industry is affected by unfair conditions imposed by the patentee.²¹⁹

If the compulsory licence is granted by an administrative tribunal in the context of anti-competitive practices, then the requirement that the applicant should have applied for a voluntary licence first will not apply.²²⁰ The compulsory licence granted in the context of section 31 will be granted subject to conditions imposed by the Patents Tribunal.²²¹ The licensee will have to pay the patentee reasonable royalty amounts which are compatible with the successful working of the invention within Zimbabwe on a commercial scale and at a reasonable profit.²²² This provision is important because it clearly explains how the royalty amounts may be calculated. A failure by the licensee to pay royalties may lead to a revocation of the licence.²²³

With specific reference to inventions or certain commodities, the Patents Tribunal may grant an applicant a compulsory licence, if the applicant has made a prior attempt to obtain a voluntary license, and if the patent relates to a substance capable of being used as food or medicine or used in the production of food or medicine.²²⁴ This provision extends to processes for the production of the categorized products and the patentee is entitled to remuneration. It is also noteworthy that the licence shall be granted for the predominant supply of the Zimbabwean market and if the compulsory licence is sought on the basis of anti-competitive conduct on the part of the patentee, the requirement to predominantly supply the Zimbabwean market falls away and the products may be exported.²²⁵

²¹⁶ Section 31 (6) (b).

²¹⁷ Section 31 (6) (c).

²¹⁸ Section 31 (6) (d).

²¹⁹ Section 31 (6) (d).

²²⁰ Section 31 (6a).

²²¹ Section 31 (8).

²²² Section 31 (8) (b).

²²³ Section 31 (9) of the Patents Act.

²²⁴ Section 32 (a) of the Patents Act.

²²⁵ Section 32 (1a) (a) of the Patents Act. This provision was inserted by the General Laws Amendment Act no.2 (Act 14 of 2002) of 2002.

In settling the terms of a licence under this section, the Tribunal is required to make sure that food, medicines, surgical, curative and environmental devices are available to the Zimbabwean public at the lowest prices “consistent with the patentees deriving a reasonable advantage from their patent rights”.²²⁶ This provision is important and unique and other SADC members may consider amending their laws similarly in order to maximize access to medicines. This submission is premised on the fact that this study is about patents making medicines expensive and frustrating access thereto. Therefore, a provision in the law expressly stating that prices of foodstuffs and medicines must be kept at their lowest is welcome.

The Patents Act also makes provision for the use of inventions by “any department of the State or any person authorized in writing by the Minister” for the service of the state.²²⁷ For the specific government use of the patent under the relevant section, the permission must be granted by the Minister in writing²²⁸ subject to terms and conditions of use that will be agreed upon between the Minister and the patentee with approval by the Minister of Finance.²²⁹ The authority by the Minister to use the invention may be granted before or after the patent has been granted²³⁰ and the patentee will be informed of such use as soon as is practicable after the use has begun,²³¹ unless it will be contrary to public interest to do so.²³² Such government use contemplates the use by the government of Zimbabwe for the service of a foreign state if the patented articles are to be used for the defence of the foreign government.²³³ Government use contemplated in this section shall be permitted to remedy a practice determined after a judicial or administrative process to be anti-competitive.²³⁴

Compulsory licences issued under this section may be useful in resolving access to medicines if the administrative process prescribed is followed to the letter. The provisions are elaborate and clear and provide for appropriate remedies to the patentee. This again is an opportunity from which other SADC members may learn and incorporate similar provisions in their domestic

²²⁶ Section 32 (2) of the Patents Act.

²²⁷ Section 34 of the Patents Act. Specific actions that may be exercised on behalf of the state include making, using and exercising any invention disclosed in a specification lodged at the patents office for the service of the state.

²²⁸ Section 34 (1) of the Patents Act.

²²⁹ Section 34 (2) of the Patents Act.

²³⁰ Section 34 (4) (a) of the Patents Act.

²³¹ Section 34 (4) (b) of the Patents Act.

²³² Ibid.

²³³ Section 34 (6) of the Patents Act.

²³⁴ Section 34 (6) (b) of the Patents Act.

patent laws. In all likelihood, the provisions sanctioning government use through another person or entity supplement those relating to state use during an emergency, discussed in the paragraph following immediately below.²³⁵

During an emergency, a person or government department may be authorized by the state to make, use, exercise or vend an invention without the patentee's prior authorization. In this specific context of national emergencies, the authorization may be granted in the following circumstances relevant to access to medicines: for the maintenance of supplies and services essential for the life of the community;²³⁶ for the promotion of productivity of industry, commerce or agriculture;²³⁷ for ensuring that whole resources of the community are available for use, and are used in a manner best calculated to serve the interests of the community;²³⁸ and for assisting the relief of suffering and the restoration of and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress because of war.²³⁹

A period of emergency covers "any period beginning on such date as may be declared by the Minister, by a statutory instrument, to be the commencement and ending on such date as may be so declared to be the termination of a period of emergency."²⁴⁰ Because disputes are likely to arise when the state uses a patented invention for an emergency situation, the relevant law provides that such disputes will be dealt with by the Patents Tribunal,²⁴¹ which shall also have the power to consider a number of external issues and make an order as to the appropriate remedy. Additionally, the Tribunal will consider any benefit or compensation which that applicant or any person from whom he derives title may have received or may be entitled to receive, directly or indirectly, from any department of the State in respect of the invention in question.²⁴²

²³⁵ Section 35 of the Patents Act.

²³⁶ Section 35 (1) (b) of the Patents Act.

²³⁷ Section 35 (1) (d) of the Patents Act.

²³⁸ Section 31 (1) (f).

²³⁹ Section 35 (1) (g).

²⁴⁰ Section 35 (2) of the Patents Act.

²⁴¹ Section 36 of the Patents Act.

²⁴² Section 36 (4) of the Patents Act.

The following section narrates and exposes how the government of Zimbabwe successfully used the “special provisions as to State use during emergency”²⁴³ in its Patents Act in order to supply affordable drugs to HIV/AIDS positive patients in the country.

5.5.2 How Zimbabwe managed to effectively use a Compulsory License

In 1999, UNAIDS considered Zimbabwe to be the country with one of the highest HIV/AIDS infection rates in the whole world.²⁴⁴ However, according to the 2012 statistics, the country had turned its fortunes and had achieved one of the sharpest declines in HIV prevalence in Southern Africa, from 27% in 1997 to just over 14% in 2010.²⁴⁵ Before this success story, it was estimated that 1, 5 million people were living with HIV/AIDS and only about 7% of that population had access to HIV/AIDS drugs.²⁴⁶ There were about 180 000 HIV/AIDS related deaths annually and more than 1, 1 million children had been orphaned due to HIV/AIDS.²⁴⁷

Faced with a possible public health disaster of monumental proportions, the Zimbabwean government decided to invoke the government use of provisions in the Patents Act²⁴⁸ in order to ensure the availability of HIV/AIDS medication for its sick population.

As has been previously discussed, Zimbabwean patent laws provide for government use of patents generally and during a state of public emergency.²⁴⁹ Such uses are sanctioned by the TRIPS Agreement for public non-commercial purposes²⁵⁰ and therefore, their inclusion in the relevant Zimbabwean law does have a textual basis in TRIPS. It is important to note that with specific reference to the ‘period of emergency’ in Zimbabwean patent law, the beginning and

²⁴³ Generally provided for in section 35 of the Patents Act.

²⁴⁴ See UNAIDS “Report on the Global HIV/AIDS Epidemic 2000” at http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2000/2000_gr_en.pdf (last visited 15/11/2013).

²⁴⁵ See UNAIDS “UNAIDS highlights Zimbabwe’s progress in responding to AIDS” (28 May 2012) at <http://www.unaids.org/en/resources/presscentre/featurestories/2012/may/20120528fszimbabwe/> (last visited 15/11/2013).

²⁴⁶ UNAIDS “AIDS Epidemic Update (2006)”, available at http://data.unaids.org/pub/epireport/2006/2006_epiupdate_en.pdf (last visited 15/11/2013).

²⁴⁷ Ibid.

²⁴⁸ The specific provision relied upon was section 34 of the Patents Act, read together with section 35 thereof.

²⁴⁹ Sections 34 and 35 of Zimbabwe’s Patents Act respectively.

²⁵⁰ Article 31 (b) of TRIPS.

end of the period is dependent entirely on the Minister's discretion, hence he/she has wide discretion to issue a compulsory licence in times of emergency.²⁵¹

Because of patent protection, antiretroviral (ARV) drugs such as GlaxoSmithKline's zidovudine, lamivudine, abacavir and nevirapine made by Boehringer-Ingelheim were very expensive and out of reach for many of Zimbabwe's poor.²⁵² In May 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs issued a notice declaring a six-month period of emergency on HIV/AIDS.²⁵³ This notice was later extended from January 2003 to December 2008.²⁵⁴ The extension of the period was in accordance with the government policy to promote manufacturing and importing of generic HIV/AIDS drugs.²⁵⁵

Very briefly, the notice was necessitated by the rapid spread of HIV/AIDS among the population of Zimbabwe, and within the six month period of the notice, the state or any person nominated by the Minister would be enabled "to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions".²⁵⁶ Additionally, the Notice would enable the state or any person authorized by the Minister "to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions".²⁵⁷ According to Correa,²⁵⁸ this Notice, which was issued in terms of section 34 of Zimbabwe's Patents Act, is sanctioned by the Doha Declaration on TRIPS and Public Health, which provides that:

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.²⁵⁹

²⁵¹ Pfumrodze J "The WTO TRIPS Agreement and Access to Medicines in Southern Africa" (2011) 13 *Botswana Law Journal* at 96.

²⁵² Pfumrodze above at 97. The author laments the fact that a triple combination with AZT/3TC+ nevirapine cost US\$1,168 per patient per year, well beyond the reach of the average Zimbabwean, where the majority lived on less than 1 US \$ per day.

²⁵³ See General Notice 240 of 2002 issued in terms of the Patents Act [Chapter 26:03] under the title "Declaration of Period of Emergency (HIV/AIDS) Notice 2002" available at http://www.wipo.int/wipolex/en/text.jsp?file_id=214688 (last visited 15/11/2013).

²⁵⁴ Pfumrodze above at 97.

²⁵⁵ Ibid.

²⁵⁶ At para 2 (a) of the Notice.

²⁵⁷ At para 2 (b) of the Notice.

²⁵⁸ Correa CM *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (2002) Geneva: WHO at 16.

²⁵⁹ Doha Declaration on TRIPS and Public Health, subparagraph 5 (c).

Upon close scrutiny, the notice reveals that the use of patented drugs would in all likelihood be confined to Zimbabwean made products or products put on the Zimbabwean market by the patentee while imports were to be confined to generic drugs.²⁶⁰

Pursuant to the notice, Varichem, a local pharmaceutical manufacturing company, was nominated by the Minister and the company agreed to produce antiretroviral or HIV/AIDS drugs and to supply three-quarters of its produced drugs to State owned health institutions at fixed prices.²⁶¹ The company, which also agreed to provide price differentials between its own drugs and those that are patented, introduced its generic drugs late in 2003.²⁶² The introduction of generics into the market lowered the price of ARVs from US\$1,168 to US\$412 per patient per year due to increased competition and yielded positive results for access to medicines.²⁶³

Despite the Zimbabwean government's positive intervention outlined above, access to HIV/AIDS medications still remains a challenge in a country with unemployment rates quoted at more than 50%.²⁶⁴ Deaths from HIV/AIDS are still very high and this could be a pointer to the fact that it is futile to use a compulsory licence to lower prices of medicines while the majority of the population remains poor and unemployed;²⁶⁵ the medicines will remain cheap but unaffordable.

5.5.3 Important Lessons for the SADC from the Zimbabwean Experience

Notably, Zimbabwe was the first developing country and a SADC member to issue a governmental use compulsory licence post the 2001 Doha Declaration on TRIPS and Public health. While the Doha Declaration permits members to use government use orders to override patents in cases of national emergency, from the Zimbabwean experience, it is axiomatic that

²⁶⁰ This emerges from a literary reading of paras 2 (a) and (b) of the Notice.

²⁶¹ Pfumrodze above at 97.

²⁶² Ibid.

²⁶³ CPTech citing a report from Medicins Sans Frontieres at <http://www.cptech.org/ip/health/c/zimbabwe/> (last visited 15/11/2013).

²⁶⁴ According to Mpofu B "Some Perceptions on the Poverty Question in Zimbabwe" at 1 available at <http://www.solidaritypeacetrust.org/download/essays/The%20Poverty%20Question%20in%20Zimbabwe.pdf> (last visited on 15/11/2013), In April 2010, UNICEF reported that 78 percent of the Zimbabwean population was "absolutely poor" while 55 percent of the population, (about 6.6 million) lived under the food poverty line.

²⁶⁵ Pfumrodze above at 97.

such use must be sanctioned by the relevant enabling municipal legislation.²⁶⁶ Quite a number of SADC members have government use provisions in their laws and these could be used to improve access to medicines. While TRIPS flexibilities are spelt out in the relevant WTO Agreement, their availability for use by a member will depend on whether or not the relevant patent laws incorporate them.

A couple of other lessons emerge for SADC members from the Zimbabwean experience. Firstly, the granting of the government licence to Varichem, spurred local pharmaceutical manufacturing capacity, and through cooperation and assistance from generic manufacturers from India, a number of local players were licensed by the government to manufacture HIV/AIDS drugs.²⁶⁷ In addition, with effect from 15 September 2010, Varichem Pharmaceuticals' antiretroviral drug manufacturing plant was certified by the World Health Organization (WHO) as fully compliant with rigorous international standards hence, the company will now be able to export the life-prolonging drugs to other countries in the region.²⁶⁸ The above is positive news for both Zimbabwe and the region and will in all likelihood inform the likely direction the region will take in pursuit of developing regional pharmaceutical manufacturing capacity for export, as sanctioned by Article 31 *bis* of TRIPS.

On the mandate to nominate a person or company to import generic drugs on behalf of the government,²⁶⁹ two drug companies, namely Datlabs and Omahn were nominated by the government to import generic drugs from India. This resulted in local competition which in turn lowered the prices of drugs significantly.²⁷⁰ It is also important to write that from a TRIPS and IP perspective, the fact that patented drugs (not generics) were excluded from the importation mandate was a very wise approach by the Zimbabwean government in light of the furore that was likely to arise had the government provided for the importation of patented drugs in the

²⁶⁶ In the Zimbabwean case, the pertinent legislative provision was section 34 of the Patents Act, read together with section 35 thereof.

²⁶⁷ Pfumrodze above at 97.

²⁶⁸ See specifically, WHO "WHO PUBLIC INSPECTION REPORT (WHOPIR) Finished Product Manufacturer" at 11, available at http://apps.who.int/prequal/WHOPIR/WHOPIR_Varichem10-14May2010.pdf (15/11/2013).

²⁶⁹ See para 2 (b) of the Notice.

²⁷⁰ Pfumrodze above at 97.

relevant notice.²⁷¹ It is submitted that fellow SADC members should take this strategy into account when amending their laws to allow compulsory licences or parallel imports.

The companies that were given the licence to import generics from India did not just do so in a vacuum, the government of Zimbabwe had to negotiate with Indian generic manufacturers and the importation was voluntarily sanctioned by the patentees. The lesson for SADC in this instance is premised on the importance of prior negotiations and the abundance of goodwill in some of the right holders especially the generic manufacturers from developing countries such as India and Brazil. Compulsory licences must always be viewed as a last resort since the mere presence of domestic legislation sanctioning them may be a very strong negotiating point for voluntary licences. This may be aptly illustrated by the fact that “on 30 May 2007, Roche, a Swiss drug manufacturer offered a voluntary licence to Varichem, for the production of a generic drug, saquinavir”.²⁷² The extension of the voluntary licence by Roche in the above context may lead one to conclude that while Zimbabwe may not have the power to threaten the use of a compulsory licence like Brazil, the mere fact that there is a possibility of granting a compulsory licence may trigger the grant of a voluntary licence.²⁷³ Therefore, the availability of legislation on compulsory licensing may have an important effect, even if no compulsory licence is granted.²⁷⁴

Therefore, despite the fact that Zimbabwe continues to grapple with the problem of access to HIV/AIDS medication for its citizens in an environment mired in poverty, high unemployment and a stagnating economy hamstrung by targeted sanctions, its 2002 Declaration of Emergency and its subsequent extension was a courageous and TRIPS compliant decision which fellow SADC members must emulate should the need arise.

²⁷¹ This is one of the issues that that led to the acrimonious litigation against South Africa’s Medicines and Related Substances Control Amendment Act, discussed in para 5.6.2 below.

²⁷² Pfumrodze above at 98.

²⁷³ Ibid.

²⁷⁴ Comides, J “European Union adopts Regulation on Compulsory Licensing of Pharmaceutical Products for Export” (2007)10 *The Journal of World Intellectual Property* at 77.

In the following section, the effective use of one of TRIPS' least used flexibilities namely, competition in law in the context of curbing anti-competitive behaviour that militates against access to medicines, is explored and lessons extracted for other SADC members.

5.6 The South African Access to Medicines Experience

Before discussing how competition law was used with positive results for access to medicines, it is necessary to give an expository account of the extent to which the relevant South African laws incorporate TRIPS flexibilities.

5.6.1 Extent of the Incorporation of TRIPS Flexibilities in South African Patent Law

It is common cause that the South African patent legislation is not without glaring weaknesses.²⁷⁵

Major weaknesses have been attributed to the absence of an examination system, some TRIPS-plus provisions, the absence of pre and post-grant opposition procedures for patent applications, a weak definition of novelty which allows ever greening and the absence of an express provision dealing with parallel imports in the relevant legislation.²⁷⁶

In the specific context of access to medicines, ever greening, which is cited as the major contributor to high drug prices due to the fact that it prevents the entry of generics into the market, has been brandished as one of the major weaknesses of the Patents Act.²⁷⁷ Other weaknesses cited are weak provisions relating to parallel imports and compulsory licences. It has often been argued that should South Africa address these and other problems to be outlined below, South Africans will realize their right to health, succinctly spelt out in section 27 of the Constitution.²⁷⁸

As far as the applicable legislation is concerned, the Patents Act,²⁷⁹ as amended by the Intellectual Property Laws Amendment Act,²⁸⁰ the Patents Amendment Act,²⁸¹ the Medicines

²⁷⁵ See for instance Laura Lopez Gonzalez "Ever greening Keeps Products Costly: Patents review Proposal Could Slash drug Prices" *Cape Times*, 10 September 2013 at 4.

²⁷⁶ This last complaint is misplaced and not entirely true because apart from section 45 of the Patents Act 57 of 1978 dealing with exhaustion of patent rights nationally, with specific reference to medicines, section 15(c) of the Medicines and Related Substances Control Amendment Act of 1997 does provide for the parallel importation of medicines, albeit in a roundabout and incoherent manner.

²⁷⁷ See generally Oh C (2011) "Domestic Legislation and Court Decisions on Intellectual Property Rights and Public Health in South Africa" 1 – 11 at <http://www.docstoc.com/search/south-africa/3> (last visited 16/11/2013).

²⁷⁸ Constitution of the Republic of South Africa 1996.

²⁷⁹ Act 57 of 1978.

²⁸⁰ Patent Laws Amendment Act of 1997.

and Related Substances Control Act,²⁸² as amended by the Medicines and Related Substances Control Amendment Act²⁸³ and the 2002 Medicines and Related Substances Amendment Act,²⁸⁴ and the Competition Act,²⁸⁵ are the most relevant laws for access to medicines. In this section, the implications of the Patents Act, the Medicines and Related Substances Control Act, the Competition Act and the provisions of the recent Draft IP policy will be discussed.

As far as patents are concerned, the relevant provisions of the law that incorporate TRIPS flexibilities are those dealing with the requirements for patentability and the duration of patents, examination of patents, state use of patents, compulsory licences, the protection of test data and parallel imports.

In South African patent law, patents are granted for 20 years²⁸⁶ for inventions that are new and they involve an inventive step and are useful in trade, industry or agriculture.²⁸⁷ This provision is seemingly in accord with the requirements laid down in the TRIPS Agreement²⁸⁸ which designates patentable subject matter as that which is new, involves an inventive step and is capable of industrial application. It may, however, be argued that the utility requirement in terms of South African law, is broader than “industrial application” in the TRIPS Agreement since it includes trade and agriculture alongside industry.²⁸⁹

With specific reference to drugs or pharmaceuticals, it seems as though the Patents Act allows for the patenting of new uses of known substances in its provision that:

..“the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date”.²⁹⁰

The above cited provision is patently TRIPS-plus because the TRIPS Agreement does not have explicit reference to the patenting of new uses of known substances. This, therefore, is a

²⁸¹ Act no. 20 of 2005.

²⁸² Act 101 of 1965.

²⁸³ Act 90 of 1997.

²⁸⁴ Act 59 of 2002.

²⁸⁵ Act 89 of 1998.

²⁸⁶ Section 46 (1) of the Patents Act of 1978.

²⁸⁷ Section 25 (1) of the Patents Act.

²⁸⁸ Article 27 of TRIPS.

²⁸⁹ Oh above at 2.

²⁹⁰ Section 25 (9) of the Patents Act.

weakness in the law which is likely to encourage evergreen patents and militate against access to medicines.

With specific reference to exclusions from patentability, certain inventions are excluded on the basis of not satisfying the requirements for patentability or being against public interest. On the one hand, discoveries; scientific theories; mathematical methods; literary, dramatic, musical or artistic works; schemes, rules or methods for performing a mental act, playing games or doing business; computer programs and the presentation of information are excluded from patentability.²⁹¹ On the other hand, methods of medical treatment (surgery, therapy or diagnosis) are excluded because they are not capable of industrial, trade or agricultural application.²⁹² Additionally, plant or animal varieties, or essentially biological processes for the production of animals or plants, with the exception of a microbiological process or the product of such a process are not patentable.²⁹³

With reference to common exceptions to patent rights, South African law permits the use of patented inventions on a non-commercial scale and in cases where early working is necessary (bolar exception) and compliance with regulatory requirements is contemplated.²⁹⁴ The use of a patented invention to obtain data for regulatory purposes will, therefore, be allowed in South African law provided that such use is on a non-commercial scale. The wording of the pertinent provision mimics the Canadian equivalent of a bolar exception.²⁹⁵ On a negative note, it does not seem that South African patent law provides for any other exceptions; and very disturbingly, the law does not *ex facie* provide for exceptions based on research, teaching or experimentation.²⁹⁶

Compulsory licences are allowed in South African law where patent rights are abused,²⁹⁷ and where such abuse occurs, any interested person may apply for a licence. Patents are deemed to be

²⁹¹ Section 25 (2) of the Patents Act.

²⁹² Section 25 (11).

²⁹³ Section 25 (4) (b) of the Patents Act. This seems to be in line with Article 27 (3) of TRIPS which encourages members to exclude from patentability *plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes* (emphasis added).

²⁹⁴ Section 69A (1) of the Patents Act.

²⁹⁵ Section 55 (2) (1) of the Canadian Patent Act (R.S. 1985, c. P-4).

²⁹⁶ It could however be argued that current exceptions based on use on a “non-commercial scale” can possibly be broadly interpreted to cover circumstances pertaining to research, education and experimentation.

²⁹⁷ Section 56 (1) of the Patents Act.

abused in four instances,²⁹⁸ namely when: the invention is not being worked in South Africa on a commercial scale;²⁹⁹ demand for the patented article is not being met adequately and on reasonable terms;³⁰⁰ refusal of the patentee to grant a licence on reasonable terms, prejudices the establishment of any new trade or industry or that it is in the public interest that a licence or licences should be granted;³⁰¹ and the demand for the patented product is being met by importation and the price charged for the patented article by the patentee, his licensee or agent is excessive in relation to the price charged in the country of manufacture.³⁰² Procedurally, a compulsory licence can be granted through formal application to the Commissioner of Patents, who will ordinarily be a judge of the high court sitting as a single judge in a High Court matter. The Patents Act does not give detailed guidelines as to how compensation can be determined, save to provide that the Commissioner must take into account ‘relevant facts’.³⁰³

For access to medicines, it seems South Africa has very robust provisions that can enable the use of compulsory licences to tackle unjustifiably expensive medicines and improve access to medicines.³⁰⁴ Save for the sketchy detail around the determination of compensation, South Africa’s compulsory licence provisions are robust and far reaching enough to cater for any eventuality of a compulsory licence.

Closely related to the issue of compulsory licensing is the often dreaded issue of government use of patents.³⁰⁵ From an access to medicines perspective, the relevant section of the Patents Act is generally understood to empower the Ministers to issue compulsory licences for public purposes, including ensuring access to a sustainable supply of affordable medicines. Although the pertinent provision does not expressly refer to “national emergency or other circumstances of extreme urgency” or to “cases of public non-commercial use” as eloquently provided for in the TRIPS Agreement,³⁰⁶ the wording in Section 4, which authorizes the use of patented inventions by the

²⁹⁸ Section 56 (2) of the Patents Act.

²⁹⁹ Section 56 (2) (a).

³⁰⁰ Section 56 (2) (b).

³⁰¹ Section 56 (2) (c).

³⁰² Section 56 (2) (d).

³⁰³ Section 57 (6). Some of the relevant factors include risks taken by the licensee, the research and development costs incurred by the patentee, and the normal costs of licenses in patents in a similar field of technology.

³⁰⁴ See specifically section 56 (2) (d) of the Patents Act.

³⁰⁵ Section 4 of the Patents Act provides for government use of patents through the relevant Minister.

³⁰⁶ Article 31 (b) of TRIPS.

Government in the public interest, without the consent of the patent holder, is consistent with the pertinent provision of the TRIPS Agreement.³⁰⁷

On the subject of data protection, the Patent Act does not refer to test data protection. However, the Medicines and Related Substances Control Act, which regulates medicines in South Africa, does contain general confidentiality provisions related to medicines.³⁰⁸ There is a general protection of information submitted in respect of the regulation of medicines against unfair commercial use.³⁰⁹ However, the Director General of Health is permitted to disclose information relating to medicines where it is deemed “expedient and in the public interest”.³¹⁰ The fact that the patent legislation does not deal with data protection is a weakness in the law which must be remedied for clarity.

With reference to the issue of parallel importation and exhaustion of patent rights, it seems that South Africa has a national exhaustion regime for patent rights.³¹¹ To clarify the legal position regarding parallel imports in the context of pharmaceuticals, the South African government passed the Medicines and Related Substances Control Amendment Act in 1997.³¹² The relevant section of the law adopts the international exhaustion of patent rights and affords the Health Minister the power to prescribe the procedure and the conditions under which a patented medicine, once put on the market, can be imported in a parallel manner into South Africa.³¹³ This law sparked a lot of controversy and resulted in acrimonious litigation against the South African government by big pharmaceutical companies. The case relating to section 15 (c) is discussed immediately below in 5.6.2.

³⁰⁷ Oh above at 5.

³⁰⁸ See section 34B, read together with section 24B of the Medicines and Related Substances Control Act, No 101 of 1965.

³⁰⁹ Section 34B of the Medicines Control Act.

³¹⁰ Section 24B of the Medicines Control Act.

³¹¹ Section 45 (2) of the Patents Act provides that, “The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article”.

³¹² Section 15 (c) of the Act.

³¹³ Section 15 (c) of the Act.

5.6.2 South Africa's Infamous Access to Medicines Case: *Pharmaceutical Manufacturers' Association of South Africa v. The President of the Republic of South Africa and Others*³¹⁴

In response to the escalating HIV/AIDS pandemic against the backdrop of expensive and unaffordable medicines, South Africa passed the Medicines and Related Substances Control Amendment Act (the Act).³¹⁵ The amendment contained in section 15C thereof scared big pharmaceutical companies and led to the vilification of South Africa as a major violator of intellectual property rights.³¹⁶

The legislation introduced parallel importation and compulsory licensing as mechanisms to improve access by providing for the importation and manufacturing of cheaper medicines.³¹⁷

Even before it was enacted, the Act was severely criticized by the international pharmaceutical industry, the United States and the European Union, even before it was enacted.³¹⁸ In February 1998, 42 applicants (big pharmaceutical companies) brought a law suit against the South African government. In the case, it was argued on behalf of the pharmaceutical industry that the provisions of section 15C violated inter alia, the TRIPS Agreement and the South African constitution, in that they were too vague since they involved a restriction of patent rights; this being a prima facie violation of property rights in section 25 of the constitution. It was further argued that the impugned legislation violated Article 27 of TRIPS³¹⁹ in that it discriminated against patent rights in the pharmaceutical field.³²⁰ The matter was viewed in a very serious light

³¹⁴ *Pharmaceutical Manufacturers Association of South Africa No v President of the Republic of South Africa*, case No. 4183/98.

³¹⁵ Act 90 of 1997.

³¹⁶ Section 15C deals with measures to ensure a supply of more affordable medicines by allowing parallel importation of drugs and the issuance of compulsory licenses under specific conditions.

³¹⁷ Although the South African government strenuously denied that the pertinent provision covered compulsory licenses, a literary reading of it clearly shows that compulsory licenses were contemplated. See for instance Bombach KM "Can South Africa Fight Aids? Reconciling The South African Medicines and Related Substances Act with the TRIPS Agreement" (2001) 19 *Boston University International Law Journal* 274 – 305, Seeratan NN "The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry" (2000-2001) 3 *Scholar* 341 – 405 at 390.

³¹⁸ See specifically, Bombach above, who wrote on the Act while it was still in Bill form.

³¹⁹ Bombach above at 281 correctly submits that had litigation been pursued to finality, the pharmaceutical companies would have been found to be flawed in treaty law because the TRIPS Agreement provides for compulsory licensing in Article 31 and parallel imports in Article 6.

³²⁰ Ostergaard RL "The Political Economy of the South Africa-United States Patent Dispute" (2000) *The Journal of World Intellectual Property* at 880 – 881.

by the US government which put South Africa on a special section 301 watch list of countries that deny adequate and effective intellectual property protection.³²¹

The South African government on the other hand argued that under its constitution, it is obliged to protect its citizens' rights to health. Treatment Action Campaign (TAC), a South African Non-Governmental Organisation representing people with HIV/AIDS joined the case as *amicus curiae* (friend of the Court). Soon thereafter, 300 000 individuals and 140 groups across 130 nations signed a petition demanding the withdrawal of the case against the South African government, which had a lot of sympathy from the TAC and like-minded organisations. The Pressure later became too much to bear for the pharmaceutical companies which had launched the suit and after the United Nations secretary general's mediation efforts, the pharmaceutical companies withdrew the suit.

In 2001 the South African government and the pharmaceutical industry pledged to work together, with the government affirming its commitment to the TRIPS and its willingness to consult with the pharmaceutical industry in the formulation of regulations in respect of section 15C. Subsequently, the US president issued an executive order forbidding the US from seeking a revision of intellectual Property laws of sub-Saharan African states that promote access to HIV/AIDS pharmaceuticals but are TRIPS compliant.³²²

The case put the TRIPS agreement and access to medicines on the international agenda, and it remained there due to more awareness about HIV/AIDS.³²³ So important was the topic of access to medicines that it was also discussed by WIPO at its commemoration of the 50th anniversary of the Universal Declaration of Human Rights in 1998.³²⁴ This case is, therefore, important in that it raised awareness about access issues to medicines from the developing countries' perspective and exposed the duplicity of the pharmaceutical industry which sought to limit South Africa's right to take advantage of TRIPS flexibilities despite the law expressly providing for compulsory licences and parallel imports.

³²¹ The US government justified South Africa's placement on the list on the basis that the Act gave the Minister ill-defined authority to authorize parallel imports, issue compulsory licenses and potentially otherwise abrogate intellectual property rights.

³²² Herstermeyer above at 16.

³²³ Herstermeyer above at 14.

³²⁴ See WIPO, "Intellectual Property and Human Rights" at <http://www.wipo.int/tk/en/hr/paneldiscussion/index.html> (last visited 20/04/2012).

In addition to having been the pacesetter in access issues in the context of compulsory licences and parallel imports, South Africa also scored an access victory to medicines by using its competition legislation in 2002 to force pharmaceutical companies GlaxoSmithKline and Boehringer Ingelheim to stop their excessive pricing of ARVs to the detriment of consumers. The next section of this chapter focuses on this case.

5.6.3 How South Africa used Competition Law to Improve Access to Medicines

In terms of the relevant provision of the TRIPS Agreement,³²⁵ Patents may, therefore, be overridden and compulsory licences issued if it can be proved that the right holder is engaged in anti-competitive conduct, such as abusing dominance in a market by charging excessively high prices for pharmaceuticals.³²⁶ In this case, the need to correct anti-competitive behaviour may be taken into account in determining the amount of remuneration as compensation. This remedy may be resorted to after going through the judicial or administrative process³²⁷ which a member seeking to rely on such a remedy must have in place. South Africa did rely on competition law to curb anti-competitive practices but a compulsory licence was never issued, as illustrated briefly below.

5.6.3.1 Competition Law as TRIPS Flexibility in South Africa

South Africa's competition law is comparable to antitrust laws which obtain in developed countries' jurisdictions and sets out rules and definitions on mergers, restrictive practices and abuse of their dominant position.³²⁸ With particular reference to access to medicines, the abuse of dominance rules in the Competition Act is relevant.³²⁹ Dominance is defined in terms of market share and market power, irrespective of how big or small a firm is.³³⁰ A firm is prohibited from abusing its dominance, with such dominance taking a variety of forms which are reproduced verbatim below:

(a) charging an excessive price to the detriment of consumers;³³¹

(b) refusing to give a competitor access to an essential facility when it is economically feasible to do so;³³²

³²⁵ Generally, compulsory licenses issued to remedy anti-competitive conduct are dealt with in Article 31 (k) of TRIPS.

³²⁶ Article 31 (k) of TRIPS.

³²⁷ Article 31 (k) of TRIPS.

³²⁸ Oh above at 8.

³²⁹ Section 8 of the Competition Act of 1998.

³³⁰ Section 7 of the Competition Act.

³³¹ Section 8 (a).

- (c) engaging in an exclusionary act, other than an act listed in paragraph (d) of section 8, if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain;³³³ or
- (d) engaging in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act;³³⁴
 - (i) inducing a supplier or customer not to deal with a competitor;
 - (ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
 - (iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
 - (iv) selling goods or services below their marginal or average variable cost; or
 - (v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

In the context of medicines, the cited section has the potential to provide a range of legal tools to challenge various anticompetitive practices such as unjustifiable refusals to license intellectual property and price gouging.³³⁵

Section 8 of the Act has been used in two cases thus far with positive results for access to medicines. The first case, *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, dealt with antiretroviral (ARV) medicines for the treatment of HIV infection while the second one, *Treatment Action Campaign v Bristol-Myers Squibb*, dealt with an antifungal medicine used to treat cryptococcal meningitis, an AIDS related opportunistic infection. Both matters did not proceed to adjudication but were settled. In this section, I highlight for illustrative purposes, the main findings of only the first case.

³³² Section 8 (b).

³³³ Section 8 (c).

³³⁴ Section 8 (d).

³³⁵ Avafia T, Berger J and Hartzenberg T *The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries* (2006) at 35 Stellenbosch: TRALAC.

*5.6.3.1 Highlights from the case of Hazel Tau and Others v. GlaxoSmithKline SA (Pty) Ltd and Others*³³⁶

The Treatment Action Campaign (TAC), an NGO, filed a complaint at the Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) on behalf of 11 HIV patients and medical professionals in September 2002.

The basis of the complaint was that the said companies had allegedly engaged in excessive pricing of ARVs to the detriment of consumers, and such a form of behaviour was prohibited by section 8(a) of the Competition Act, 89 of 1998. The complainants further alleged that the excessive pricing of ARVs was directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults.³³⁷

The complainants asked the Commission to investigate and refer the matter to the Competition Tribunal for relief contemplated by section 58 of the Act, in the form of an Order against GSK and BI ordering them to stop their excessive pricing practices; a declaration to the effect that GSK and BI had conducted a prohibitive practice; and further, a fine of up to 10% of their annual South African turnover.³³⁸

After investigating the matter for a year, the Competition Commission ruled that it was referring the case to the Tribunal because GSK and BI in their refusal to license their patents to generic manufacturers for a reasonable royalty, was in contravention of the Competition Act (GSK and BI had only entered into a licensing agreement with one generic producer, Aspen Pharmacare on royalty terms of 30% and 15%).³³⁹ The Commission further held that the defendants had abused their dominant positions in the market by excessive pricing to the detriment of consumers; denying a competitor access to an essential facility and engaging in an exclusionary act.

³³⁶ See “Statement of complaint in terms of section 49b (2)(b) of the competition act 89 of 1998”, available at <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf> (last visited 19/11/2013).

³³⁷ See para 107 of the statement of complaint, available at <http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc> (last visited 17/11/2013).

³³⁸ Oh above at 10.

³³⁹ Ibid.

In addition to the above findings, the Commission also stated that it would ask the Tribunal to make an order authorizing the making of generic versions of the drugs in question. The case did not proceed to be heard by the Tribunal on its merits since in December 2003, GSK and BI conceded to settlement which saw the two companies agreeing to allow select generic companies to manufacture and sell some of their antiretroviral drugs in sub-Saharan Africa in return for a royalty that does not exceed 5% of net sales of the relevant antiretroviral drugs.³⁴⁰ This was a significant access victory to medicines, and for the first time, generic versions of patented drugs were to be commercially available in South Africa.³⁴¹

5.6.3.1 Lessons from Hazel Tau for Fellow SADC Members

South Africa is the only SADC member to have successfully used competition law to deal with anti-competitive behaviour in the context of access to medicines. The way in which the matter was dealt with affords useful lessons to the SADC region.

Firstly, this case was brought by the TAC, a civil society organization which took ‘big pharma’ on while the government watched. This illustrates the importance of empowering civil society organisations in the SADC region, as the honest evaluation of the Botswana context earlier showed. The case, therefore, shows that competition policy instruments can indeed be used to great effect, particularly in a context where other key role-players – such as developing countries’ governments and generic pharmaceutical manufacturers – are either unwilling or unable to act.³⁴²

Secondly, this case shows that competition legislation may play a complementary role to the general patent law provisions dealing with compulsory licences. It has been reported earlier that Botswana’s competition Act does not apply to patents and such legislative self-emasculation is unfortunate. SADC members need not only have robust competition policies and laws, but also need to have law that can be applied in practice to curb all forms of anti-competitive conduct, like was aptly demonstrated in this case.

³⁴⁰ The agreement, setting out the terms and conditions of the settlement, is available online: <http://www.tac.org.za/Documents/DrugCompaniesCC/GARPP-BI-Settlement-20031209.pdf> (last visited 17/11/2013).

³⁴¹ Avafia, Berger and Hartzenberg above at 40.

³⁴² Avafia, Berger and Hartzenberg above at 40.

5.6.4 Recent Developments in South Africa: The Draft IP Policy and Its likely Implications for access to Medicines

The weaknesses in the South African IP law generally and patent law in particular, were recently acknowledged by the South African government through the Draft Intellectual Property Policy.³⁴³ The most important provisions of the policy which are likely to have a positive impact on access to medicines are those dealing with: forms of IP;³⁴⁴ IP and public health;³⁴⁵ IP and indigenous knowledge;³⁴⁶ IP, Competition, Public Policy-making, compulsory licensing and technology transfer;³⁴⁷ patent reform;³⁴⁸ enforcement of IP;³⁴⁹ and overall recommendations.³⁵⁰

There are a number of provisions in the draft IP Policy which are likely to impact directly or indirectly on access to medicines.³⁵¹ Due to the specific limitations imposed by the scope of this study,³⁵² this section focuses on patents and public health provisions outlined in chapter 1 of the draft policy only.³⁵³ This is a major part of the policy dealing with patents and access to medicines and on the whole, reflects the spirit and purport of the policy on matters affecting patents and access to medicines.³⁵⁴

Although the section dealing with patents in chapter 1 of the policy document offers a simplistic definition of a patent (“a patent is associated with technology transfer, public health and substantive search and examination”),³⁵⁵ the policy makes commendable recommendations that a substantive search and an examination process be followed in South Africa.³⁵⁶ This takes care of the incessant criticism of the South African patent system thus far. The fact that the current patent system promotes the lodging of ‘weak’ patents is also acknowledged and specifically

³⁴³ See Department of Trade and Industry South Africa, “Draft National Policy on Intellectual Property 2013: Invitation for the Public to Comment on the National Policy on Intellectual Property 2013 (Notice 918 of 2013)”, published in Government Gazette no. 36816 on 4 September 2013 (hereafter Draft IP Policy), available at www.gov.za/documents/download.php?f=198116 (last visited 19/11/2013).

³⁴⁴ Draft IP Policy at 8 – 20.

³⁴⁵ Ibid at 21 – 22.

³⁴⁶ Draft IP Policy at 23.

³⁴⁷ Ibid at 23 – 29.

³⁴⁸ Ibid at 31.

³⁴⁹ Ibid at 42 – 44.

³⁵⁰ Draft IP Policy at 44.

³⁵¹ The following chapters of the policy are glaringly relevant in this context: chapter 1, 2, 4, 5, 7, 8, 9, and 10.

³⁵² See the scope and limitations of this study in chapter One above.

³⁵³ At 8 – 14.

³⁵⁴ The ‘spirit and purport’ of the policy are captured succinctly in the objectives of the policy, outlined at page 4 of the policy document.

³⁵⁵ See chapter 1 (a) of the policy document at 8.

³⁵⁶ At 10 – 11.

singled out as an item to fix.³⁵⁷ This shows that the policy does identify real problems with the current patent law and the government should be applauded for this correct diagnosis.³⁵⁸

The policy does acknowledge the country's massive disease burden and acknowledges that as a member of the WTO, South Africa, like other developing countries, may take advantage of the flexibilities offered by the TRIPS Agreement to access medicines.³⁵⁹ The policy then correctly recommends that South Africa amends its patent laws to incorporate TRIPS flexibilities and reflect public health exceptions to patentability.³⁶⁰

Bilateral trade agreements have been cited as obstacles to access to medicines in some instances when TRIPS-plus obligations are incorporated into them.³⁶¹ The draft IP policy cites instances when certain developing countries are forced to concede and agree to renounce patent flexibilities allowed in TRIPS in exchange for economic benefits not related to intellectual property and public health.³⁶² In response to such unfortunate occurrences, the policy recommends that South Africa must not enter into such agreements. Furthermore, it reiterates that South Africa must discourage other developing countries from concluding such agreements which undermine TRIPS.³⁶³

It is heartening to note that in the current SADC/EU EPA negotiations and those that have been concluded, IP issues are not on the agenda but there is a possibility that they may be brought on board.³⁶⁴ The fact that bilateral trade agreements are singled out as an IP policy reform item is a

³⁵⁷ At 11. However the drafters of the policy use a terminological in exactitude ("newness) to refer to the common term "novelty", widely used in the law of patents to denote patents that are non-obvious.

³⁵⁸ However, the Policy was passed after incessant pressure from civil society and NGOs such as the TAC, Doctors without Borders and Section 27 through a campaign dubbed, "Fix the Patent Laws Campaign". For details of the campaign and current goings on, visit <http://www.fixthepatentlaws.org/?cat=7> (last visited 19/11/13).

³⁵⁹ See para 1 (a) (iii) of the policy at 9.

³⁶⁰ Chapter 1 paragraph (iii) of the policy and the accompanying recommendations.

³⁶¹ See generally Phiri DS "Economic Partnership Agreements and Intellectual Property Rights Protection: Challenges for the Southern African Development Community Region" (2009) *SAIA Occasional Paper No. 48* at 1 – 36.

³⁶² For a comprehensive discussion and analysis of the subject of TRIPS-plus provisions in bilateral agreements and access to medicines, see Mitchell AD and Voon T "Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law" (2009) 43 *Journal of World Trade* at 571 – 601.

³⁶³ Chapter 1 paragraph iv and the accompanying recommendations.

³⁶⁴ European Commission (2011) "Fact sheet on the interim Economic Partnership Agreements SADC EPA GROUP" at www.trade.ec.europa.eu/doclib/html/142189.htm (last visited 19/11/2013).

bold step for South Africa, a SADC member with a considerable amount of influence in the region.³⁶⁵

It has been outlined above that the South African patent system does not provide for pre and post-grant opposition to patents. Other countries, for example, India,³⁶⁶ do provide for pre-grant and post-grant opposition to patents and the draft policy recommends that South Africa adopts such a form of opposition to patents.³⁶⁷ Adopting the procedure would ensure that only novel processes and products whose making involves an inventive step are granted patent status, as long as they satisfy the utility requirements. I embrace this policy proposal and opine that it will indeed augur very well for access to medicines in South Africa should the Patents Act be sympathetically amended.

On the issue of world patent harmonization, the policy notes that the World Intellectual Property Organisation (WIPO) has abandoned its initial ill-informed proposal of a world patent modelled on the European Patent Office (EPO), US Patent and Trade Marks Office and the Japanese Patent Office.³⁶⁸ Had this proposal been allowed to see the light of day, it would have eroded countries' sovereign rights to grant their own patents using their own laws.

It is submitted that the TRIPS Agreement remains the 'world patent system' which takes into account individual countries' sovereign rights to grant patents according to the minimal standards provided for in the TRIPS Agreement. The policy recommends that should the issue of a world patent be raised again, South Africa should resist it with all her might to preserve the patent granting policy space as guaranteed by the TRIPS Agreement.³⁶⁹ This recommendation is important and South Africa's adherence to it will ensure that the country's policy space to use TRIPS flexibilities is not compromised.

On data protection, it has been said elsewhere³⁷⁰ that the TRIPS Agreement provides for data protection against unfair commercial use but does not provide for data exclusivity.³⁷¹ The

³⁶⁵ Saurombe A "The role of South Africa in SADC Regional Integration: The Making or Braking of the Organization" (2010) 5 *Journal of International Commercial Law and Technology* at 124- 131.

³⁶⁶ Section 3(d) of the amended Indian Patents Act, 1970 as amended by The Patents (Amendment) Act, 2005. See further, Chapter Six below.

³⁶⁷ Para 1 (a) (v) of the Draft IP Policy at 9.

³⁶⁸ Para 1 (a) (vi) of the policy at 10.

³⁶⁹ Ibid.

³⁷⁰ See the discussion on the 'bolar exception' above.

existence of this exception, which allows members to permit generic medicine manufacturers to undertake and complete the task of obtaining regulatory approval from national regulatory authorities for generic versions before original patents expire, was confirmed by the WTO in a panel ruling involving Canada and the European Union.³⁷² The policy notes with concern the behaviour of some multinational pharmaceutical companies which lobby their governments to put pressure on developing countries to introduce laws that protect data exclusivity.³⁷³ This kind of behaviour does not augur well for access to medicines since it will in all likelihood delay the entry of generics into the local market since generic companies would not be able to conduct research and experiments before the patent expires. The policy, therefore, correctly urges South Africa to continue protecting data in terms of TRIPS prescriptions³⁷⁴ but not allow data exclusivity.

On the introduction of substantive search and the examination of patents processes, the positive aspects of this intervention have been discussed above. Suffice it to say at this stage that the policy recommendation on this point³⁷⁵ is noble and will have positive spin-offs for access to medicines. However, the introduction of this recommendation into the South African patents system will require that staff at the patents office be trained and capacitated to deal with examinations. This will entail using the little available local expertise in our research institutions such as science councils and universities before looking beyond our borders to countries such as India, who have made phenomenal success of this process. Further, the WIPO and other WTO members may be asked to help in terms of their mandate to provide technical assistance in that specific regard.

The policy also comments and makes incisive recommendations on two new items which I regard as administrative rather than pure IP issues. The first issue is the harmonization of the database of the Medicines Control Council (MCC) and the Companies and Intellectual Property Commission (CIPC).³⁷⁶ While it is good that the two related government departments share information and access each other's databases with relative ease, it is submitted that this should be done in a manner that does not delay the introduction of new medical products on the market.

³⁷¹ Article 39 of TRIPS.

³⁷² See WTO Panel Report on *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R 17 March 2000 available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (23/09/2013).

³⁷³ Para 1 (a) (vii) at 10.

³⁷⁴ In terms of the relevant provision of the Patents Act, section 69A provides for data protection.

³⁷⁵ Chapter 1 paragraph viii and the accompanying recommendations.

³⁷⁶ Para 1 (a) (ix) at 11.

The second issue relates to whether or not applicants for medical patents should be ‘rewarded/appeased’ for delays in the approval of their medicines by granting them an extension to the 20 year patent term.³⁷⁷ While patent extension may be interpreted as TRIPS-plus, it is not per se illegal since the TRIPS Agreement grants 20 years as the minimum period.³⁷⁸ Patent extension will delay the entry of generics into the South African market and should be discouraged.³⁷⁹

The Draft Policy also considers issues relating to parallel importation,³⁸⁰ compulsory licences,³⁸¹ disclosure of information on patent,³⁸² generic medicines³⁸³ and patents affected by competition law.³⁸⁴ It is to be noted, nevertheless, that these issues are not elaborated upon because this was done earlier in this chapter, albeit in a different context. Suffice it to say here that with respect to the listed issues, should they be implemented in an amended Patents Act, access to medicines for South Africans will be enhanced.

Finally, the draft policy should be commended for coming up with an important provision dealing with “alternatives to IP”.³⁸⁵ In terms of the draft two alternative mechanisms for promoting innovation are the ‘subsidy’ and the ‘prize’.³⁸⁶ The subsidy involves direct or indirect payment by the government to the innovator for pursuing new technologies. The risk of loss in this instance is to be shared by the government and the innovator. This approach is widely used by the US government in sensitive areas such as the military technologies and the development of vaccines to address bio-weapons threats. The subsidy approach is widely used by the South African government through the NRF system, for example, to train more PhD holders or improve qualifications of academics at universities. The only shortcoming of the system is that it is not usually targeted at obtaining patents. It is recommended that the government works with current subsidy programmes and target patents as outcomes. This will in all likelihood spur innovation in

³⁷⁷ Para 1 (a) (x) at 11.

³⁷⁸ See Article 33 of TRIPS.

³⁷⁹ See chapter 1 paragraph x of the draft policy at 11.

³⁸⁰ See ‘recommendations’ at 21.

³⁸¹ See ‘recommendations’ at 21 and detailed explanations of compulsory licensing models at 23 - 25.

³⁸² At 12.

³⁸³ At 13.

³⁸⁴ Ibid.

³⁸⁵ Chapter 1 paragraph J and accompanying recommendations at 19.

³⁸⁶ At 19.

all the fields of technology including pharmaceuticals. Such subsidies are allowed in the terms of the WTO Agreement as non-actionable R/D subsidies.³⁸⁷

The ‘prize’ approach involves the establishment of a pre-determined award that innovators have to try to achieve. This is based on the premise that the person seeking the prize will expand his/her own resources to achieve it. Whether this approach encourages innovation is yet to be established beyond reasonable doubt but the draft policy recommends that this approach be explored as well.³⁸⁸

Alternatives to IP are important and may be used to come up with innovative approaches that yield solutions that are directly relevant to South Africa’s peculiar circumstances.

To sum up on South Africa’s Draft IP Policy, the document has its heart in the right place although it does not in any way refer to exceptions to patents based on research, experimentation and educational purposes. This weakness of the current patents legislation must be addressed and one hopes that public comments on the draft will be taken into account.³⁸⁹ If the public health provisions of the current Patents Act were to be amended in a manner that incorporates all of the policy proposals, its legal provisions would be enhanced and there will be little to criticize in the law. This would in all likelihood yield positive results for access to medicines in South Africa.

Conclusion

This Chapter must be read together with Chapter Four and be regarded as a sequel to and continuation of the issues addressed in Chapter Four. The main aim of this chapter was to give a critical expository account of the actual use of TRIPS flexibilities in the SADC region with

³⁸⁷ The relevant WTO Agreement dealing with subsidies is the Agreement on Subsidies and Countervailing Measures (SCM Agreement), available at http://www.wto.org/english/docs_e/legal_e/24-scm.pdf (last visited 19/11/2013). In terms of Article 3 of the SCM Agreement, two categories of subsidies are prohibited, namely export and local content subsidies. Export subsidies are subsidies contingent, in law or in fact, whether wholly or as one of several conditions, on export performance. On the other hand, local content subsidies are contingent, whether solely or as one of several other conditions, upon the use of domestic over imported goods. These two categories of subsidies are prohibited because they are designed to directly affect trade and thus are most likely to have adverse effects on the interests of other Members. Therefore, subsidies to spur innovation and boost patents will not be prohibited as long as they are applied in adherence to the national treatment and the most favoured nation principles.

³⁸⁸ Page 19 of the Draft IP Policy.

³⁸⁹ In response to the South African Minister of Trade and Industry (DTI), Rob Davies’ invitation for public comment on the Policy 30 days from 4 September 2013, I did submit a 30 page proposal to the DTI on the 29 of September 2013 responding to most issues in the Draft policy touching on public health matters. One of the points I raised was that the research and experimentation exception to patents must be included in the final policy and indeed in the mooted amendments to the Patents Act.

particular emphasis on the laws of three selected members, namely, Botswana, South Africa and Zimbabwe. By and large, most SADC members including LDCs do incorporate most of the basic TRIPS flexibilities in their IP legislation.

Botswana seems to have gone a step further by updating her IP laws and bringing them in line with the recent developments at the WTO level. Such developments include the domestication of some aspects of Article 31 *bis* of the TRIPS Agreement and a number of express references to importing generics. This is depicted by the country's honest self-evaluation which identifies weaknesses in the law and suggests appropriate remedial action. The section of this chapter dealing with Botswana compliments the self-evaluation and adds value thereto by making further suggestions for improvement, such as amending or repealing provisions that criminalize patent infringement. Zimbabwe, on the one hand, does have very robust provisions on compulsory licenses and government use of patents which were applied in 2002 with positive local pharmaceutical production results. However, the country remains bedevilled by economic problems which diminish the access gains to medicines introduced by the local production of affordable HIV/AIDS drugs and the granting of WHO approved facility status to the local generic producer, Varichem. South Africa, on the other hand, does have good IP laws that are yet to be put to the test of litigation in the context of access to medicines. On a positive note, South Africa has shown that it can use competition law as an access tool to medicines and this may be a positive lesson for fellow SADC members. Additionally, South Africa, under immense pressure from civil society organizations recently published a Draft IP policy which will inform future IP law reform generally, and access to medicines in particular. While the Draft Policy may be labelled a belated response to a problem that has been glaring this long while, it has very apt recommendations that favour access to medicines.

On the subject of the prevention of evergreen patents, it has been reported that most of the members except Botswana, Malawi, Zambia and Zimbabwe do not have robust provisions in their patent laws to prevent ever greening. However, for the four countries mentioned, and in the context of pharmaceutical patents, the patenting of products that are 'mere mixtures' of known medical and food substances is expressly prohibited. While this reads as good law at face value, the specific mention of 'food' and 'medicines' as exceptions to patents in that context may lead

to WTO litigation based on discrimination on the grounds of technology.³⁹⁰ The SADC members whose laws attempt to limit ever greening but only confining it to medicines and food should consider taking the cautionary step of reviewing their laws to cover ‘mixing’ in the other fields of technology.

On a cautionary valedictory note, while I celebrate the acknowledgement and inclusion in Botswana’s IP law of Doha and Article 31 *bis* issues, I equally bemoan the fact that Botswana has not ratified the relevant amendment to the TRIPS Agreement. The implication is that as long as the non-ratification persists, Article 31 *bis* will remain a waiver that will not be applicable in Botswana. The same cautionary message applies to other SADC members, bar the Republic of Zambia and Mauritius.³⁹¹

³⁹⁰ Article 27 (1) of TRIPS poignantly provides that, “Subject to the provisions of paragraphs 2 and 3, patents *shall be available for any inventions, whether products or processes, in all fields of technology*, (my emphasis) provided that they are new, involve an inventive step and are capable of industrial application”.

³⁹¹ At the time of writing, the only SADC members which had ratified the permanent amendment to the TRIPS Agreement were Zambia and Mauritius. See specifically WTO, “Members Accepting Amendment of The TRIPS Agreement” at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 19/11/2013).

CHAPTER SIX

LITIGATING ACCESS TO MEDICINES: THEMATIC LESSONS FOR THE SADC REGION FROM OTHER DEVELOPING COUNTRY JURISDICTIONS

6. Introduction

In Chapter Five above, we outlined the use of TRIPS flexibilities in the SADC region by identifying the legal and policy instruments in individual countries that deal with access to medicines and the use of TRIPS flexibilities. Detailed expositions in three specific countries, namely, Botswana, South Africa and Zimbabwe revealed examples of good practice in different contexts of access to medicines. The Botswana experience showed a good example of an across the board incorporation of TRIPS flexibilities in all aspects of patent law, while the Zimbabwean experience showed the effective use of government use orders. The South African experience on the other hand showed that competition law can be used as an access to medicines tool in dealing with the abuse of patent rights; and at the same time, the country's recent Draft IP Policy depicts a country that has learned from past mistakes wrought by procrastination around IP law reform.

Very importantly, Chapter five highlighted the lessons the SADC can learn from individual country experiences in order to improve access to medicines in the region. The fact that these lessons come from within the region itself is a positive development despite this being limited in that it may be regarded by critics as inward looking. It becomes imperative, therefore, that lessons for improving access to medicines through taking maximum advantage of the TRIPS flexibilities be drawn from elsewhere. However, in identifying the source of lessons for SADC from outside the region, it is important to pick regional sources of lessons from countries with similar socio-economic conditions to SADC.

In this chapter, therefore, a critical expository comparative account of the access to medicines litigation experiences in India, Thailand and Kenya is rendered with the view of ascertaining further thematic lessons for SADC (in addition to those learned in Chapter Five) from other developing country jurisdictions.

The Indian experience highlights in very simple terms how the legislative inclusion of TRIPS flexibilities around the requirements for patentability¹ can be effectively used to curb incremental patenting and limit the proliferation of ever green patents.² While the Indian legislative inclusion of the relevant TRIPS flexibility may be regarded as going slightly beyond the minimum prescribed by the TRIPS Agreement,³ such inclusions are TRIPS-compliant despite being TRIPS-plus. At the end of this chapter, it is recommended that SADC members embark on IP legislative reforms along similar lines as India and this legislative reform approach forms the crux of the recommendations in Chapter Seven.

The Kenyan experience is very relevant for SADC IP law reform and the incorporation of TRIPS flexibilities in that it clearly spells out how not to legislate for border measures in the context of counterfeiting. The case also spells out unequivocally that the right to health should trump the right to IP, hence it illuminates the recommendation made in Chapter Seven that in order to improve access to medicines, SADC must adopt a different theoretical framework⁴ and use the rights-based approach.⁵

It will be recalled that in chapters four and five above, we highlighted that very few SADC members have pre-grant patent opposition provisions in their laws and for those that have provisions on same, the Regulations do not clearly provide for the effective use of the procedure. The Thai experience highlights the importance of patent opposition procedures especially the pre- and post-grant procedures in access to medicines. In the Thai case study, the relevant law dealing with patent opposition is narrated before highlighting how the procedure was used in litigation. It is hoped that the SADC members will learn some useful things about patent opposition from Thailand and incorporate similar provisions in their own laws.⁶

¹ Generally provided for in Article 27 of TRIPS.

² According to Eisenberg R “The Problem of New uses” (2005) 5 *Yale Journal of Health Policy, Law, and Ethics* at 717, ever greening is a practice consisting in the extension of the commercial life of a patent, through the filing of applications for new uses of the same product patent, or for marginally improved substances or derivatives. Ever greening is frowned upon because it has anti-competitive effects, delays the entry of generics on the market and negatively impacts on drug prices.

³ The specific legislative provision, which will be discussed in its proper context in ensuing paragraphs, is section 3 (d) of the Indian Patents Act 39 of 1970, dt. 19-9-1970, amended by Patents Act 15 of 2005, dt. 4-4-2005.

⁴ See Chapter Two of this study and the recommendations in Chapter Seven.

⁵ See Chapter Three of this study and the recommendations in Chapter Seven.

⁶ SADC IP law reform in various areas allowed by the TRIPS Agreement including introducing pre- and post-grant patent opposition procedures is one of the main recommendations made by this study in Chapter Seven below.

6.1 Limiting ever greening and Incremental Patenting: Novartis AG v Union of India and Others⁷

On 1 April 2013, the Indian Supreme Court delivered a very important⁸ judgment in *Novartis AG v Union of India and Others* (hereafter Novartis case) in an appeal that had been brought to it by Novartis, a Swiss-based pharmaceutical company with business presence in India, against rejection by the Indian Patent Office of a product patent application for a specific compound, the beta crystalline form of Imatinib Mesylate.⁹ Novartis lost the case because the Supreme Court ruled that the beta crystalline form of Imatinib Mesylate failed both the tests of invention and patentability.¹⁰

The crux of the matter was whether or not the appellant was entitled to a patent for the beta crystalline form of the compound Imatinib Mesylate, which is a therapeutic drug for chronic myeloid leukaemia and certain kinds of tumours and marketed under the name ‘Glivec’ or ‘Gleevec’.¹¹

It is now appropriate to delve into the facts of the case before exposing what the pertinent legal provisions that the Supreme Court relied upon provide, which led to a rejection of Novartis’ case.

6.1.1 The Pertinent Facts and other Background Information

The drug Glivec, manufactured by Novartis Pharmaceuticals, was originally invented by Jurg Zimmerman, a medicinal chemist, who invented a number of derivatives of N-phenyl-2-pyrimidineamine.¹² The name Imatinib was given to one of the derivatives as a non-proprietary name by the World Health Organisation.¹³ The derivatives, including Imatinib are capable of inhibiting certain protein enzymes and have valuable anti-cancer properties, which makes them

⁷ Civil Appeal No. 2706-2716 of 2013, Supreme Court of India, judgment delivered 1 April 2013.

⁸ The importance of this judgment and the case was highlighted by the Supreme Court’s remark at para 22 that, “but in the end all agreed that given the importance of the matter, this Court may itself decide the appeals instead of directing the appellant to move the High Court”.

⁹ Abbott FM “Inside Views: The Judgment in Novartis v. India: What the Supreme Court of India Said” (2013) *Intellectual Property Watch* at 1 available at <http://www.ip-watc.org/2013/04/04/the-judgement-in-novartis-v-india-what-the-supreme-court> (last visited 8/11/2013).

¹⁰ *Novartis AG v India* at para 195. The tests for invention and patentability are provided for in section 2(1) (j) - (ja) and section 3 (d) of the Patents Act.

¹¹ *Novartis AG v India* at para 3.

¹² *Ibid* at para 5.

¹³ *Ibid*.

suitable for the treatment of warm blooded animals.¹⁴ Imatinib and other derivatives were submitted to the US Patent Office for the registration of a patent therein on 28 April 1994 and the patent sought was granted in 1996.¹⁵

After further research revealed that the beta crystalline form of Imatinib¹⁶ is more stable, Novartis sought to patent this in the US as well and after initial opposition from the Patent Office, a patent was granted in the US.¹⁷ Novartis also applied for a patent in India for the same product in 1998,¹⁸ but the patent was only considered in 2005, when India became truly compliant with the TRIPS Agreement.¹⁹

The basis for Novartis' patent application for the beta crystalline form of Imatinib in India was an alleged inventive step that materialized when a two-stage invention process involving the introduction of a specified amount of beta crystals into the base form of Imatinib was embarked upon.²⁰ Very specifically, the claims in the patent application alleged the following about the Beta crystalline form of Imatinib:

- (a) It had more beneficial flow properties;²¹
- (b) It had better thermodynamic stability;²² and that
- (c) It had lower hygroscopicity than the alpha crystalline form of Imatinib.²³

It was alleged that the above mentioned properties made the beta crystalline form of Imatinib 'new' and superior due to its ability to store better and be processed easily, having 'better

¹⁴ *Novartis AG v India* at para 3.

¹⁵ The patent was granted under US Patent number 5 521 184.

¹⁶ Imatinib Mesylate marketed in India as Glivec.

¹⁷ US patent number 6 894051.

¹⁸ Application No. 1602/MAS/98. Novartis applied for a patent of Imatinib Mesylate in Beta crystal form at the Chennai Patent Office on 17 July 1998 (Novartis case at para 8).

¹⁹ From 1 January 2005, India allowed drug patent protection in order to comply with the requirements under TRIPS. See specifically Chauduri S "Multinationals and Monopolies: Pharmaceutical Industry in India after TRIPS" (2012) XLVII *Economic and Political Weekly* at 46.

²⁰ *Novartis AG v India* paras 6 – 7.

²¹ *Ibid* at para 8.

²² *Ibid*.

²³ *Ibid*.

processability of the methanesulfonic acid addition of a compound formula I' coupled with the advantage of storing and processing.²⁴

Two important developments occurred before the patent application was considered by the Chennai Patents Office. Firstly, the Patents Act was amended and section 3 (d)²⁵ was introduced. Secondly, before the patent application was considered, it had attracted five pre-grant oppositions.²⁶ The most vocal oppositions came from rival pharmaceutical companies and patient groups, basing their opposition mainly on the fact that the alleged invention was anticipated, obvious and ran afoul of section 3 (d) of the Patents Act.

The matter relating to the patentability of the beta crystalline form of Imatinib was heard by the Assistant Controller of Patents and Designs and the application was rejected.²⁷ The Assistant Controller of Patents and Designs rejected the application on the basis that the invention was anticipated by reason of prior publication;²⁸ lack of novelty and not meeting the acid test of section 3 (d).²⁹

Novartis appealed the decision of the Assistant Controller of Patents and Designs to the High Court in Madras, in addition to asking for an order that section 3 (d) was unconstitutional and also fell afoul of the TRIPS Agreement.³⁰ During that time, the Intellectual Property Appellate Body (IPAB) had not yet been formed. After the IPAB had been formed, the matter was remitted to it by the Madras High Court. Despite ruling in favour of Novartis by reversing the findings of the Assistant Controller on novelty and non-obviousness, the IPAB ruled that the patent could not be granted in light of the provisions of section 3 (d) of the Act, which, according to the IPAB, introduces a higher standard of inventive step and that what is patentable in other

²⁴ *Novartis AG v India* at para 8.

²⁵ Section 3 (d) excludes from patentability “*the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant*” (my emphasis).

²⁶ *Novartis* case at para 13. Pre-grant opposition is provided for in section 25 of the Patents Act of 1970 as amended.

²⁷ The matter was heard on 15 December 2005.

²⁸ This was based on the fact that patents for the same subject matter had been granted under the Zimmerman patents.

²⁹ *Novartis* case at para 14.

³⁰ *Ibid* at para 15.

countries will not necessarily be patentable in India.³¹ The IPAB went a step further and observed that the specific section was particularly targeted at drugs/pharmaceutical substances.³²

Very peculiarly, the IPAB referred to the pricing policy of Novartis, which had exclusive marketing rights over Glivec, sold at 1 20000 Rupees per month³³ per required dose and concluded that the patentability of the subject product would fall foul of section 3 (b) of the Act, which prohibits the granting of patents on certain inventions the exploitation of which could cause public disorder, among other social ills.³⁴

Novartis then appealed the decision of the IPAB to the Supreme Court of India, which was initially reluctant to hear the appeal but was swayed by the public interest in the matter³⁵ and the delays that had accompanied the finalisation of the matter and judgment was delivered on 1 April 2013.

6.1.2 The Supreme Court Judgment

Before delivering its judgment, the Supreme Court of India per Aftab Alam J reduced the issues at stake in the case to an enquiry into the true import of section 3(d) of the Act and how it interplays with clauses (j) and (ja) of section 2(1) of the Act.³⁶ The key question to answer in the opinion of the Court was, “does the product which Novartis claims as a patent qualify as a new product?”³⁷ As a corollary of the question, it was crucial to enquire into whether the product in question had a characteristic feature that *involves a technical advance over existing knowledge that makes the invention not obvious to a person skilled in the art* (emphasis added).³⁸ After affirming that the meaning of an invention is delimited by clauses (j) and (ja) of section 2 (1) of the Patents Act, the Court went further and asked the rhetorical question of whether a product qualifying as an invention under the relevant clauses of section 2(1) could have its patentability

³¹ *Novartis AG v India* at para at para 17.

³² *Ibid.*

³³ On the other hand, the price of generic equivalents was about 10 000 Rupees per person per month.

³⁴ *Novartis case* at para 19.

³⁵ *Ibid* at paras 21 – 22.

³⁶ *Ibid* at para 3.

³⁷ *Ibid.*

³⁸ *Novartis case* at para 3.

status questioned under section 3 (d).³⁹ The Court did answer the rhetorical question in the course of the judgment.

Clauses (j) and (ja) deleted section 5 of the previous Patents Act, which prohibited product patents in India, and at the same time, amendments were effected to section 3, introducing section 3 (d).⁴⁰ The Court opined that in order to understand the purport and objects of the amendments, it was important to identify the mischief parliament wanted to check.⁴¹ The object which section 3(d) sought to achieve was to prevent ever greening, provide easy access to life-saving drugs to citizens and realise the constitutional obligation to provide good health care to citizens.⁴²

After a detailed exposition of India's legislative history⁴³ relating to intellectual property generally and patents in particular, the Supreme Court concluded that the law was passed in order to protect India's policy space to afford good health to its citizens while complying with the basic prescripts of the TRIPS Agreement.⁴⁴ The Court opined that patent protection of pharmaceutical and agricultural chemical products might have the effect of putting life –saving medicines beyond the reach of a very large section of the population,⁴⁵ hence the amendments were justified.

The Court clarified the pertinent legal provisions as follows.⁴⁶ The 1970 Patents Act as amended in 2005 requires that inventions be new (not anticipated) and involve an inventive step⁴⁷ and be capable of being made or used in an industry.⁴⁸ The requirement that an invention must involve an inventive step implies that there must be a feature that involves a technical advance as

³⁹ *Novartis AG v India* at para 3.

⁴⁰ *Novartis* case para 24 – 26.

⁴¹ *Ibid* at para 26.

⁴² The Supreme Court at para 18 cited with approval the object which was spelt out by the Madras High Court in earlier litigation in the matter.

⁴³ *Novartis* case at paras 31 – 46.

⁴⁴ *Ibid* at para 66.

⁴⁵ *Ibid*.

⁴⁶ At paras 88 – 89.

⁴⁷ Section 2 (1) (j) (i) – (iii) of the Act.

⁴⁸ Section 2 (1) (ac) of the Act.

compared to existing knowledge or having economic significance or both.⁴⁹ Further, this feature should be such that the invention is not obvious to a person skilled in the art.⁵⁰

With specific reference to section 3 (d), the Court first of all observed that section three provides for “what are not inventions”. Under section 3(d), the following are not inventions within the meaning of the Act,--

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or (emphasis in the original) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

From the above cited provisions of section 3(d) of the current Patents Act, the words in bold were grafted onto the pre-2005 section 3(d) of the Patents Act of the 2005 amendment of the law.⁵¹ The new section 3(d) adds the words in bold at the beginning of the provision; deletes the word ‘mere’ before ‘use’ in the old provision,⁵² and adds an explanation at the end of the clause.⁵³ Very importantly, section 3(d) does have a detailed explanation that fully contextualises the extent of the exclusions.⁵⁴ Citing Indian Parliamentary Debates, the Supreme Court observed that section 3(d) is targeted at 80% drugs and pharmaceutical products and 20% at agricultural chemicals.⁵⁵ This was a bold admission by the Court that section 3(d) targets specific fields of technology (pharmaceuticals and agricultural chemicals) since nothing arose in the context of the section in other fields of invention.⁵⁶

⁴⁹ Novartis case at para 89.

⁵⁰ Ibid.

⁵¹ Novartis case para 95.

⁵² The full text of the old section 3 (d) is hereby reproduced verbatim for information as follows: “(d) the mere discovery of any new property or mere new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

⁵³ Ibid at para 96.

⁵⁴ The explanation provides that for the sake of the clause in section 3 (d), “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”.

⁵⁵ Norvatis case at paras 97 – 98.

⁵⁶ Ibid. There is a likelihood that section 3 (d) may be impugned at the WTO dispute settlement level on the ground that it is discriminatory in terms of targeting patents in specific fields of technology; contrary to the TRIPS Agreement, which provides in Article 27.1 that patents shall be available in all fields of technology, and that patent rights must be enjoyable “without discrimination” as to “the field of technology”. However, see for a counter argument Lewis-Lettington R and Banda C *A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPs Flexibilities in Malawi* (2004) at 19, in which the authors convincingly argue that such discrimination should be characterized as addressing problem areas rather than technical fields.

It was submitted on behalf of Novartis that section 3(d) was not an exception to patentability. Hence once a substance satisfies the requirements in section 2(1) (j) and (ja), it satisfies the requirements of patentability, consequently, section 3(d) did not apply to the Novartis case.⁵⁷ This submission was made notwithstanding the concession by counsel for Novartis that the aim of section 3(d) was to prevent trifling change and ever greening while allowing and encouraging incremental patenting.⁵⁸ With specific reference to public health and the use of TRIPS flexibilities, Novartis argued that the best route was to make use of compulsory licenses,⁵⁹ revocation proceedings⁶⁰ and multiple stages of patent opposition procedures⁶¹ rather than use section 3 (d).⁶²

The Supreme Court dismissed the above submissions on a number of grounds.⁶³ Firstly, the court held that section 3(d) is not a provision *ex majorie cautela* (out of abundant caution) as was submitted on behalf of Novartis when taking into account the totality of the historical development that led to the enactment of the provision.⁶⁴ Secondly, the Court cautioned that the relevant provision was enacted to deal with chemical patents and pharmaceuticals by setting additional qualifications for the patentability of such products.⁶⁵ Thirdly, and very importantly, the Court clarified the position by stating that the door was wide open for true inventions but closed by section 3(d) for repetitive patenting or the extension of patent terms on spurious grounds.⁶⁶ In coming to the conclusion that section 3(d) applied to the case, the Court emphasized that different standards are set for things of different classes to qualify as inventions; and for medical drugs and other chemical substances, the invention threshold is set higher.⁶⁷

It was also argued on behalf of Novartis that the production of Imatinib Mesylate from Imatinib in a free base form was a result of a step involving a technical advance when compared to current knowledge, thus bringing into existence a new substance.⁶⁸ The Supreme Court rejected this

⁵⁷ Novartis case para 99.

⁵⁸ At para 100.

⁵⁹ In terms of Chapter XVI of the Act.

⁶⁰ As provided for in sections 63, 64 and 65 of the Patents Act.

⁶¹ In terms of section 25 of the Patents Act.

⁶² Novartis case at para 101.

⁶³ See paras 102 – 104.

⁶⁴ At para 102.

⁶⁵ At para 103.

⁶⁶ Ibid.

⁶⁷ Novartis case at 104.

⁶⁸ At para 106.

argument and ruled that the production of Imatinib Mesylate did not constitute an invention as contemplated in the current law of India.⁶⁹ In dismissing the submission, the Supreme Court remarked thus:

“...we firmly reject the appellant’s case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmerman patent”.⁷⁰

Therefore, the specific product did not satisfy the test of an ‘invention’ as laid down in section 2(1) (j) and (ja) of the Patents Act.⁷¹

With specific reference to the beta crystalline form of Imatinib, it was submitted on behalf of Novartis that section 3 (d) applies if a substance is a new form of a known product having known efficacy, and ‘known’ in the specific context meant proven and well established while ‘known efficacy’ meant “efficacy established empirically and proven beyond doubt”.⁷² Citing with approval the case of *Monsanto Company v Caramandel Indag Products (P) Ltd*,⁷³ the Supreme Court disagreed and rejected the submission on the basis that it was wrong in both fact and law.⁷⁴ The court sealed the dismissal of the submission with the powerful observation that the beta crystalline form of Imatinib Mesylate is a new form of a known substance, namely, Imatinib Mesylate, with well-known efficacy.⁷⁵ Therefore, the fact that the beta form of Imatinib was a product that claimed to enhance the form of its old counterpart triggered the application of section 3 (d).⁷⁶

Very specifically, the Court observed that in its application for a patent, Novartis averred that all the therapeutic qualities of the beta crystalline form of Imatinib Mesylate were also possessed by Imatinib in free base form. This, therefore, raised the question of whether an enhanced efficacy over a known substance as demanded by section 3 (d) existed.⁷⁷ The Court held that the correct ‘efficacy’ to consider in section 3(d) is ‘therapeutic efficacy’ in the specific context of medicines.⁷⁸ The Court further noted that the test for enhanced therapeutic efficacy must be

⁶⁹ At para 133.

⁷⁰ At para 157.

⁷¹ Ibid.

⁷² Novartis case at para 158.

⁷³ *Monsanto Company v Caramandel Indag Products (P) Ltd* (1986) 1 SCC 642.

⁷⁴ Novartis case at para 159.

⁷⁵ At para 161.

⁷⁶ Ibid.

⁷⁷ Novartis case at para 163.

⁷⁸ At 179 -180.

applied strictly.⁷⁹ The Court, therefore, concluded that the physico-chemical properties of beta crystalline Imatinib Mesylate⁸⁰ may be beneficial but do not add anything to therapeutic efficacy.⁸¹ On the contention submitted on behalf of Novartis that the beta crystalline form of Imatinib had increased bioavailability, the Court held that an increased bioavailability, in the absence of compelling proof, may not necessarily lead to an enhancement of therapeutic efficacy;⁸² hence Novartis' bid for a patent for the beta crystalline form of Imatinib Mesylate had to fail.⁸³

In conclusion, the Court firmly ruled that the impugned form of Imatinib failed the test of invention as provided for in section 2(1) clauses (j) and (ja) and section 3(d) and it did not have enhanced therapeutic efficacy and Novartis' appeal had to inevitably fail.⁸⁴

In order to avoid doubt and a possible misinterpretation of its judgment in light of the overflowing public interest in the matter both in India and Internationally, the Supreme Court issued a valedictory note of clarity.⁸⁵ The Court held quite correctly, in my view that the import of its judgment was not to outlaw incremental inventions of chemical and pharmaceutical patents; but that only those chemical and pharmaceutical inventions that did not lead to the enhancement of therapeutic efficacy were barred by the judgment.⁸⁶ This clarification is welcome for jurisprudential certainty and puts Indian patent law on the subject in a positive light.

As anticipated, the decision was warmly welcomed by access groups and patent organisations in India and beyond. Given India's key role in the global supply of affordable medicines, both patented and generic, there is no gainsaying that the decision has worldwide,⁸⁷ including SADC, implications.

⁷⁹ Novartis case at para 182.

⁸⁰ Namely that it has more beneficial flow properties, better thermodynamic stability and lower hygroscopicity.

⁸¹ At para 187.

⁸² At para 189.

⁸³ At para 190.

⁸⁴ At para 195.

⁸⁵ At para 191.

⁸⁶ At 191.

⁸⁷ Lofgren H "India's Novartis Patent Ruling Puts Health Before Profits" (2013) *The Conversation* at 1.

6.1.3 An Evaluation of the case and Lessons for SADC

From the above narration of facts and the outline of the decision of the Supreme Court of India, it is important to emphasize what the court said and did not say.⁸⁸ The court did not say a new form of a known compound could not be patented; neither did it say that improving bioavailability characteristics of a drug may not result in enhanced efficacy.⁸⁹ Rather, the court left open the issue of whether enhanced efficacy refers narrowly to the curative effect of the drug or more broadly to improved safety and reduced toxicity of the drug.⁹⁰ This clarity is important for allaying the fears of the US and like-minded countries that always conceive of the contextual application of TRIPS flexibilities as an affront to IP rights.

For SADC, the way in which the Indian Supreme Court dealt with the application of section 3 (d) in the specific context should be encouraging. SADC members must be emboldened by this decision and embark on IP law reform that takes into account each member's individual social and other needs. As previously mentioned, section 3 (d) is TRIPS-plus but it does not follow that TRIPS-plus IP legislative provisions are WTO-illegal.⁹¹ South Africa has taken the lead and has boldly stated in its Draft IP Policy that it will not tolerate incremental patenting and a proliferation of ever green patents.⁹²

The decision in Novartis is also important for other reasons,⁹³ which are very relevant for the context obtaining in the SADC.

Although the rejection of Novartis' claims was met with criticism from the pharmaceutical industry as shifting the balance too much in favour of the protection of public health,⁹⁴ the fact that the decision did give prominence to public health issues over IP must be celebrated as relevant to the current SADC situation crying for reform. In the judgment itself, the Supreme Court in the course of narrating the history of IP law in India said that the Committee under the

⁸⁸ Abbott above at 3.

⁸⁹ Ibid.

⁹⁰ Novartis case at para 191.

⁹¹ Abbott at 3 submits that there is nothing wrong with the Indian strict standard and a similar approach was followed by the US Patent Office until the decision in the Court of Appeals for the Federal Circuit, in the case of *In re Brana* 34 USPQ2d at 1441 (Fed. Cir. 1995).

⁹² See Chapter Five above.

⁹³ Some authorities like Raju KD "Interpretation of section 3(d) of the Indian Patents Act 2005: A case Study of Novartis" (2008) 2 *Indian Journal of Intellectual Property Law* at 7, regard the case and its development as a 'saga'.

⁹⁴ Barazza S "Incremental Pharmaceutical Innovation in India: the Supreme Court's Judgment in the Novartis *Gleevec* case" (2013) 8 *Journal of Intellectual Property Law and Practice* at 776.

chairmanship of Justice N. Rajagopala Ayyangar “took a fresh look at the law of patents to completely revamp and recast it to best sub-serve the (contemporary) needs of the country”.⁹⁵ Patent systems are not created in order to satisfy the interests of the inventor but rather to take care of the interests of the economy.⁹⁶ The above observation rings very true for the SADC region which should revamp its patent laws by taking advantage of TRIPS flexibilities in the context of regional priorities. Indeed, the rejection of Novartis’ application was widely regarded as victory for public health, which is always in constant clash with the pharmaceutical industry.⁹⁷

The debate over the patentability of pharmaceuticals has been intense and in the majority of instances emotional to the extent of becoming political when the right to patent exclusivity is pitted against the right to public health.⁹⁸ The Supreme Court of India displayed sensitivity to the potential conflict, both for social and economic reasons.⁹⁹ The Court did, in actual fact, show that it was better aware of the conflict when it clearly recognized that the current IP system seeks to promote both innovation and social economic welfare of India, thus making the benefits of the patented invention available at reasonably affordable prices to the public.¹⁰⁰

It is worth buttressing the observations in the foregoing paragraph that the decision in Novartis relating to the interpretation of section 3(d) was well reasoned and that similar decisions have been handed down in other parts of the developed world in similar contexts.¹⁰¹ The main aim of section 3 (d) as previously explained is to prevent ever greening and avoid the issuance of patents that are of a low quality and add insignificant improvements to the state of the art.¹⁰² The concern with evergreen patents is not unique to India.¹⁰³ It is also important to note that the

⁹⁵ Novartis case at para 34.

⁹⁶ Ibid at para 36.

⁹⁷ ‘t Hoen E “A Victory for Global Public Health in the Indian Supreme Court” (2013) 34 *Journal of Public Health Policy* at 370.

⁹⁸ Barazza above at 786.

⁹⁹ Ibid.

¹⁰⁰ Ibid at 786.

¹⁰¹ Ibid at 786 – 787. The pertinent cited cases are *Pfizer Inc. v Apotex Inc.* [2007] 480 F 3d 1348; *Takeda Chemical Industries Ltd v Alphapharm Pty Ltd* [2007] 492 F 3d 1350; *SmithKline and French Laboratories v Evans Medical Aid Ltd* [1989] FSR 561; *In re Dillon* [1990] 919 F 2d 688; *In re Deuel* [1995] 51 F 3d 1552; *In re Elli Lilly and Company v Premo Pharmaceutical Laboratories Inc* [1980] 630 F 2d 120 ; and *Les Laboratoires Servier v Apotex Inc* [2008] EWCA 445.

¹⁰² Roderick P and Pollock AM “India’s Patent Laws under Pressure” (2012) 380 *The Lancet* at 2.

¹⁰³ In the EU, the European Commission looked into the issue and produced a “Pharmaceutical Sector Inquiry”, which is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last visited 20/09/2013). The US side of the debate is ably canvassed in Glasgow LJ “Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry gone too far?” (2001) *The Journal of Law and*

patent which Novartis sought to register in India was initially rejected by the US patent authorities for lack of novelty and only granted on appeal in May 2005.¹⁰⁴ Ever greening is compounded by weak patent examination systems and chokes technological progress.¹⁰⁵ In the SADC region, it has been reported elsewhere that a number of member states do not provide for a patent examination system, hence ever greening is likely to proliferate.¹⁰⁶

Nowhere else in the SADC region is the problem better illustrated than in South Africa. According to the Treatment Action campaign (TAC) and Médecins sans frontières (MSF), in South Africa, Novartis managed to register a patent for a ‘new use’ of Imatinib which does not expire until 2022, even though the original patent was set to expire earlier in 2013.¹⁰⁷ To treat chronic myeloid leukaemia for one year in South Africa using Novartis’ Imatinib costs over R387,000, a price out of reach for most South Africans and medical aid schemes. The stark irony is that what Novartis lost in the Supreme Court of India was gained in South Africa through the registration of a secondary new use form of Imatinib. This should be a lesson for fellow SADC members to seriously consider patent law reform that takes care of the loopholes in their laws relating to the requirements for patentability and the absence of a patent examination system. Patent thickets around a single molecule are particularly perverse in the pharmaceutical drug industry when “minor modifications such as changes in size, colour, dosage, delivery mechanisms and compositions are either simultaneously or subsequently patented”.¹⁰⁸ India should be applauded for nipping this practice in the bud in the Novartis case as has been highlighted above.

On the other hand, when pharmaceutical companies seek to maximize profits by patenting incrementally despite the obvious lack of novelty and inventive step, such behaviour, as was the case with Novartis in this instance, may fairly be characterized as patent abuse aimed at

Technology at 227, while for Australia, Chalmers RA “Evergreen or Deciduous? Australian Trends in relation to the ‘evergreening’ of Patents” (2006) 30 *Melbourne University Law Review* at 29

¹⁰⁴ Coventry DR “Novartis Firmly Put in Place” (2013) *HardNews* at 1 available at <http://www.hardnewsmedia.com/2013/07/593?page=show> (last visited 03/11/2013).

¹⁰⁵ Ibid.

¹⁰⁶ See specifically, Chapter Four above.

¹⁰⁷ See TAC and MSF “SA’s Dept of Trade and Industry Delay Patent Law Reform, while local Drug Prices Remain Excessive”, available at <http://www.fixthepatentlaws.org/?p=638> (last visited 03/12/2013).

¹⁰⁸ Coventry above at 2.

registering patents over minor insignificant changes in order to extend monopoly prices.¹⁰⁹ It is submitted that in addition to having robust legislative provisions along similar lines to India's section 3(d), SADC members may react to such forms of abuse through the deployment of compulsory licenses for abuse, as ably provided for in most IP legislations of the member states.

The Novartis judgment delivers the clearest and loudest message that the problem of low quality patents continues, aided and abetted by low quality patent examinations in the absence of pre- and post-grant patent opposition. May be it is now time to have many third world emulations of India's section 3(d), and such emulation seems to have already started in all earnest in Argentina, China and Thailand.¹¹⁰ The decision in Novartis must be celebrated taking into account how it testifies to the "flawed project of global harmonization of intellectual property laws",¹¹¹ which currently remains a pipedream which SADC and the developing world can transform into context-specific reality through what Musungu, Villanueva and Blasetti characterize as 'South-South cooperation'.¹¹²

The Novartis decision demonstrates that TRIPS flexibilities are not a paper tiger and can be used despite the pressure from big pharmaceutical companies and the US government.¹¹³ From the precedent set by the Novartis case, it is now possible for governments in developing countries (including the SADC) to set stringent patentability criteria for pharmaceuticals in order to facilitate the early entry of life-saving, low cost generics.¹¹⁴

Because countries like India, China, Brazil and Thailand bring political and economic resources to bear in their interactions with multinational pharmaceutical companies and governments in the US and Europe,¹¹⁵ such strength may be used collaboratively to the benefit of other developing countries through South-South cooperation.¹¹⁶ It will be recalled that pharmaceutical product patents were not recognized in India between 1972 and 2005, which is a situation that enabled

¹⁰⁹ At least this seems to have been the view of the Supreme Court in the Novartis case at para 19 wherein the Court opined that such high prices are prone to result in the creation of public disorder.

¹¹⁰ Coventry above at 3. The author further adds that there were reports soon after the judgment that Australia and Canada were considering provisions similar to section 3 (d).

¹¹¹ Coventry above at 3.

¹¹² See generally Musungu SF, Villanueva S and Blasetti R *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks* (2004) 35 – 79.

¹¹³ Lofgren above at 3.

¹¹⁴ Lofgren above at 3.

¹¹⁵ Ibid.

¹¹⁶ Musungu, Villanueva and Blasetti above at 46.

the generic drug industry to flourish in India.¹¹⁷ This enabled India to supply the domestic market and external markets (both developed and developing) with affordable generic drugs.¹¹⁸ For example, it is reported that the entry of Indian firms in the global drug supply market¹¹⁹ lowered the prices of first-line triple combination antiretrovirals (ARVs), used in the treatment of HIV, from US\$15 000 per person per annum in the year 2000 to less than US\$120 in 2012.¹²⁰ While the drug in dispute in the Novartis case had nothing to do with HIV/AIDS, this disease is very important for SADC, and had the Supreme Court interpreted section 3(d) in favour of Novartis or struck it down completely, this would have had a devastating effect on access to medicines generally and HIV/AIDS drugs in particular. The importance of this decision in an HIV/AIDS context is aptly captured by Loon Gangte, president of the New Delhi Network of Positive People (DNP+), interviewed by William New on the eve of the decision on the Novartis case when he said, “We rely on the availability of affordable AIDS drugs and other essential medicines made by the Indian generic manufacturers to stay alive and healthy”.¹²¹

In concluding the discussion of the lessons for SADC from the Novartis case, it is important to refer to the role that was played by civil society groups to highlight the high stakes and importance of access to medicines. It has been reported that the outcome is consistent with the pattern in the 1990s of a *de facto* coalition between health advocates, NGOs and some governments, including India, desirous of limiting the impact of IP on access to medicines.¹²² It needs to be recalled that various advocacy groups, such as Médecins sans frontières, Health Gap in the US, Delhi Network of Positive People and the Swiss-based Berne Declaration took part in lobbying against the Novartis case.¹²³ Additionally, leading up to the Novartis AGM, demonstrations were held in a number of US cities such as Boston, New York and Washington, while in India, more demonstrations were held as a way of drawing attention to the Novartis

¹¹⁷ Lofgren H “David and Goliath: Novartis Challenges India’s Patent Law” (2012) *The Conversation* at 2 (hereafter Lofgren 2).

¹¹⁸ Ibid.

¹¹⁹ The importance of India as the ‘pharmacy of the world’ was highlighted in the letters from the HIV/AIDS Director of the WHO and the Director of Advocacy, UNAIDS, highlighting the importance of India in the world pharmaceutical market, reproduced by the Supreme Court of India in paras 76 – 77 on the Novartis judgment.

¹²⁰ Lofgren 2 above at 2.

¹²¹ New W “Indian Supreme Court to Hear Novartis Challenge to India’s Patent Law” (2011) *Intellectual Property Watch* at 1.

¹²² Lofgren at 3.

¹²³ Esalimba R “Novartis Persists in Challenge to the Indian Patent Law; India Rejects More Aids Drugs Patents” (2009) *Intellectual Property Watch* at 1.

case.¹²⁴ The role of civil society in promoting access to medicines has been mentioned and emphasized elsewhere,¹²⁵ and need not be repeated here, save to say that apart from South Africa, most SADC countries have limited civil society activity, or like in Zimbabwe, selectively criminalise civil society activities. In the Novartis case, there was a coalition of civil society groups from within India and beyond. The success of such a coalition should be an informative thematic lesson for SADC in the context of regional IP reform to improve access to medicines.

The Novartis case is therefore very important in the context of this study because it clearly shows that with a government that is sensitive to the peculiar public health needs of its people, it is possible to take full advantage of the TRIPS flexibilities aided by an independent judiciary and a robust civil society that works well with its global counterparts. The decision scored a victory for the generic industry in India by arresting incremental patenting and ever greening. The victory was achieved through the deployment of patentability provisions and opposition procedures in the Indian Patents Act.

It is now appropriate to look at the problem of incremental patenting and how it can be remedied through the use of patent opposition procedures in a comparative jurisdiction with a different patent legislative history than India. Once again, like we did with the case of Novartis, thematic lessons will be extracted for the SADC access to medicines law reform project.

6.2 Effective use of Patent Opposition in Thailand

Thailand, the only developing country in South East Asia that did not fall under colonial rule,¹²⁶ is moving very fast into globalisation and international trade.¹²⁷ Because Thailand's economy is highly export oriented, this makes it very vulnerable to foreign pressures and external economic dynamics.¹²⁸ As an example of this foreign pressure, in 1992 the Office of the United States Trade Representative (USTR) pressurized and forced Thailand to introduce product patents¹²⁹ and pipeline pharmaceutical patent protection together with market exclusivity under a Technical

¹²⁴ Hermann RM "Novartis Before India's Supreme Court: What's Really at Stake?" (2012) *Intellectual Property Watch* at 2.

¹²⁵ See Chapter Five above.

¹²⁶ Gulik CV "The Right to Health in International Human Rights Law: Reflections from Thailand, South Africa and the Philippines" (2004) *Law and Development.Org* at 9.

¹²⁷ Wibulpolprasert S "Mobilising of Domestic Resources for Essential Drugs in Developing Countries: Case study from Thailand" (2013) at 1 available at http://www.wto.org/english/tratop_e...08wibulproprasert_e.doc (last visited 06/12/13).

¹²⁸ Ibid.

¹²⁹ Thailand had until then, like India, only provided for process patents.

Safety Monitoring Programme.¹³⁰ This programme enhanced the increasing drug prices and reduced the accessibility of essential drugs.¹³¹

The current Thai Patent Law provides for parallel imports, bolar-type exceptions and compulsory licenses, TRIPS flexibilities which are not easy to take advantage of due to the conditions imposed by the law, which has been labelled as TRIPS-plus.¹³² While the limitation on access to drugs has been noticeable in all therapeutic classes in Thailand, the situation has been made dire by the HIV/AIDS pandemic, with specific reference to the antiretroviral drugs.¹³³

In Thailand, more than 400 000 people lived with HIV/AIDS in 2013.¹³⁴ In the year 2000, more than 1 million people were reported to be HIV-infected and there were more than 100 000 sick people with full blown AIDS.¹³⁵ Additionally, it was estimated that less than 5% of the Thai HIV/AIDS patients could afford double antiretroviral therapy.¹³⁶ While several antiretroviral products are registered in Thailand, only azidothymidine (AZT) and Didanosine (DDI) are classified as essential drugs.¹³⁷ Generic versions of AZT were readily available as early as 1993 while there were no generics for DDI. This led to litigation by Thai activist groups in the case of *Access Foundation and others v Bristol-Myers Squibb Co. Ltd and Others*, (Didanosine case)¹³⁸ in which a post-grant patent challenge was brought against Bristol-Myers Squibb with positive access to medicines results.¹³⁹ Because the post-grant challenge was made possible through Thailand's progressive patent laws allowing for such, it is appropriate to first give an outline of the patent opposition in Thailand before outlining the facts of the case and the subsequent decision of the court.

¹³⁰ Wibulpolprasert above at 1.

¹³¹ Ibid.

¹³² Timmermans K and Hutadjulu T "The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals" workshop held in Jakarta, Indonesia from 2-4 May 2000 at 36.

¹³³ Timmermans and Hutadjulu above at 37.

¹³⁴ See UNAIDS "Thailand" at <http://www.unaids.org/en/regionscountries/countries/thailand/> (last visited 06/12/2013).

¹³⁵ Timmermans and Hutadjulu above at 37.

¹³⁶ Ibid.

¹³⁷ Timmermans and Hutadjulu at 37. AZT was approved for marketing in Thailand in 1987 while ddI was approved in 1992.

¹³⁸ *Access Foundation and others v Bristol-Myers Squibb Co. Ltd and Others* IP 93/2545 [2002] THCIPITC 1 (1 January 2002).

¹³⁹ The case is discussed in 6.2.3 below.

6.2.1 A Short Primer on Patent Opposition in Thailand

In terms of Thailand's Patents Act,¹⁴⁰ patents may be granted for invention patents,¹⁴¹ design patents¹⁴² and petty patents.¹⁴³ An invention is defined in the Patents Act as "any discovery or invention resulting in a new product or process, or any improvement of a product or process".¹⁴⁴ A design on the other hand refers to "any configuration of a product or composition of lines or colours which gives a special appearance to a product and can serve as a pattern for a product of industry or handicraft".¹⁴⁵ Petty patents are utility model patents and are granted to 'inventions' that are new and industrially applicable but lack an inventive step and the term thereof is six years.¹⁴⁶

In general terms, patent opposition may be characterized as a general term which refers to the various ways in which challenges to the validity of a patent, either during the patent application review period or after the patent has been granted may be brought. In Thailand, the patent opposition procedure was introduced in 1979 and the country's pre-grant opposition procedure has proved to be greatly useful, as evidenced by several decisions of the Thai Board of Patents.¹⁴⁷ The patent opposition procedure prevents undeserving patents from dominating the market and stifling competition.¹⁴⁸ This improves patent quality and in the context of access to medicines, it ensures that generic medicines are introduced unhindered by patent extensions based on minor modifications of the original patent as soon as the patent expires. Additionally, opposition creates an incentive for third parties and competitors to make the opposition application accurate and convincing, thus aiding the patents offices by lessening the patent examination burden.¹⁴⁹ In an environment with a vibrant patent opposition culture, patent litigation may be reduced and social welfare enhanced.¹⁵⁰

¹⁴⁰ Patent Act B.E. 2522 (1979), as Amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999) (hereafter Patents Act).

¹⁴¹ From sections 3 – 55 of the Patents Act.

¹⁴² From sections 56 – 65 of the Patents Act.

¹⁴³ From sections 65*bis* - 65*decies* of the Patents Act.

¹⁴⁴ Section 3 of the Patents Act.

¹⁴⁵ *Ibid.*

¹⁴⁶ Vachanavuttivong D and Adcock A *Intellectual Property in Thailand: Registration Protection and Commercialisation* (2012) at 7.

¹⁴⁷ Puasiri W "Improving Patent Quality through Pre-grant Opposition in Thailand" (2013) 8 *Journal of International Commercial Law and Technology* at 219.

¹⁴⁸ *Ibid.*

¹⁴⁹ Puasiri above at 223.

¹⁵⁰ *Ibid.*

The patent pre-grant opposition procedure¹⁵¹ in Thailand allows an interested person to oppose the registration of a patent within 90 days after the patent application has been published.¹⁵² There are a number of safeguards built into the Thai law to allow patent opposition to proceed in a fair and just manner. If an opposition is rejected by the Director General of the Department of Intellectual Property, the aggrieved party may appeal to the Board of Patents.¹⁵³ If the Board of Patents rejects the appeal, then it is possible to take the matter up with the Central Intellectual Property and International Trade Court within 60 days of the Board's rejection.¹⁵⁴ It is still possible, if the Court rejects the appeal, to take the matter further to the Intellectual Property and International Trade Division of the Supreme Court of Thailand for further recourse.¹⁵⁵

From the above outline of the different appeal routes, it is evident that Thailand has a good systematic patent law and takes patent opposition, for which there are robust provisions, very seriously. Therefore, in the context of this study, the patent system is worthy of study¹⁵⁶ as an example of a patent opposition system from which other countries, including the SADC region can learn.

The patent opposition process as outlined by the Patents Act is summarized in the schematic diagram below which is by and large self-explanatory.

¹⁵¹ Provided for in Sections 30 – 34 of the Patents Act.

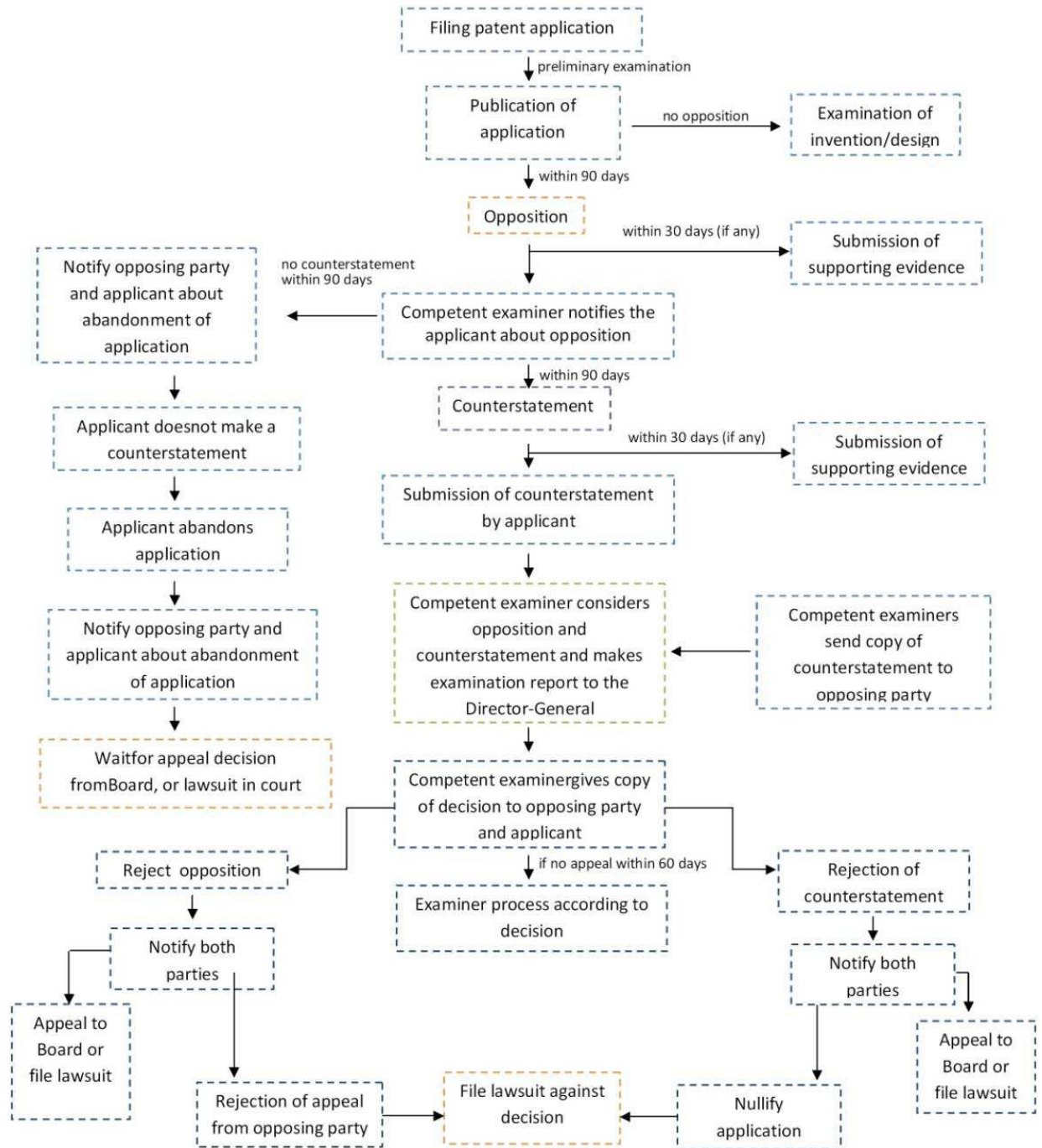
¹⁵² Section 28 of the Patents Act.

¹⁵³ Pwasiri above at 227.

¹⁵⁴ Ibid.

¹⁵⁵ Ibid.

¹⁵⁶ Pwasiri above at 227.



Flowchart of the Thai Patent Opposition Process (Source: Puasiri W (2013):134)

6.2.1.1 Brief Explanatory note on the Flowchart

The Thai Department of Intellectual Property publishes a list of new patents in the gazette and online¹⁵⁷ every month. After a patent application has been published, anyone wishing to oppose may make notification of the opposition on the ground that he is entitled to the patent or the application does not comply with specific sections of the Patents Act.¹⁵⁸ The opposing party who wishes to submit evidence supporting his opposition may do so within 30 days of the filing of notice of opposition, upon payment of a fee.¹⁵⁹ The applicant for a patent has an opportunity to oppose the notice of opposition within 90 days of receipt of the notice from the officer. The applicant can supply evidence to his opposition by submitting a counterstatement accompanied by a modest fee.¹⁶⁰ The Director General will then make a determination and inform the parties accordingly, and any aggrieved party may appeal the outcome in terms of the procedure outlined in 6.2.1 above.

6.2.2 Examples of Successful Pre-grant Patent Opposition in the Pharmaceutical context in Thailand

The most important category of opposition involves medicine because patented medicines are sold at high prices which the majority of sick people in Thailand cannot afford.¹⁶¹ Such patents are likely to have negative effects on other pharmaceutical companies, inventors, NGOs and individual families.¹⁶² Therefore, successful pharmaceutical oppositions by individual patients, government organisations and NGOs have secured justice, social benefits and the right to life by making it possible for patients to access affordable life-prolonging medication.¹⁶³

¹⁵⁷ The online version is published on the department's website available at <http://www.ipthailand.go.th/ipthailand/index.php?lang=en> (last visited 06/12/2013).

¹⁵⁸ Namely sections 5 (lack of novelty, inventive step and utility); 9 (specific exclusions from patentability, such as plants and animals); 10 (inventor not qualified to apply for a patent); 11 (patent applied for in the course of employment which should designate employer as the applicant) and 14 (applicant does not qualify on basis of nationality or membership of convention country).

¹⁵⁹ At the time of writing, the fee was 250 Thai Baht, almost equivalent to R80.

¹⁶⁰ The fee is 50 Thai Baht, equivalent to about R16.

¹⁶¹ Puasiri above at 245.

¹⁶² Ibid.

¹⁶³ Ibid.

6.2.2.1 *The Case of Thai Mixed Herbal Medicines*

Chulalongkorn University applied for a patent for a mixed herb formula for the treatment of HIV/AIDS patients but the application was opposed on the basis that the formula was well known in Thailand traditional medicine circles.¹⁶⁴ Additionally, the formula had been published in several journals and patent applications, hence it was alleged that it was part of the state of the art.¹⁶⁵ In a decision that was delivered in 2004,¹⁶⁶ the Director General rejected the application for the patent on the basis that the formula had no inventive step or no new healing results after the mixing, thus upholding the opposition.

The University appealed the decision of the Director General to the Board of Patents, which upheld the Director General's decision for the same reasons.¹⁶⁷ The successful opposition yielded positive results for HIV/AIDS patients who continued to make use of inexpensive Thai traditional herbs in an open market uninhibited by patent thickets. This decision is important for SADC in the context of indigenous knowledge and traditional medicine as these are issues which are not uniformly regulated in member countries.

In the next two decisions, it was a government department, namely the Government Pharmaceutical Organisation (GPO), which filed patent oppositions against foreign pharmaceutical companies.

6.2.2.2 *Thai Government Department Opposition against Intermune Inc.*¹⁶⁸

In this case, Intermune Inc., a global biopharmaceutical company with its headquarters in the US town of Brisbane, applied for a patent in Thailand for a method of treating chronic hepatitis C in patients who had previously failed to use antiretroviral therapy.¹⁶⁹ Thailand's Government Pharmaceutical Organisation (GPO) opposed the application on the basis that it was a patent for a method of treatment of a disease or ailment, contrary to the provisions of existing patent law.¹⁷⁰

¹⁶⁴ Pwasiri above at 245 – 246.

¹⁶⁵ Ibid.

¹⁶⁶ Decision of Thai Board of Patents No. 10/2547.

¹⁶⁷ Pwasiri above at 246.

¹⁶⁸ 2010 Decision of the Thai Board of Patents NO. 1/2553.

¹⁶⁹ Pwasiri above at 247.

¹⁷⁰ Section 9(4) of Thailand's Patents Act prohibits the patenting of "methods of diagnosis, treatment or cure of human and animal diseases". This provision seems to be based on Article 27 (3) (a) of the TRIPS Agreements which urges WTO members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals".

While the Director General rejected the opposition, the Board of Patents upheld it and ruled quite correctly, in my view, that the specific application ran afoul of section 9(4) of the Patents Act. The pertinent section, which prohibits the patenting of methods of treating disease, was truly written for the public benefit.¹⁷¹

6.2.2.3 Thai Government Department Opposition against Novartis' Organic Compound

In this case, Novartis International AG, applied for an invention patent in Thailand for the integration of an organic compound, but the GPO opposed the application on the basis that it did not relate to a new invention since it had been disclosed in a US patent application¹⁷² four years ago.¹⁷³

Although Novartis countered the opposition by saying that the invention had an inventive step and was different from the US patent, the Director General went ahead and rejected the application for a patent on the basis of the GPO opposition.¹⁷⁴ Novartis appealed the decision of the Director General to the Board of Patents, arguing that the product for which the patent was applied for was unique in that its integration yielded unexpected results thus producing certain inhibitors that were very beneficial in combatting blood pressure.¹⁷⁵ The Board of Patents ruled that in addition to the alleged invention not being new in light of an earlier US patent, the unexpected result claimed by Novartis did not exist since no improved result was found. For that reason, Novartis' application for a patent had to fail and the opposition succeeded.

In all the cases briefly outlined above, pre-grant patent opposition proved to be an effective tool with which to monitor patent quality. To sum up, the opposition process is necessary since it unearths patents of a poor quality and also protects social benefits, such as the right to health. It is appropriate to recommend that developing countries, particularly SADC members must adopt patent opposition procedures. Had the patents not been opposed and granted, this would have had a negative effect on access to medicines. Furthermore instituting revocation proceedings would have added more legal red tape and the usual frustrations that usually accompany litigation. The

¹⁷¹ Pwasiri above at 247.

¹⁷² The GPO cited US patent No. 5952356 as the US patent in question.

¹⁷³ See Decision of the Thai Board of Patents No. 1/2554.

¹⁷⁴ Pwasiri above at 247.

¹⁷⁵ Ibid.

lessons for SADC law reform in sympathy to access to medicines are axiomatic; it is now time to adopt post grant patent opposition in the same way as it was recently done in Botswana.¹⁷⁶

In the context of access to medicines, one major thing in common between Thailand and most SADC countries is the prevalence of the HIV/AIDS pandemic. Therefore, a detailed discussion of a successful patent opposition in the context of the pandemic is very appropriate in this chapter. The Didanosine case, decided by the Thai Central Intellectual Property and International Trade Court¹⁷⁷ in 2002 is very important in the Didanosine case Thai HIV/AIDS struggle and has some useful lessons for SADC. Following is a discussion of the Didanosine case.

6.3 Effective Post-grant Opposition: the Didanosine Patent Case¹⁷⁸

The most widely recognized case of patent opposition which was brought to Thailand's Central Intellectual Property and International Trade Court in 1999 involved a suit against the department of Intellectual Property with respect to the grant of a patent to Bristol Myers Inc. for the antiretroviral drug Didanosine (DDI).¹⁷⁹

It is important to write that the original patent application by Bristol Myers for DDI did not attract any pre-grant opposition for unexplained reasons.¹⁸⁰

6.3.1 The Factual Background to the Dispute

The plaintiffs were the AIDS Access Foundation, an NGO advocating for the rights of people living with HIV/AIDS in Thailand, and two people living with HIV/AIDS while the defendants

¹⁷⁶ See Chapter Five above.

¹⁷⁷ I had the rare privilege of visiting this Court in Bangkok and interacting with some judges and support staff on the 12 November 2013 as a delegate to the International Conference on Trade and IP Law, organized by the International Association of IT Lawyers from 11-15 November 2013.

¹⁷⁸ Because the full text of the judgment in this case is only available in the Thai language, I had to rely on an outline of the translated facts, the decision and excerpts, available on the website of Global Health and Human Rights Database at <http://www.globalhealthrights.org/asia/aids-access-foundation-and-ors-v-bristol-myers-squibb-and-department-of-intellectual-property/> (last visited 06/12/2013). Another rather short version of the judgment translated by Warakhom Liangpandh for UNDP and published by the University of Pretoria Centre for Human Rights is available at www.chr.up.ac.za/undp/doc/caselaw1.pdf (last visited 06/12/2013).

¹⁷⁹ Pwasiri above at 247.

¹⁸⁰ According to Pwasiri above at 247, it may be possible that the opposition parties were not able to file an application within the mandatory 90 days or they did not know about the application until a patent was granted.

were Bristol Myers Inc. and Thailand's Department of Intellectual Property, which was later summoned by the court as a co-defendant.¹⁸¹

Bristol Myers Inc. applied for a patent for DDI,¹⁸² a reverse transcriptase inhibitor effective against HIV/AIDS and used in combination with other antiretroviral (ARV) drugs.¹⁸³ The patent claim specified that the invention was a "better formula for oral use of Dydeoxy Purine Nucleocide" and stipulated the dosage as "from about 5 to 100mg per dose".¹⁸⁴ The Department of Intellectual Property granted the patent with the specified dosage but later 'conspired'¹⁸⁵ with Bristol Myers Inc. to intentionally delete the phrase "from about 5 to 100 mg per dose" and left the patent claim widely encompassing.¹⁸⁶ This deletion had the effect of allowing Bristol Myers to produce HIV/AIDS medication of whatever dosage, which negatively affected the rights of others to use the medicine.¹⁸⁷

6.3.2 *The Parties' Contentions*

The plaintiffs claimed that the amendment was unlawful and that the Court must compel Bristol Myers to revert to the old dosage stipulation.¹⁸⁸ The plaintiffs further argued that without the stipulation, Bristol Myers' patent would be too broad to the extent of severely restricting access to affordable medication in violation of the rights of HIV-positive people in Thailand.¹⁸⁹ It was further submitted on behalf of the plaintiffs that Bristol Myers must pay for the cost of publishing the amended patent claim in five daily newspapers for 10 days.¹⁹⁰

Bristol Myers in its defence argued that it had no legal relationship with the plaintiffs; hence the plaintiffs were not entitled to apply to the court for the amendment sought.¹⁹¹ The plaintiffs therefore, did not have the authority to take the legal action they sought to take and furthermore, they had no authority to force Bristol Myers to advertise the amended patent in the daily

¹⁸¹ *Access Foundation and others v Bristol-Myers Squibb Co. Ltd and Others* (Didanosine case) at 1 – 2. The summoning of the Department of Intellectual Property happened pursuant to section 57 (3) (b) of Thailand's Civil Procedure Code.

¹⁸² Patent No. 7600.

¹⁸³ Didanosine case at 1.

¹⁸⁴ Didanosine case at 1.

¹⁸⁵ The Court, at 1 characterised the deletion as an 'illegal amendment'.

¹⁸⁶ *Ibid.*

¹⁸⁷ *Ibid.*

¹⁸⁸ *Ibid.*

¹⁸⁹ *Ibid.*

¹⁹⁰ *Ibid.*

¹⁹¹ *Ibid* at 2.

newspapers as claimed.¹⁹² Bristol Myers claimed to have inverted a ‘better formula for oral use of Deydeoxy Purine Nuecleocide’ as categorized in the patent specification and that the invention had a positive effect on the treatment of HIV/AIDS.¹⁹³ Bristol Myers argued that the improved product should be regarded as a positive contribution and advantage to people with HIV/AIDS, including the plaintiffs.¹⁹⁴ Bristol Myers submitted that it had complied with the relevant Thai laws by submitting the application for a patent, advertising the application and submitting it for examination. Additionally, Bristol Myers had effected an amendment to its application, which amendment ought to be regarded as not being material to the invention.¹⁹⁵ The fact that the amendment was accepted by the Department of Intellectual Property deemed the invention legal.¹⁹⁶ Bristol Myers sought to rely on section 36 *bis* of the Patents Act, which provides that the scope of an invention shall be determined by the claims, and reasoned that the amendment did not adversely affect the plaintiffs because the portion for use must be in accordance with what is detailed in the claims.¹⁹⁷

The Department of Intellectual Property (DIP), which was cited as a co-defendant, argued that the plaintiffs had no *locus standi* in the matter because they were not manufacturers of medicines.¹⁹⁸ The DIP further argued that the two other plaintiffs, both of them HIV/AIDS sufferers, could choose other medicines to cure HIV/AIDS without having to use DDI.¹⁹⁹ The DIP also argued that the case did not fall into any of the class of cases stipulated in the law where certain categories of injured or interested parties are entitled to apply for an amendment of a defendant’s patent.²⁰⁰ The DIP also submitted that the fact that the dosage specification of ‘from about 5 to 100 mg per dose’ was removed from the specification did not imply that Bristol Myers was entitled to manufacture ARV medicine of any dosage as claimed by the three plaintiffs.²⁰¹

¹⁹² Didanosine case at 2.

¹⁹³ *Ibid.*

¹⁹⁴ *Ibid.*

¹⁹⁵ *Ibid.*

¹⁹⁶ *Ibid.*

¹⁹⁷ *Ibid.*

¹⁹⁸ *Ibid.*

¹⁹⁹ *Ibid.*

²⁰⁰ The specific provision is section 54 of Thailand’s Patents Act which provides that any patent granted not in compliance with the provisions of Section 5, 9, 10, 11 or Section 14 shall be invalid, and any interested person or prosecutor may submit an application for invalidity to the court.

²⁰¹ Didanosine case at 2.

The DIP argued that the defendant's claims, as delimited by section 36 *bis* were narrow enough to show that only medicine prescribed in the details of the invention would be manufactured.²⁰²

6.3.3 *The Decision of the Court and Ratio*²⁰³

In the course of delivering its judgment, the court identified and settled the following issues which it characterised as in dispute:²⁰⁴

- Whether the plaintiffs' rights had been infringed, and whether they were interested parties entitled to make the claim;
- Whether the plaintiffs were entitled to force the defendant to register the amendment to the patent claim and pay the cost of advertising the amendments in daily newspapers;
- Whether the amendment to the patent claim by the defendant, which was sanctioned by the co-defendant ought to be regarded as material, and whether it was lawful; and
- Whether rights of a patent holder are limited to those stipulated in the patent claim, or details of the invention must also be considered as part of the scope of such rights.

With specific reference to the issue of *locus standi*, the court reasoned that the first plaintiff, AIDS Access Foundation was a juristic person in the category of a foundation with the objective of promoting physical and mental welfare of HIV/AIDS patients as well as to cooperate with other non-profit organisations.²⁰⁵ The other plaintiffs were categorized by the court as patients infected by HIV/AIDS. Having so characterised the plaintiffs, the court went further and reasoned that the defendant as the holder of the patent had an absolute power to prevent others from seeking to benefit from DDI, whether to manufacture, use, sell or import the medicine into the Kingdom of Thailand.²⁰⁶ The court, therefore, ruled that despite the plaintiffs not being in the business of manufacturing pharmaceuticals, they were interested parties to varying degrees and in appropriate contexts.²⁰⁷ Therefore, the plaintiffs were held to have *locus standi* in the matter.

²⁰² Didanosine case at 2.

²⁰³ Ibid.

²⁰⁴ Didanosine case at 3.

²⁰⁵ Didanosine case at 6

²⁰⁶ Ibid at 7.

²⁰⁷ Ibid. The Foundation, which has a function of helping HIV/AIDS patients to access medicines, was an interested party on that basis while the AIDS sufferers were directly affected by the existence of the patent on DDI.

The second issue that the court disposed of was the question of whether or not the amendment made to the patent specification by the defendant, which amendment was sanctioned by the co-defendant, was material and lawful. The amendment in question was the deletion from the specification of the words “from about 5 to 100 mg per dose”. Citing from the relevant provision of the Patents Act,²⁰⁸ which defines a product ‘invention’ as the creation or development that results in a new product, the court came to the conclusion that medicine which may be granted patent status may, therefore, be the invention of a new medicine product.²⁰⁹

Having thus reasoned, the court came to the conclusion that the formula or the determination of dosage of the medicine is an essential part of the invention of medicine products.²¹⁰ The court noted that amendments to patent claims are allowed by the law²¹¹ if such amendments are not material to the invention.²¹² The phrase “material to the invention” refers to both details of the invention and the patent claim, not only one of them.²¹³ The court, therefore, reasoned that the deletion of the phrase “from 5 to 100 mg per dose” from the original patent claim changed the materiality of the claim resulting in the patentee receiving protection for an unlimited dosage, going beyond the scope originally stipulated.²¹⁴ The amendment was therefore illegal and ran afoul of section 20 of the Patents Act, which provides that an applicant for such an amendment must comply with the rules and procedures stipulated in the Ministerial Regulations.²¹⁵

The final issue that fell for determination was whether the plaintiffs could force the defendant to register the amendment to the claim and pay the costs of advertising the amendment in the daily newspapers. The court ruled that in cases where the law does not prohibit a particular amendment, the plaintiffs are entitled to amend the patent claim and if the defendant fails to register the amendment, the co-defendant, the DIP, shall amend the patent claim of the defendant pursuant to the judgment of the court.²¹⁶ The court, therefore, held that the request of the

²⁰⁸ Namely section 3 of the Patents Act.

²⁰⁹ Didanosine case at 8.

²¹⁰ Ibid.

²¹¹ Section 20 of the Patents Act.

²¹² Ibid at 9.

²¹³ Ibid.

²¹⁴ Ibid.

²¹⁵ Clause 24 of the Thai Ministerial Regulations No 13 of 1992 requires that the applicant must submit the application to amend without changing any materiality therein before the advertisement of the application for a patent, except where exempted by the Director General.

²¹⁶ Didanosine case at 10.

plaintiffs that the phrase “from 5 to 100 mg per dose” be inserted in the defendant’s patent claim must be upheld.²¹⁷ The reason for this decision was that members of the public were only aware of the dosage as per the phrase, in terms of the patent that was advertised; and that when the phrase was removed, this was not advertised and strictly speaking, was not in the public domain.²¹⁸

On the narrow question of whether or not the plaintiffs could force the defendant to advertise the amendment and pay for it in the local newspapers, the court held that such a request had no legal basis and could not be upheld.²¹⁹

Accordingly, the court ruled that Bristol Myers and the DIP were required to implement the amendment of the invention and reinstate the original dosage formula of “from 5 to 100 mg per dose”.²²⁰

6.3.4 An Evaluation of the Case and Lessons for SADC

It is important to note that in this case, patent opposition was used to protect the rights of HIV-positive Thai citizens to access affordable medicines. The right to health did triumph over patent monopoly which would have had deleterious effects on access to medicines due to the broad patent claims resulting from the deletion of the phrase “from 5 to 100 mg per dose”.

In the course of delivering its judgment, the court remarked that medicines are important for human beings and very distinct from other products which consumers may or may not choose for consumption.²²¹ The rights to life and the health of the human being were cited as more important than any other property rights including IP.²²² The court referred to the Doha Declaration on TRIPS and Public Health²²³ and emphasized that the TRIPS Agreement must be interpreted and implemented in a manner which is supportive of public health, especially the promotion and access to medicines for all.²²⁴

²¹⁷ Didanosine case at 2.

²¹⁸ Didanosine case at 10.

²¹⁹ Ibid.

²²⁰ Ibid.

²²¹ Didanosine case at 7.

²²² Ibid.

²²³ It has been argued in some circles such as the Patent Database above at 2 that this decision was among the first judgments to refer to the Doha Declaration directly.

²²⁴ This was a contextual application of paragraph 4 of the Doha Declaration on TRIPS and Public Health.

By citing the Doha Declaration, the judgment shows that Thailand is not afraid of interpreting its law in a manner which is supportive of the country's own enforcement of the right to health, and by extension access to medicines for all. This should be good news for the SADC region, which is urged to consider domesticating the Doha Declaration and other TRIPS flexibilities along the lines of Botswana's Industrial Property Act. The reason why the Thai court in this case was able to apply the provisions of the Doha Declaration and come to an appropriate decision promoting access to medicines and the right to health was that the relevant municipal law incorporated the aspects of the Doha Declaration. The lesson for SADC in this context is short and simple – patent law reform incorporating TRIPS flexibilities and the Doha Declaration is long overdue.

In resolving the issue of interested parties, it is important that the court ruled that those living with HIV/AIDS could be injured by a broad patent blocking access to affordable medicine; hence they qualified as interested parties.²²⁵ It is submitted that it is sound legal reasoning to rule that those in need of medicines as well as those who fight for their rights, such as the AIDS Access Foundation, are interested parties to the granting of a patent. This should encourage civil society organisations²²⁶ and people living with HIV/AIDS and other prevalent diseases in the SADC region to challenge the grant of patents limiting access to medicines at both the pre- and post-grant stages of the patent application process.

From an access to medicines perspective, the court ruled that the amendment to the patent claim was unlawful because the removal of the dosage limitation expanded the scope of protection way beyond what was initially described and disclosed to the public in the original patent document.²²⁷ The ruling on this point is important in that by ordering that the defendant revert to the original dosage formula, this meant that non-patented DDI dosage forms could then be produced by generic manufacturers, with obvious positive outcomes for access to medicines. The decision is, therefore, very important, not just in the access to medicines fight in Thailand, but also in other developing countries as it affirms the fact that it is possible for public interest

²²⁵ Didanosine case at pages 7 – 8.

²²⁶ Ford N, Wilson D, Bunjumnong O and Angerer TVS (Ford et al) "The role of Civil Society in protecting public health over commercial Interests: lessons From Thailand" (2004) 363 *THE LANCET* at 561, the main civil society organisations promoting access to medicines in Thailand are Thai Foundation for Consumers (founded in 1983); Thai NGO Coalition on Aids (TNCA – formed in 1989); Thai Network for People Living with HIV/AIDS (TNP+ - established in 1998) and Médecins sans frontières (which began working in Thailand in 1994 at the invitation of local NGOs).

²²⁷ Didanosine case at 8 – 9.

groups to challenge patents.²²⁸ In Thailand, civil society groups have been very crucial in reaffirming the human right to health by challenging the actions of big pharmaceutical companies²²⁹ and the belligerent actions of powerful governments such as the US government.²³⁰

It will be recalled that in 1996, the generic production of Didanosine was blocked by Bristol Myers against the background of a very expensive branded version of the drug.²³¹ The US pharmaceutical industry had been complaining since 1975 that lack of product patent protection in Thailand was a market barrier to entry in Thailand, leading the US government to put pressure on Thailand to introduce stronger patent protection or face trade sanctions.²³² Thailand capitulated and introduced a series of reforms which entrenched the rights of multinational pharmaceutical patent holders at the expense of public health and investment in the local pharmaceutical manufacturing market.²³³ In 1999, the Thai GPO, supported by several local NGOs,²³⁴ submitted a request for a compulsory license to the DIP for DDI.²³⁵ In addition, the activists submitted a letter in the year 2000 to the US government, asking it not to retaliate if a compulsory license was granted.²³⁶ Despite the US government's indication in its response that it would not oppose a compulsory license issued in compliance with the TRIPS Agreement, the fear of retaliation still lingered on and the use of a compulsory license was rejected.²³⁷

The narrative outlined above relating to Thailand is very relevant to the SADC situation. In Chapter Seven below, one of the problems identified as militating against access to medicines is

²²⁸ See for example on a different but related note, an open letter dated 18 July 2012 ("Thai Civil Society opposes Gilead's Patent application") and signed by Thai Network of People Living with HIV/AIDS; AIDS Access Foundation, Alternative Agriculture Network; Friends of Kidney Failure Patients Club; Cancer Patient Network; Foundation for Consumers, the Rural Pharmacist Foundation, Foundation for Aids Rights; Thai NGO Coalition on AIDs; Drug Study Group; Biodiversity and Community Right Action Thailand, Thai Holistic Health Foundation and Ecological Alert and Recovery – Thailand available at <http://donttradeourlivesaway.wordpress.com/2012/07/18/thai-civil-society-opposes-gilead> (last visited 10/12/2013).

²²⁹ Dukes MN "Accountability of the Pharmaceutical Industry" (2002) 360 *THE LANCET* 1682 – 1684.

²³⁰ Bond P "Globalisation, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with US Firms and Politicians" (1999) 29 *International Journal of Health Service* 765 – 792.

²³¹ Ford et al above at 560. It is reported that the brand drug cost more per month (US\$136) than the average wage of an office worker which stood at US\$120.

²³² Limpananont J *Thailand: the Impact of pressure from the US – patents, pills and public health: can TRIPS deliver?* (2002) at 41 – 43.

²³³ Wilson D, Cawthorne P, and Aongsonwang S "Global Trade and Access to Medicines: AIDS Treatment in Thailand" (1999) 354 *THE LANCET* at 1893 – 1895.

²³⁴ The list of NGOs included Thai Network of People living with HIV/AIDS and MSF.

²³⁵ Ford et al above at 560.

²³⁶ Ibid at 561.

²³⁷ Ibid.

the lack of political will on the part of SADC members to implement TRIPS flexibilities and use them effectively to access medicines. Secondly, due to the weak economies and an over dependence on donor money in some SADC countries, the fear of retaliation remains real in the region. The Thai experience shows that with a proactive civil society, the decision to actualize TRIPS flexibilities may have to be made by the judiciary which is an independent institution from government. If the courts are truly independent, the government can amend the laws which will be independently and contextually applied by the courts, thus neutralizing the fear of retaliation. In any event, the only envisaged form of retaliation would be a listing on the US government's Section 301 Watch list; action which does not seem to be WTO-legal to start off with and may be actionable in terms of the dispute settlement process of the WTO.²³⁸

The lesson for SADC, therefore, is that member states must, in addition to embarking on IP law reform in the context of making their laws TRIPS-compliant, also strengthen the judicial process so that courts can effectively protect the right to health by passing judgments whose net effect would be the achievement of access to medicines for all, as optimistically provided for in the Doha Declaration.

By 2005, developing country WTO members were expected to be fully compliant with the TRIPS Agreement;²³⁹ and without generic competition, the cost of all new medicines would largely depend on the price set by the patent holder.²⁴⁰ This case highlights the problems faced by developing countries in the specific context and shows that intergovernmental organisations like WIPO should scale up their efforts of integrating developing countries into the TRIPS community by aiding them in implementing patent protection, including patent examination. This assistance must also address developing countries' challenges emanating from using the Doha Declaration and other TRIPS flexibilities.

Because Thailand has very clear provisions on pre- and post-grant patent opposition which have been applied in real disputes in the local courts, it is a good jurisdiction for SADC to learn from. The thematic lessons are similar to those drawn from India since patent opposition will in all likelihood lead to improved patent quality if successful. Just like in the case of *Novartis AG v*

²³⁸ See generally Blue Sky M "Developing Countries and Intellectual Property Enforcement Measures: Improving Access to Medicines Through WTO Dispute Settlement" (2011) 3 *Trade Law and Development* at 409.

²³⁹ Ford et al at 562.

²⁴⁰ Ibid.

India, weak patents with an incremental effect were stopped in their tracks and patent quality was enhanced in favour of access to medicines.

6.4 Anti-Counterfeiting Laws as Access to medicines Barriers: The Kenyan Experience as Reflected in *P.A.O and Others v Attorney General and Another*²⁴¹

The case discussions and analysis relating to Indian and Thailand above touched on pertinent aspects of IP law reform in order to keep underserving patents out of the system. It was shown that underserving and weak patents can be barriers to access to medicines if requirements for patentability are not made stringent and patent opposition procedures are weak or non-existent.

This section of the chapter focuses on a slightly different theme in that it deals with a case of law reform that initially had no direct bearing on traditional IP issues but was linked thereto by its effects on access to medicines. In this section, therefore, I discuss a Kenyan case that highlighted an impediment to access to medicines in the form of anti-counterfeiting legislation whose full implementation was likely to have a negative effect on the right to life, human dignity and health by limiting access to medicines generally and generics in particular had the Kenyan High Court not intervened. The case is very relevant to the aims and objectives of this study because it highlights the link between the rights to life, human dignity and health in the context of access to affordable essential medicines with particular emphasis on generic drugs.

6.4.1 The Factual and other Relevant Background to the case

In 2009, three Kenyans living with HIV/AIDS, namely, Patricia Osero Ochieng (P.A.O), Maurice Atieno, and Joseph Munyi approached the Kenyan High Court with a petition expressing an apprehension that their rights to life, health and human dignity under the Kenyan constitution were threatened by the Anti-Counterfeit Act of 2008,²⁴² specifically sections 2, 32 and 34 thereof.²⁴³ The parties viewed the legislation as affecting or likely to affect their access to affordable and essential drugs including generic drugs thereby infringing their fundamental rights as categorized above.²⁴⁴

²⁴¹ *P.A.O and Others v Attorney General and Another* [2012] eKLR High Court of Kenya, Petition No. 409 of 2009, available at http://kenyalaw.org/Downloads_FreeCases/85611.pdf (last visited 11/12/2013-hereafter PAO case).

²⁴² The Anti-Counterfeit Act No. 13 of 2008, assented to by the President of the Republic of Kenya on 24 December 2008, published in the Kenyan Government Gazette as Notice number 97 on 30 December 2007, available at [http://www.tbvtvn.org/VBLienQuanTBT/QCKT%20nuoc%20ngoai/KEN133\(english\).pdf](http://www.tbvtvn.org/VBLienQuanTBT/QCKT%20nuoc%20ngoai/KEN133(english).pdf) (last visited 12/12/2013).

²⁴³ PAO case above at para 1.

²⁴⁴ PAO case at para 1.

The Anti-Counterfeit Act was enacted to combat counterfeit trade and its objects are broadly spelt out as “to prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes”.²⁴⁵ The Anti-Counterfeiting Agency came into being in 2010.²⁴⁶ The Act also provides for what constitutes counterfeiting offenses and lists the accompanying penalties.²⁴⁷

The AIDS Law Project, an NGO registered in Kenya also joined in the proceedings as an interested party in support of the petition in 2010,²⁴⁸ while Mr Anand Grover, the United Nations Special Rapporteur for Health also joined in as an interested party in 2011 in the capacity of amicus curiae.²⁴⁹ The first respondent was the Attorney General of Kenya while Kenya’s Anti-counterfeit Agency, which was represented by its Board Chairman, Mr Allan George Njogu Kamau, joined in the petition as the second respondent.²⁵⁰

The petitioners had won a temporary reprieve against the application of sections 2, 32 and 34 of the Act in 2010 when Justice Wendoh granted temporary orders to suspend the application of the relevant sections pending the finalisation of the matter on the return date.²⁵¹ The final judgement in the matter was delivered by the High Court in Nairobi (per Justice Mumbi Ngugi) on 4 April 2012 and this judgement is the subject of discussion in this section of the chapter.

The petitioners sought orders on the following specific prayers:²⁵²

- A declaration that the fundamental rights to life, human dignity and health as protected in Articles 26(1), 28 and 43 of the Kenyan Constitution encompass access to affordable essential medicines and drugs including generic drugs;²⁵³

²⁴⁵ Preamble to the Act.

²⁴⁶ Nyachae J and Ogendi P “Anti-Counterfeiting and Access to Generic Medicines in Kenya” (2012) 13 *ESR Review* at 12.

²⁴⁷ Ibid. section 32 of the Act creates counterfeiting offenses and potentially criminalises the manufacture and importation of generics into Kenya.

²⁴⁸ At para 4.

²⁴⁹ At para 6.

²⁵⁰ At paras 7 – 8.

²⁵¹ Nyachae and Ogendi above at 12.

²⁵² At para 2.

²⁵³ At para 2(a).

- A declaration to the effect that in so far as the Anti-Counterfeit Act limited accessibility to affordable and essential drugs including generics for HIV/AIDS, it infringed on the petitioners' right to life, human dignity and health;²⁵⁴
- A declaration that the enforcement of the Act in as far as it affected access to affordable and essential medicines particularly generics was a breach of the petitioners' right to life, human dignity and health as protected by the constitution;²⁵⁵ and
- And any other orders, directions, declarations and remedies as the High Court could deem fit and just in the circumstances.²⁵⁶

6.4.2 *The Parties' Contentions*

As an elaboration to the four items outlined above as specific prayers brought before the High Court, other specific averments were also made by the petitioners.²⁵⁷ Firstly, the petitioners had the apprehension that in the event of the Act being applied and enforced as it is, they would be denied their right to enjoy the highest attainable standard of health because HIV/AIDS drugs would be expensive when generics are barred by the Act.²⁵⁸

The petitioners alleged that the Anti-Counterfeit Act posed a serious danger to persons living with HIV/AIDS because of the potential negative effects likely to arise out of the application of sections 2,²⁵⁹ 32²⁶⁰ and 34.²⁶¹ They further alleged that the state had failed to acknowledge and exempt generic drugs and medicine from the definition in section 2, thus leaving generic drugs vulnerable to classification as counterfeit goods.²⁶²

²⁵⁴ At para 2(b).

²⁵⁵ At para 2(c).

²⁵⁶ At para 2(d).

²⁵⁷ See paras 9 – 25 of the Judgment in PAO.

²⁵⁸ At para 11.

²⁵⁹ The specific complaint against section 2 was that it defined counterfeiting too broadly and this could lead to abuse by both IP right holders and overzealous customs and other IP enforcement officers who may regard generics as counterfeits.

²⁶⁰ With specific reference to this section, the argument was that it potentially criminalized the manufacture of generic drugs, together with their importation into Kenya.

²⁶¹ The concern with this section hinged on the fact that the powers of Commissioner of the Kenya Revenue Authority could be abused to seize and detain generic drugs, lumping them together with counterfeit goods.

²⁶² At para 14.

Leaving the definition as it is effectively bans the manufacture and importation of generics into Kenya and does not take into account the state's obligations in terms of the relevant legislation.²⁶³ It was also submitted on behalf of the petitioners that the state had not clarified the legal position availed by the Industrial Property Act, which allows for exceptions necessary to make generic drugs available in Kenya.²⁶⁴ The petitioners further argued that the application of the Act would infringe on their right to life, human dignity and health as guaranteed in the Kenyan Constitution.²⁶⁵

The Aids Law project (ALP) as an interested party made submissions that sought to rely extensively on the constitution, namely that the Act infringed on the right to life, human dignity and health for persons living with HIV/AIDS. Additionally, the ALP argued that the legislation had the potential to violate the constitutional right to the protection of family life.²⁶⁶ The ALP also submitted arguments premised on the protection of the rights of the child wherein it argued that since the government relies heavily on generic drugs for its public health programmes, limiting access to generics would lead to more child-headed households.²⁶⁷

The amicus curiae submitted his arguments in fulfilment of his mandate as the U.N Special Rapporteur on Health, who is enjoined to make recommendations on issues surrounding the right to health, particularly as it relates to laws, policies and practices that may be obstacles to the realisation of the right to health.²⁶⁸ The Special Rapporteur submitted that despite the Act's noble objective of prohibiting trade in counterfeit goods, it was likely that in its current written form then, it would endanger the rights to life and health as protected in the Kenyan Constitution.²⁶⁹ The definition of counterfeit goods in that Act²⁷⁰ encompassed generic drugs in Kenya and elsewhere and was likely to adversely affect the manufacture, sale, and distribution of generic drugs.²⁷¹ Having submitted that the definition of counterfeit goods in the Act conflated generic

²⁶³ At para 14. The specific legislation is the HIV and AIDS Prevention and Control Act of 2006.

²⁶⁴ Industrial Property Act 3 of 2001.

²⁶⁵ In Articles 26(1), 28 and 43 respectively of the Kenyan Constitution.

²⁶⁶ Article 45(1) of the Kenyan Constitution.

²⁶⁷ The argument was based on section 53(2) of the constitution, guaranteeing the right to basic health care services.

²⁶⁸ At para 33.

²⁶⁹ At para 34.

²⁷⁰ In section 2 of the Act, the definition of counterfeit goods includes the **“manufacture production...or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such a manner and to such a degree that those other are identical or substantially similar copies of the protected goods”** (emphasis in the original).

²⁷¹ At para 34.

medicines with counterfeit medicines, the Special Rapporteur came to the conclusion that such conflation was likely to have a serious and adverse impact on the availability, affordability and accessibility of low-cost high quality medicines.²⁷² The Rapporteur then concluded that such a situation could lead to the seizure and prohibition of medicines that have been approved by Kenyan regulatory authorities on the basis that they are counterfeit.²⁷³ This unjustified limitation on the use of generic drugs by Kenyans would amount to a violation of the right to health as guaranteed by the constitution and international treaties.²⁷⁴ The Rapporteur went further on to submit, on the basis of international obligations concerning IP law and otherwise that such a violation would be unjustifiable.²⁷⁵

Following is a summary of the respondent's case. By passing the HIV and Aids Prevention Act in 2006, the government of Kenya showed that it cared for its people and the term 'generic drugs' in the Anti-Counterfeiting legislation should not be construed as synonymous with 'counterfeit drugs'.²⁷⁶ In terms of the constitutional right to health, the duties of the state include inter alia ensuring that people attain the highest standard of health care, enjoy the right to life and the enactment of legislation such as the Act in dispute was one of the ways of fulfilling the duty.²⁷⁷ The petitioners' fears were unfounded because the definition of counterfeit in the Act as it relates to medicines is very clear and specific and does not give rise to any form of ambiguity.²⁷⁸ There was no need to expressly provide for exemption of generic drugs in the Act because section 2 provides that nothing in it shall derogate from existing provisions in the Industrial Property Act, and that in the event of a conflict, the provisions of the Industrial Property Act would prevail.²⁷⁹ Finally, the respondent submitted that the application of the impugned provisions of the Act would not lead to a violation of rights and that granting the order as prayed for would lead to a breach and not the protection of the petitioners' fundamental

²⁷² At para 35.

²⁷³ At para 36.

²⁷⁴ At para 36.

²⁷⁵ At para 37.

²⁷⁶ At para 38.

²⁷⁷ At para 39.

²⁷⁸ At para 40.

²⁷⁹ At para 41.

rights.²⁸⁰ The respondent's conclusion was that the petition was nothing more than an abuse of the court process and such abuse had to be dismissed.²⁸¹

6.4.3 Matters that fell to be decided by the Court

After an extensive outline of the socio-economic context of the petition,²⁸² the court summarised the crux of the matter and identified the issues that fell to be decided. The crux of the dispute was therefore, reduced to a determination of two crucial questions,²⁸³ namely:

- Did the state, by enacting section 2 of the Anti-Counterfeiting Act in its present form, and by providing the enforcement provisions in sections 32 and 34, violate its duty to ensure that conditions are in place under which citizens can lead a healthy life? and
- Will these provisions deny the petitioners' access to essential medicines and thereby violate their constitutional rights under Articles 26(1), 28 and 43(1), as well as section 53 with regard to the rights of children?

6.4.4 The Judgment of the High Court

The judge, taking into account the submissions and counter arguments of the parties, analysed the definition of the provisions of the Anti-Counterfeiting Act²⁸⁴ and came to the firm conclusion that the definition of 'counterfeit' in section 2 of the Act was likely to be read as including generic medication, thus agreeing with the submission of the amicus on the issue.²⁸⁵

While noting that the respondents had argued that the intention of the Anti-Counterfeit Act was to safeguard the petitioners and similar situated rejoinders against the use of counterfeit medicines, the judge, however, concluded that a reading of the Act showed a different intention. Citing from sections 32,²⁸⁶ 33²⁸⁷ and 34²⁸⁸ of the Act, the High Court observed that the tenor and

²⁸⁰ At para 43.

²⁸¹ Ibid.

²⁸² At paras 44 – 67.

²⁸³ At para 67.

²⁸⁴ At paras 68 -78.

²⁸⁵ At para 78.

²⁸⁶ This section makes it an offense for any person have in his possession or control in the course of trade, any counterfeit goods and prohibits a number of activities relating to counterfeits, such as manufacturing, selling, exhibiting, distributing, importing and transiting through Kenya of counterfeit goods.

²⁸⁷ Section 33(1) of the Act gives the IP right holder, his successor in title, licensee or agent in respect of any protected goods the right to complain to the executive director of the Anti-Counterfeiting Agency upon reasonable suspicion that a crime has been committed is being committed or about to be committed in terms of section 32.

object of the Act is to protect the IPRs of individuals.²⁸⁹ The court reasoned that had the Act's intention been to safeguard consumers from counterfeit medicine, then it would have laid greater emphasis on standards and quality.²⁹⁰ Therefore the court reasoned that the Act was not meant to protect the rights of the petitioners and members of the general public from substandard medicine, rather, it prioritised the enforcement of IP rights in dealing with counterfeit medicines.²⁹¹ To buttress this point, the judge remarked that the protection of consumers "may have been a collateral issue in the minds of the drafters of the Act".²⁹²

Coming to the right to life, dignity and health, the judge remarked that securing these rights in situations like those faced by the petitioners who suffer from HIV/AIDS would not be possible using a vague proviso which may lead to the enforcement the law without having a clear understanding of the differences between generic and counterfeit medicine.²⁹³ The judge concluded on this point that it would be an abdication of responsibility on the part of the state, with specific reference to the right to life, human dignity and health to include in legislation ambiguous provisions impacting on the access to essential medicines, especially when the interpretation of the ambiguities remains squarely within the domain of IPR holders and customs officials.²⁹⁴ To drive the point home, the judge firmly held that there can be no room for ambiguity where the right to life and the health of the petitioners and many other Kenyans who are affected by HIV/AIDS are at stake.²⁹⁵

The court disagreed with the respondent on the point of the applicability of the Industrial Property Act, namely that the Act would prevail over the Anti-Counterfeiting Act. The court held that because the Anti-Counterfeiting Act, having been promulgated later than the Industrial Property Act,²⁹⁶ and, therefore, being later in time, would prevail over the Industrial Property Act

²⁸⁸ Section 34 (1) gives the IP right holder the right to apply to the Commissioner in the prescribed manner to seize and detain suspected counterfeit goods if the right holder has valid grounds for suspecting that that importation of counterfeit goods may take place. This relates to goods featuring, bearing embodying or incorporating the subject matter of that IP and imported into or entering Kenya during the period specified in the application.

²⁸⁹ At para 82.

²⁹⁰ At para 82.

²⁹¹ Ibid.

²⁹² Ibid.

²⁹³ At para 84.

²⁹⁴ Ibid.

²⁹⁵ Ibid.

²⁹⁶ The Industrial Property Act was passed in 2001 while the Anti-Counterfeiting Act came into full operation in 2010.

in the event of a conflict, hence the proviso in section 2 would not be of much help to the petitioners.²⁹⁷ Therefore, should the Anti-Counterfeiting Act be implemented as it was, it would pose a danger to the right of the petitioners to access essential medicines which they require daily in order to live.²⁹⁸ The court, therefore, reasoned that the right to access essential medicines was of the greatest importance and more critical than the protection of intellectual property rights that the Act sought to protect. Therefore, the right to life, dignity and health of the petitioners in this case was held to take precedence over intellectual property rights.²⁹⁹ This pronouncement by the judge was precedent-setting and very relevant to the aims and objectives of this study, which sought to strike a balance between IPRs and access to medicines in the context of the right to health. As the cliché goes, “the Kenyan High Court has spoken”.

Citing from General Comment N0.17,³⁰⁰ the judge went on to hold that while IPRs should be protected, their protection must not jeopardise fundamental rights such as the right to life.³⁰¹ The judge was of the firm view that IPRs must give way to the fundamental rights of the citizens in the position of the petitioners.³⁰²

The judge summarised the essence of her judgment by highlighting the following issues: Firstly, she ruled that sections 2, 32 and 34 of the Act threatened to violate the right to life, human dignity and the health of the petitioners as protected by the relevant laws.³⁰³ Secondly, she emphasised that the above specific rights encompass access to affordable and essential medicines including generic medicines.³⁰⁴ Thirdly, to the extent that the Act severely limited or threatened access to affordable medicines and essential drugs including generics for HIV/AIDS, it infringed on the right to life, human dignity and health.³⁰⁵ Fourthly, the judge ruled that the enforcement of the Act was a breach of the petitioners’ rights to life, human dignity and health in so far as it affected access to affordable medicines and generics.³⁰⁶

²⁹⁷ At para 85.

²⁹⁸ At para 85.

²⁹⁹ At para 85.

³⁰⁰ See Chapter three above for a detailed discussion of the salient health provisions of this General Comment.

³⁰¹ At para 86.

³⁰² Ibid.

³⁰³ At para 87.

³⁰⁴ At para 87(a).

³⁰⁵ At para 87(b).

³⁰⁶ At para 87(c).

On a disappointing note, the court in its final analysis urged rather than ordered the state to reconsider section 2 of the Anti-Counterfeit Act in light of its constitutional obligation to ensure that citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of the petitioners and others who depend on generic drugs are not put in jeopardy.³⁰⁷

6.4.5 Analysis of the case and Lessons for SADC

For purposes of the objectives of this study, this case is important in that it unequivocally states that IPRs are important but such importance must be subordinated to the rights to life, human dignity and health.³⁰⁸ It has been argued by some commentators³⁰⁹ that the decision effectively settles the debate about the supremacy of human rights over intellectual property rights and by extension private interests including commercial interest.³¹⁰

Many countries in the SADC region have constitutions providing for the right to health hence it would be easy for them to protect access to medicines basing such protection on the right to health. For example, in South Africa, the right to health is characterised as one of the fundamental rights, imposing an obligation on the state to take progressive steps to realise this right within its available resources.³¹¹ The Constitution of Zimbabwe also provides for very elaborate provisions on the right to health³¹² along similar lines to the constitution of South Africa, but goes a step backwards by specifying that the right may only be enjoyed by citizens and permanent residents.³¹³ On the other hand, the same constitution progressively provides for the right to access to health care services for all persons with chronic illnesses.³¹⁴ The decision in the POA case, therefore, reassures those SADC members that are reluctant to legislate progressively to access generic drugs that the rights to life, human dignity and health strongly favour derogation from patent rights in favour of patient rights.

³⁰⁷ At para 88. At the time of writing, the amendments had not been effected.

³⁰⁸ At para 86.

³⁰⁹ See Nyachae and Ogendi above at 14.

³¹⁰ Ibid.

³¹¹ In terms of section 27 of the South African Constitution, the right to health encompasses access to health care services, including reproductive health and no one may be refused emergency health services. Section 27 (2) urges that state take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights mentioned in section 27, including the right to health.

³¹² Generally in section 76 of the Zimbabwean constitution.

³¹³ Section 76(1) of the Zimbabwean constitution.

³¹⁴ Section 76(2) of the Zimbabwean constitution.

The rights-based approach used in this case in the context of potential violations to the rights to life, human dignity and health augurs very well for this study. The court cited decisions of Kenyan courts,³¹⁵ other African courts³¹⁶ and International law³¹⁷ and came up with a sound and well-reasoned judgment with useful lessons for other jurisdictions including SADC. The same rights-based approach is recommended as a solution to the SADC access to medicines problems in Chapter Seven below. Therefore, this case raises the important issue of access to medicines as a fundamental human right, against the background of universal consensus that access to medicines constitutes an integral part of the right to health.³¹⁸

The fact that the court ruled that ambiguous anti-counterfeiting legislation may lead to unfavourable results for access to affordable essential drugs must be applauded.³¹⁹ While counterfeit medicines are bad from an IPR holder and the patient point of view, generic drugs are not necessarily fake drugs. Confusing generic drugs with fake drugs will surely lead to seizures of genuine generics with obvious negative implications for access to medicines.³²⁰ This apprehension is starkly illustrated by the seizure by customs officials in EU countries of over 20 consignments of legitimate generic medicines transiting through the EU since late 2008.³²¹ In the EU case, despite the medicines, destined for treatment sites in Africa and South America, being in ‘transit’, and thus not intended for domestic consumption in the EU, the consignments were still detained.³²² The apprehension on the part of the petitioners on this aspect did have a basis which the court agreed with. For the SADC region, the obvious lesson is that IP legislation, its

³¹⁵ For example the unreported case of *Peter Waweru v R Nairobi Misc.* Civil Application No. 118 of 2004.

³¹⁶ The South African case of *Fose v Minister of Safety and Security* CCT 14/96 and *Minister of Health v Treatment Action Campaign* (TAC) (2002) 5 SA 721 (CC).

³¹⁷ The WTO TRIPS Agreement and General Comment No. 14 on the Right to Health.

³¹⁸ On this specific aspect, see for example, Durojaye E “Advancing Gender Equity in Access to HIV Treatment through the Protocol to the African Charter on the Rights of Women” (2006) *African Human Rights Law Journal* 187 and Hongerzeil HV et al “Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?” (2006) 360 *The Lancet* at 305.

³¹⁹ At para 78.

³²⁰ According to the PAO judgement at para 22, the petitioners were apprehensive that if the provisions of the Anti-Counterfeit Goods Act were applied, customs authorities would seize generic drugs, like what in the Netherlands and Germany in 2008 when generics destined for Brazil and Vanuatu respectively were seized by customs authorities while in transit.

³²¹ This was based on a controversial reliance on European Union customs rules encapsulated in EC Council Regulation 1383/2003 and the European Customs Code, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1383:en:HTML> (last visited 13/12/2013), whose provisions are similar to Kenya’s section 34.

³²² MSF “How Kenya’s 2008 Anti-Counterfeit Act Could Endanger Access to Medicines” (2010) *Medecins Sans Frontieres Briefing Document* at 4.

enforcement and the policies and procedures guiding the drug regulatory authorities must be transparent and not muddle generics with fake drugs.

The TRIPS Agreement allows for the use of provisional measures including the seizure of goods infringing IPRs in certain circumstances and subject to specified conditions.³²³ For example, if the right holder has a reasonable suspicion that a *counterfeit trademark* (emphasis added) is about to be imported, he can write to competent customs authorities and ask them that such counterfeits must not be released into commerce.³²⁴ Such noble provisions of the TRIPS Agreement may be abused by right holders to keep genuine competitors at bay and perpetuate monopoly prices. Should this happen in the context of access to medicines, the result will be bad for access to affordable medicines including generic drugs. The case highlights the importance of generic drugs for access to medicines with specific reference to HIV/AIDS. It is estimated that in 2011, there were 1.6 million Kenyans living with HIV/AIDS and Kenya's national HIV/AIDS treatment programme relies quite substantially on antiretroviral medicines from India.³²⁵

The major lesson for SADC on the aspect of confusing generic drugs with counterfeits is illustrated by the case of South Africa's Draft IP policy,³²⁶ which clearly states that generic medicines are important in that their presence is likely to lead to a reduction in prices. The policy correctly recommends that through education and awareness, law enforcement officers must be made to understand that generics are not counterfeit medicines.³²⁷ The policy further urges law enforcement agencies not to seize generic drugs or goods in transit under the pretext that they are counterfeit.³²⁸ There can be no better lesson than this for SADC members, and there is a strong possibility that this inclusion in South Africa's Draft IP Policy of 2013 may have been inspired by the judgement in the POA case.

This case reaffirms the importance and viability of public interest litigation in advancing social rights and justice. It has been argued that health rights litigation can be useful in holding a government accountable for its failure to realise the right to health within its jurisdiction.³²⁹ This

³²³ See TRIPS Articles 50 -59.

³²⁴ Article 51 of TRIPS.

³²⁵ Nyachae and Ogendi above at 14.

³²⁶ See South Africa's Draft IP Policy at 13.

³²⁷ Ibid.

³²⁸ Ibid.

³²⁹ Hogerzeil above at 305.

point is buttressed by the submission by Pieterse that social rights litigation including health rights litigation has the potential of advancing social and redistributive justice in society, especially to the poor.³³⁰ The TAC case in South Africa, decided in 2002, clearly illustrates the veracity of the foregoing observation. From the POA case, it is clear that the petitioners did have support from civil society and other interested stakeholders. The involvement of Kenya's AIDS Law Project and the U.N special Rapporteur in the case was very illuminating and enriched the submissions before the court. Civil society organisations in the SADC, region, therefore need to be adequately empowered in order to bring IPRs challenges to domestic courts. This will yield positive results for social justice in the region. The outcome of this case did not yield positive results only for the petitioners, on the contrary, the implications went beyond Nairobi and Kenya into other African countries and developing countries in other continents because it is now possible to attack patent rights on the basis that they violate fundamental human rights. This is another positive spin-off of social rights litigation, which has tremendous potential for alleviating the suffering of vulnerable groups by ensuring that affirmative remedies satisfy their immediate vital needs within society.³³¹

When the POA case is interpreted broadly, it would seem that failure by a government to invoke and take advantage of TRIPS flexibilities in order to facilitate access to affordable and essential medicines for its citizens may be actionable as a violation of the obligation to safeguard the right to life and health as provided for in numerous international instruments.³³² On the other hand, adopting measures that make the state unable to take advantage of TRIPS flexibilities may also be actionable.³³³ For example, LDCs have been given the latitude not to be TRIPS compliant until 2016 with respect to pharmaceutical products and until 2021 with respect to other fields of technology; yet some LDCs have passed IP laws and even signed economic partnership agreements which erode their ability to take advantage of TRIPS flexibilities.³³⁴ Public interest

³³⁰ Pieterse M "The Potential of Socio-Economic Rights Litigation for the Achievement of Social Justice: Considering the Example of Access to Medical Care in South African Prisons" (2006) 50 *Journal of African Law* at 118.

³³¹ Liebenberg S "Needs, Rights and Transformation: Adjudicating Social Rights" (2005) 8 *Centre for Human Rights and Global Justice Working Paper* (Economic and Social Rights Series) at 6 – 7.

³³² Durojaye E and Murugi-Mukundi G "States Obligations in Relation to Access to Medicines: Revisiting Kenyan High Court Decision in P.A.O and Others v Attorney-General and Another" (2013) 17 *Law, Democracy and Development* at 41.

³³³ Ibid.

³³⁴ See Article 70 of the TRIPS Agreement read together with paragraph 7 of the Doha Declaration on TRIPS and Public Health.

litigation may be the only viable tool with which to address such transgressions in the interest of access to affordable essential medicines. Such a stance was confirmed by the reasoning of the African Commission in the case of *Purohit v the Gambia*,³³⁵ which seems to suggest that failure by African governments to provide access to medicines for vulnerable and marginalised groups such as people living with HIV/AIDS would amount to a violation of the right to health and constitute an act of discrimination in contravention of Articles 2 and 3 of the Charter. The above observation should serve as a warning to SADC member states, some of which have signed TRIPS-plus trade agreements, while others have prematurely embraced the TRIPS Agreement, to the obvious detriment of access to medicines.³³⁶

Despite the above outlined celebratory aspects of the judgment in the PAO case, some commentators³³⁷ have expressed reservations about the outcome on a number of grounds. Firstly, despite finding that the impugned provisions of the Anti-Counterfeiting Act were bad law and deserved amendment, the court did not order but rather urged the state to change the law.³³⁸ Due to the importance of the matter of access to medicines, the expectation was that the court ought to have given a more definite and precise order to the state.³³⁹

The case did not refer to non-discrimination despite the fact that the Anti-Counterfeit Act may jeopardise access to medicines for HIV/AIDS patients, thus implying that the state indirectly discriminated against people living with HIV/AIDS.³⁴⁰ It is submitted that while it is acknowledged that the provisions of the Anti-Counterfeiting legislation are likely to adversely affect access to HIV/AIDS drugs, especially generics, there was no need to allege discrimination because the negative effects of the legislation were likely to impact on other health spheres beyond the HIV/AIDS theme.

³³⁵ *Purohit and Another v The Gambia* (2003) AHRLR 96 (ACHPR 2003, African Communication No. 241/2001 (2003).

³³⁶ Malawi and Zambia would squarely fit into this class, since they have gone ahead and legislated for product patents including pharmaceuticals despite their LDC status.

³³⁷ Namely Durojaye and Murugi-Mukundi above at 42 – 45.

³³⁸ Durojaye and Murugi-Mukundi above at 42.

³³⁹ Ibid.

³⁴⁰ Citing from the case of *Legal Resources Centre v Zambia* [2000] AHLRP 84 (ACHPR 2001] para 63, Durojaye and Murugi-Mukundi argue that the principles of non-discrimination in Articles 2 and 3 of the African Charter are fundamental for the enjoyment of other rights guaranteed in the Charter.

While the judge in the case did cite international legal instruments and jurisprudence of the U.N Human Rights system on the right to health and even referred to other jurisdictions, namely, South Africa, no direct reference was made to the jurisprudence of the African Commission. Such an omission is unfortunate given the fact that Kenya has ratified the African Charter.³⁴¹ Therefore, the failure to cite or even refer to the jurisprudence of the African Commission must be regarded by SADC members as an unfortunate exception rather than the norm.³⁴²

Despite the above criticism of the judgement, this case is important because it is one of the few cases in Africa where a court has had the opportunity to decide the difficult matter of the state's obligation with regard to IP and the right to health. The decision does clarify the duty of the state using a revolutionary, progressive, rights-based approach which is precedent-setting, timely and contemporaneous. The judgement may, therefore, be regarded as significant victory for people living with HIV/AIDS and others in need of life-saving medicines in Kenya, Africa and the SADC region. A discussion of the decision therefore adds a lot of value to the aims and objectives of this study, and largely illuminates the recommendations made in Chapter Seven below.

Conclusion

It is appropriate to conclude this chapter by summarising the highlights from the discussions of the jurisprudence in the three countries under focus. Firstly, the Indian experience highlights that a country can tighten the requirements for patentability in specific fields of technology in line with its own unique problems, such as the prevalence of diseases. In the Novartis case, the court used existing IP law principles, namely, the requirements for patentability³⁴³ and prevented the granting of a patent that was not new and was likely to perpetuate patent monopolies. The patent for the beta crystalline form of Imatinib Meyslate was declined because it did not have an enhanced efficacy as a 'new drug'.

The Thai experience highlights the importance of both pre- and post-grant patent opposition procedures in order to keep undeserving patents out of the system, improve patent quality and

³⁴¹ Durojaye and Murugi-Mukundi above at 44.

³⁴² This is made even graver by the fact that in terms of Article 2 of the Constitution of the Republic of Kenya, the constitution is supreme law of the country and the general rules of international law 'shall form part of the law of Kenya'.

³⁴³ Novelty, involvement of an inventive step and utility.

facilitate the early entry of generic drugs into the health system. The Didanosine case clearly illustrates that in the absence of good laws and an active civil society community that keeps the activities of government officials and big pharmaceutical companies under check, some patents may be granted with unlimited rights thus making it impossible to introduce competition in the form of generic drugs. In the Didanosine case, the patent claims were initially amended, in collusion with officers in the Thai Patents Office, to cover limitless dosage forms. Had the amendments seen the light of day through no opposition, it would have been impossible for anyone to manufacture generic forms of Didanosine in Thailand, despite the legislation allowing for such.

The Kenyan case study is slightly different from the others in that it deals with counterfeiting, a subject that is usually covered in most jurisdictions by drug regulatory policies and not IP law. Using the rights-based approach, the Kenyan High Court ruled that Anti-Counterfeit legislation that is ambiguous and has the potential of leading to conflating generic drugs with counterfeits may lead to a violation of the rights to life, human dignity and health. Furthermore, the Kenyan case study highlights the fact that human rights are superior to IPRs, which must give way as and when the need arises. Poorly drafted laws, whose interpretation and application may lead to the curtailment of the rights to life, human dignity and health must be avoided in order not to frustrate the goal of access to affordable essential medicines and drugs, particularly generic drugs.

The SADC region has many lessons to learn from the case studies if it seriously intends improving access to medicines for SADC citizens. The lessons hover around IP law reform, the right to health, the role of civil society in public interest litigation and other collaborations beyond civil society. Except for the Indian case, most access to medicines concerns canvassed by the case studies were on the issue of HIV/AIDS medication, a sensitive subject for the SADC region, which faces increasing HIV/AIDS infection rates. Civil society organisations were active in all the three case studies, thus highlighting an important lesson for SADC in that specific context. In light of the above reasons, this chapter is an important cog in the wheel of the rest of this work. It clearly shows that the access to medicines problem for the developing countries and the SADC region in particular may be resolved through a third world/south-south approach. Solutions lie in the WTO instruments that SADC members signed, which instruments allow

member states to adopt measures that will ensure access to medicines for their citizens, guided by the local and regional conditions which obtain in each member state. It will, therefore, be possible for SADC members to curb incremental patents through adopting patent opposition procedures like is currently the case in Thailand; to prevent the patenting of minor variations to drugs, such as colour or shape, which does not enhance efficacy like what happened in India and not to confuse generic drugs with counterfeit drugs, like what almost happened in Kenya. In all the three case studies discussed in this chapter, existing national, regional and international IP laws and policies were used in order to safeguard and preserve the right of citizens of the respective countries to access affordable essential medicines in order to live in a dignified manner and fully enjoy the right to health without any illegal limitations.

CHAPTER SEVEN

SUMMARY, RECOMMENDATIONS AND AREAS FOR FURTHER RESEARCH

7. Introduction

What has been examined in the preceding chapters engages the subject of access to essential medicines under the WTO TRIPS Agreement from a comparative SADC perspective. However, what is recapitulated in this chapter is a broad overview of the dimensions of access to medicines in the SADC region under the TRIPS Agreement accompanied by proposed solutions, in the form of recommendations to ameliorate the access to medicines problem in developing countries generally, and the SADC region in particular.

It must be emphasised as part of the recommendations that the SADC as a region has many institutional deficiencies;¹ and in order to ensure that such deficiencies do not militate against the goal to take advantage of TRIPS flexibilities and access to essential medicines, a common approach to the recommendations outlined below must be adopted.²

The proposed recommendations on their own would be inadequate in resolving the access to medicines problem in the SADC region. Therefore, areas for further research are also suggested as an additional complimentary step to take in the direction of improving access to medicines. Four objectives are intended to be accomplished by this chapter.

First, the chapter begins with a brief summary and discussion of the principal findings of the study. Second, the chapter attempts to explore the importance of the theories of intellectual property rights and the rights-based approach as possible solutions to the SADC access to medicines problem. Third, the chapter explores the prospects of regional pharmaceutical manufacturing in the SADC region, in light of current capacity, aided by pooled procurement and the permissive provisions of Article 31 *bis* of the TRIPS Agreement and a possible South-

¹ See generally Zenda F *The SADC Tribunal and the Judicial Settlement of International Disputes* (2010), LLD thesis submitted to the University of South Africa at 19 – 25.

² This common approach resonates with other recommendations in other different areas of regional integration such as those suggested in the context of the harmonisation of trade laws by Dlagnekova P “The Need to Harmonise Trade-Related Laws within Countries of the African Union: An Introduction to the Problems Caused by Legal Divergence” (2009) 15 *Fundamina* 1 – 37.

South cooperative approach. Fourth, it seeks to explain specific shortcomings in the law and proposes recommendations for law reform alongside the strengthening of the capacity of regional civil society groups in order to spur access to medicines litigation. Finally, the chapter suggests a tentative future regional research agenda which will bolster access to medicines in the SADC member states.

This chapter, therefore, is organised under the following headings: (1) A brief Restatement of the Research Problem, Aims and Objectives; (2) Summary and discussion of the Main Findings; (3) Theories of Intellectual Property; (4) Prospects of the Rights-based Approach; (5) Prospects of Regional Pharmaceutical Manufacturing of Drugs and Pooled Procurement; (6) Suggestions for Law Reform and Enhanced Role of Civil Society Groups; (7) Research Agenda for the Future.

7.1 A brief Restatement of the Research Problem, Aims and Objectives

Brevity requires that a restatement of the research problem begins on the note that, taken together, TRIPS flexibilities and human rights lie at the heart of access to medicines in the SADC region. The court cases analysed in the case studies in Chapter Six do attest to the fact that access to medicines is indeed a human right which must inform the jurisprudence seeking to enquire into the relationship between intellectual property and human rights.

While the TRIPS Agreement gives WTO members the leeway to protect patents and other forms of intellectual property in a manner that takes care of each member's unique problems by resorting to TRIPS flexibilities, in practice in the pharmaceutical context, SADC members have been reluctant to take full advantage of these flexibilities. The reluctance may be attributed to a number of factors, such as the lack of domestic research and pharmaceutical manufacturing capacities; insufficient technical and infrastructural capacities for medicines regulation; inefficient pharmaceutical procurement systems, bilateral and other political pressures against the use of TRIPS flexibilities; lack of capacity to address anti-competitive practices and abuse of patents; and difficulties in accessing pricing and other patent status information.³ Limited

³ Munyukwi E and Machedze R "Implementation of the TRIPS Flexibilities by East and Southern African Countries: Status of Patent Law Reforms by 2010" (2010) 80 *Equinet Discussion Paper* at 22.

purchasing power of the citizens of the developing countries is also often cited as an impediment to taking full advantage of TRIPS flexibilities.⁴

It is appropriate to posit that in order to improve access to essential medicines by SADC countries, there is a need to actualise the flexibilities provided for in the TRIPS agreement, the Doha Declaration, the August 2003 Decision and the subsequent proposed amendment, introduced in 2005, which brought in Article 31 *bis* of TRIPS relating to compulsory licences. The envisaged actualisation will require a paradigm shift in legal policy in the form of amendments to existing intellectual property laws in the member states and, a reinterpretation of the relevant WTO provisions, which have been the subject of litigation in disputes involving pharmaceuticals and access to medicines in other jurisdictions.

Only scant attention has been given to the potential of regional trading blocs and developing country solutions to the problem of access to medicines. Few studies have in fact examined in-depth the extent of incorporation and the use of TRIPS flexibilities in the SADC region beyond lamenting the fact that the flexibilities are currently not being taken advantage of by SADC member states. This study, therefore, proffers home-grown solutions to the SADC access to medicines problem through the aid of jurisprudence from other developing countries.

It is in view of such shortcomings in the literature that this study specifically focused on the following aims and objectives:

Three main aims were targeted by this study. The first aim was to analyse WTO legal instruments and ascertain their adequacy in balancing the rights to health and intellectual property in the context of pharmaceutical patents. The second aim, which was closely related to the first one, was to show through an examination of international human rights legal documents and other instruments that there is potential for conflict between intellectual property rights and the right to health in the context of access to essential medicines in general and for the SADC region in particular. Through an analysis of selected SADC members' intellectual property legislations, comparative law and the rights-based approach, the third aim of the study was to propose viable solutions to the SADC access to medicines problem.

⁴ Zaheer M and Riaz AS "Flexibilities under TRIPS: Implementation Gaps between Theory and Practice" (2013) 1 *Nordic Journal of Commercial Law* at 3.

In order to achieve the above stated aims, the study focused on the following pertinent objectives, which were to a large extent achieved, namely:

- (a) To outline basic tenets of WTO and IP law through an exploration of theories of intellectual property and legal historical origins;
- (b) To outline and discuss the tenets of the rights-based approach and explain how it can be applied to the problem of access to medicines as a human right in order to humanise it;
- (c) To critically analyse specific regional instruments and SADC Policy documents relating to access to medicines and establish the extent of incorporation of TRIPS flexibilities in SADC member states' legislation;
- (d) To analyse selected SADC members' intellectual property policies and legislation and expose how each country used some of the flexibilities to improve access to medicines for its citizens;
- (e) Extract thematic lessons for other SADC members' from the practice of selected SADC members and other developing countries, namely India, Thailand and Kenya; and
- (f) To propose solutions to SADC access problems to medicines through making recommendations and suggesting areas for further research.

The above aims and objectives were achieved through a critical expository account of the issues relating to the law of patents, the TRIPS Agreement, the evolution of the access debate to medicines and theories of intellectual property; access to medicines as a human right; an exposition of the TRIPS flexibilities; the actual use of TRIPS flexibilities in the SADC region and comparative litigation regarding access to medicines. In the next section immediately below, a summary of each of the above topics and the main findings thereon are rendered.

7.2 Summary and discussion of the Main Findings

In addition to Chapter One above, Chapter Two focussed on concepts, theories, and legal historical issues relating to access to medicines. The chapter established that the common forms of intellectual property identified as such by many WTO members including non-members include patents, designs, trademarks and copyright. Other forms of intellectual property such as geographical indicators and integrated circuits were identified in their specific context. From a WTO TRIPS perspective, the chapter established that members are enjoined to respect intellectual property rights and adhere to the principles of national treatment and most favoured nation treatment. With specific reference to pharmaceutical patents, the chapter clearly showed that traditionally, many current WTO members did not provide patent protection for pharmaceuticals due to their role of preserving lives. However, the TRIPS Agreement mandates WTO members to provide intellectual property right protection to all products irrespective of the field of technology and subject to specifically listed exceptions, such as the protection of human health and the environment. The chapter established that patents are an impediment to access to medicines and the rights therein must be sensitively enjoyed subject to the listed TRIPS exceptions (flexibilities).

In the African context, problematic issues relating to access to medicines started when South Africa sought to amend its Medicines Control Act to introduce parallel imports and compulsory licences. The opposition to South Africa's law by big pharmaceutical companies clearly showed that access to medicines is a political issue disguised in the law of patents. The South African case in 1998 was the very first attempt by a SADC member to domesticate TRIPS flexibilities, namely compulsory licences and parallel imports. This chapter further showed that access issues to medicines regarding the use of compulsory licences or threats to use them did also become a topical issue in the developed world in light of the anthrax scare case in 2001. Bayer had to supply its drug, Cipro, to the US and Canadian governments at very cheap prices because an Indian generic company had offered to supply the drug at half the cost.

It is ironic that in the Cipro case, the US position starkly contrasts with its pro patent rights approach in the South African medicines case and thus smacks of duplicity. Despite the Cipro case, the US has stridently remained an ardent defender of stringent patent protection in sympathy with its pharmaceutical industry. This chapter established that there is a tug of war

between patent rights of pharmaceutical companies and the rights of the poor in the developing and the least developed countries to access affordable medicines.

In a bid to unravel the effect of patents on medicines, the chapter examined some theories of intellectual property and attempted to strike a balance between the justification of intellectual property rights and the right to access medicines. The chapter concluded that the theory of rewards is important for innovation and technological development but must be used to reward innovation that targets diseases that matter in developing countries and the LDCs.

Chapter Two, therefore, established the conceptual and theoretical background to the study and affirmed that while fidelity to the tenets of the TRIPS Agreement by WTO members is important, the same agreement gives members a lot of leeway to derogate from patent rights in sympathy with access to medicines, and the developing countries, including SADC members must take advantage of this leeway. The chapter affirms the truism that taking full advantage of TRIPS flexibilities such as parallel imports and compulsory licensing will ensure that the rights to life, human dignity and health are realized for the world's poor.

Chapter Three explored the issue of access to medicines as a human right and established that despite the alleged conflict between patents and human rights, access to medicines is indeed a human right backed by regional and international instruments. The chapter established that in order for people in the developing countries and the LDCs to enjoy access to affordable medicines, there is a need to engage in a balancing act which weighs intellectual property rights against human rights especially the right to health. After an examination of the SADC instruments, namely, SADC Protocol on Health, SADC Pharmaceutical Business Plan and the Strategy for Pooled procurement, the chapter concluded that human rights values are imbued in the instruments. Because not being able to access affordable essential medicines, which are invented as 'benefits of scientific progress', violates the right to life, human dignity and health, chapter three concluded that human rights must trump patent rights in certain circumstances. This trumping can be effected through the employment of the rights-based approach, which was discussed and appropriately contextualized in this chapter. The main conclusion of Chapter Three is that the rights-based approach must be employed to hold the state accountable for violating the right to health, which is a fundamental right identified in the Universal Declaration on Human Rights, Declaration of Alma Ata; UN General Assembly documents and African and

other regional instruments. The overall conclusion of the chapter is that human rights must trump intellectual property rights.

Chapter Four provided an overview of the WTO TRIPS flexibilities and attempted to gauge the extent of incorporation of the flexibilities in the SADC members' IP legislation. The main findings of this chapter may be summarised as follows. Firstly, not all SADC members must comply with the requirements of the TRIPS Agreement since more than half of them are LDCs which should not bother providing for pharmaceutical patents until 2016, and other forms of intellectual property until 2021. Despite this, all SADC members have patent laws protecting product patents including pharmaceuticals. In a snap survey of SADC patent laws, the chapter established that all SADC members provide for compulsory licences and government use of patents while the incorporation of other TRIPS flexibilities was not as systematic with each country cherry picking the flexibilities that it desires at any given time. This is a major weakness and this chapter recommended that all SADC members incorporate minimum TRIPS flexibilities in their IP legislation. Three SADC members, namely Malawi, Zambia, and Zimbabwe exclude the patenting of new use forms of patents relating to food and medical products while the rest do not expressly prohibit new use patents. This promotes weak patents that are minor embellishments to previously patented products which is a practice pejoratively known as ever greening. On the whole, SADC members have incorporated TRIPS flexibilities in their laws despite being reluctant to take advantage of the legal provisions in practice.

Most SADC members have not taken advantage of TRIPS exceptions to patentability in order to introduce patent examinations, patent oppositions and strengthen provisions around novelty and the requirement that a patent must involve an inventive step. This makes it easy for patent holders to invent around a patent and extend its lifespan thus frustrating the early entry of generics. The chapter recommends that SADC members engage in patent law reform that will see each member taking more advantage of the flexibilities. However, the chapter noted that there are some SADC members namely, Botswana, South Africa and Zimbabwe which have taken the patent law reform project quite further than the rest, hence their experiences must inspire other members.

In Chapter Five, a detailed discussion of the Botswana, South African and Zimbabwean experiences with the actual use of TRIPS was rendered. Botswana, which is chosen as an

example of good practice has the most recent patent law which incorporates Article 31 *bis* of TRIPS by reference. This was lauded in this chapter as a good start from which other SADC members can learn. However, there are three problems with Botswana's recent patent law which this chapter highlighted. Firstly, the new law criminalises patent infringement to the detriment of generic drug production and innovation. Secondly, while the law provides for pre-grant patent opposition, the process is not actualised by the regulations to the Act, and this omission does not augur well for access to medicines. Finally, Botswana is currently in negotiations which will culminate in it acquiring membership of the Economic Partnership Agreements (EPAs) with TRIPS-plus provisions, to the obvious detriment to access to medicines. The chapter recommended that Botswana must remedy the impugned provisions and reconsider its position in the EPA negotiations.

Zimbabwe's patent laws have good provisions on parallel importation, government use of patents and compulsory licensing. This chapter also focused on how Zimbabwe managed to issue a government licence to manufacture ARVs in 2002 after declaring a state of emergency due to HIV/AIDS. The matter is important to other SADC members, especially those that have never invoked any of the TRIPS flexibilities for access to medicines despite the high disease burden.

This chapter also focussed on the use of TRIPS flexibilities for access to medicines in South Africa by focusing on the 1998 Medicines and related Substances Control Amendment Act litigation, the use of competition law and South Africa's recent Draft IP Policy, which has extensive proposals on TRIPS and public health. Again, like with the discussions of the Botswana and Zimbabwean experiences, this chapter identified specific lessons that fellow SADC members could learn from South Africa in the context of access to medicines.

Chapter Six explored the access theme to medicines for SADC further by looking at other developing countries' jurisdictional experiences with the use of TRIPS flexibilities in the context of access to medicines. The chapter focused on using exceptions to patentability in the Indian case of *Novartis AG v Union of India and others*; using patent opposition procedures in favour of access to medicines in Thailand; and fixing anti-counterfeit legislation so that it does not compromise access to medicines in Kenya.

From the case discussions, the chapter extracted thematic lessons for SADC countries covering such issues as the importance of civil society in the access battle for medicines, the role of the state in protecting the right to life, human dignity and health in the context of access to medicines, the differences between counterfeit medicines and generics, preventing evergreen patents through strict legislative requirements for patentability such as India's section 3(d), and improving patent quality through effective opposition like was the case in Thailand. Chapter Six, like all the other chapters preceding it, knitted all the objectives of the study together and showed that the human rights approach may be used to favour access to medicines if civil society and other non-governmental groups are vigilant enough to keep the government on its toes.

Finally, Chapter Seven concluded the study very well by bringing all the issues discussed in the previous six chapters together. The chapter made six recommendations and suggested three areas for further research in order to improve access to medicines. The recommendations, most of which are likely to yield positive access results to medicines if implemented, emphasise among other things, law reform, and the rights-based approach, using a hybrid theoretical framework to improve access to medicines and empowering civil society groups in the SADC region to deal with the technical and legal aspects of access to medicines.

The recommendations are regarded as an important part of this study because their implementation will in all likelihood take care of the lacuna identified in the statement of the problem in chapter one above and deal with most of the gaps in the SADC members' legal and policy frameworks as identified in chapters four to six above. It is now appropriate to conclude this study by rendering an account of its recommendations and suggested areas for further research. This is done in the section immediately below.

7.3 Recommendations

From the above narration of the findings in the pertinent chapters of this study, it is evident that the proposed recommendations would canvass the following cross-cutting issues:

- (a) Theories of intellectual property;
- (b) Human rights and the rights-based approach;
- (c) Prospects of regional manufacturing of pharmaceutical products;
- (d) The prospects of pooled procurement of pharmaceuticals in the SADC region;
- (e) SADC IP patent law reform; and

- (f) Alternative approaches including the role of civil society.

This discussion of the recommendations, which forms a very important part of this study, is crucial in that it shows the study's contribution to the body of knowledge in the subject area under focus.

7.3.1 Theories of Intellectual Property

Taking a retrospective look at Chapter Two, one may safely conclude that from the history of access to medicines, it is evident that the problem is not unique to the developing countries. As such, developed countries also have a share of the access to medicines problem. However, the problem becomes more acute when it comes to the developing countries generally and the SADC region in particular. The chapter discussed some of the theories of intellectual property namely, utilitarian theories,⁵ natural rights theories, incentives theories, rewards theories, prospect theories and Jean-Jacques Rousseau's social contract theory. The study suggested that a hybrid theoretical approach to intellectual property may be useful in resolving the access to medicines problem for SADC.

It has been argued in terms of the incentives theory that intellectual property law provides the creators thereof with incentives to produce new knowledge which solves the underproduction problem likely to materialise if knowledge was non-excludable.⁶ However, IP law is unjust because current consumers finance the inventor's efforts (by paying monopoly prices) to the benefit of future consumers, who will enjoy innovation at marginal cost.⁷ Overreliance on the incentive theory leads to the unjust result that drugs for baldness are more important than those for malaria,⁸ tuberculosis, dengue fever, HIV/AIDS and cholera, diseases that largely affect poor people in the developing and the least developed countries. Patients in the developing countries and the LDCs lack the ability to pay while drugs for baldness enjoy a multibillion dollar market.⁹

⁵ See generally Morrissey M *An Alternative to Intellectual Property Theories of Locke and Utilitarian Economics* (2012) unpublished MA dissertation submitted to Louisiana State University at 1 – 56.

⁶ Belleflame P "How Efficient is the Patent System? A General Appraisal and Application to the Pharmaceutical Sector" in Gosseries A, Marciano A and Strowel A *Intellectual Property and Theories of Justice* (2008) at 213.

⁷ Ibid.

⁸ Sunder M "Review of Intellectual Property and Theories of Justice, co-edited by Axel Gosseries, Alain Marciano and Alain Strowel. London: Palgrave Macmillan, 2008, 296 pp." (2010) 3 *Erasmus Journal for Philosophy and Economics* at 116.

⁹ Ibid.

Understanding intellectual property in terms of incentives creates the wrong impression that the ability to pay is not an important consideration.¹⁰

Pharmaceutical companies are against compulsory licences because the industry argues that they undermine patent protection and reduce the incentive to invest in the development of new and innovative medicines.¹¹ This argument may be appealing for other classes of pharmaceuticals but with regard to drugs for HIV/AIDS treatment, whose development is largely financed through research fellowships and public funds to universities, the argument is not that attractive.¹²

Rewards should, therefore, be for genuine cases commensurate with the services rendered and not to provide for astronomical profits for some minor additions to drug efficacy which is a notorious activity known in pharmaceutical circles as ever greening.

To deal with the unjust effects of the rewards theory, a number of mitigating approaches, such as differential pricing, use of parallel imports and the introduction of an alternative reward system for specific medical research are hereby proposed for the SADC region. The alternative reward approach will entail the government identifying specific diseases and incentivising research therein by rewarding pharmaceutical companies to produce and sell at marginal costs to anyone.¹³ South Africa does acknowledge the possible efficacy of such a rewards approach in its Draft IP Policy (2013) discussion dealing with alternatives to IP.

Some theoreticians have argued that the access to medicines problem can be resolved to a large extent by resorting to the principle of justice in the distribution of social health needs.¹⁴ The justice-based approach to patents must surely consider social and economic inequalities by focusing on health needs (needs principle) than the ability to pay.¹⁵ This is because patents are barriers to affordability and only generate investment where profitable markets exist and they do not work for drugs needed to address diseases that prevail in developing countries¹⁶ and the SADC region. Therefore, some form of unique pharmaceutical justice, which draws from but

¹⁰ Ibid.

¹¹ Bombach KM “Can South Africa Fight Aids? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement” (2001) 19 *Boston University International Law Journal* at 282.

¹² Bombach above at 282.

¹³ Belleflame P above at 223.

¹⁴ See for instance, Dietsch P “Patents on Drugs – the Wrong Prescription?” in Gosseries A, Marciano A and Strowel A *Intellectual Property and Theories of Justice* (2008) at 230 – 231.

¹⁵ Dietsch above at 233.

¹⁶ Smith RD, Correa C and Oh C “Trade, TRIPS and Pharmaceuticals” (2009) 373 *The Lancet* at 686.

modifies John Rawls' theory of justice for all regardless of social position, income and talent,¹⁷ must be introduced to benefit the least advantaged in the developing countries and SADC. This form of justice can work very well with distributive justice because 'certain scarce commodities should be distributed less unequally than the ability to pay for them'.¹⁸

Therefore, the rewards aspect of patents in the context of access to medicines in the SADC region should be inspired by the social environment because while claiming robust patent protection may create short term benefits for the patent holder, in the longer term, it is likely to create social inequities and imbalances.¹⁹ In the same vein, Gold et al cited by Odusei aptly observe that:

“...the recognition that innovation is a social, collaborative phenomenon changes the way that policy makers, researchers, industry and technology consumers ought to view and appreciate IP: as something to be shared and built upon rather than something to accumulate for its own sake.”²⁰

Elaborating on his needs principle, Dietsch in total agreement with Gold above emphasises that accepting the principle implies that the invention of certain drugs, namely those that result in the maximal reduction of the global disease burden, is more important than inventing others.²¹ Consequently, placing innovation and invention in a social context implies that a theoretical compromise which tries to address both people's health needs and rewards inventors to some extent is imperative.²²

To actualise the needs principle in the SADC context, it is hereby recommended that TRIPS-based solutions hinging largely on contextual SADC law reform as elaborated in 7.4.4 below are seriously considered. The forms of envisaged reforms that easily come to mind are the strengthening of novelty and inventive step requirements, not awarding patents for minor embellishments to drugs, introducing patent opposition and using compulsory licences as discussed in various sections of this study. The rewards theory, which currently favours

¹⁷ Dumitru S “Are Rawlsians Entitled to Monopoly Rights” in Gosseries A, Marciano A and Strowel A *Intellectual Property and Theories of Justice* (2008) at 57 – 93.

¹⁸ Dumitru above at 93.

¹⁹ See for this incisive observation Odusei P “Exploiting Patent Regulatory ‘Flexibilities’ to Promote Access to Antiretroviral Medicines in Sub-Saharan Africa” (2011) *Journal of World Intellectual Property* at 5.

²⁰ Gold et al (2008) *Toward a New Era of Intellectual Property: From Confrontation to Negotiation, A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property* available at http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf (last visited 10/10/2009).

²¹ Dietsch above at 238.

²² Dietsch above at 237.

pharmaceutical companies, can in actual fact be realigned to better serve access to medicines if SADC members consider giving rewards to pharmaceutical companies according to the impact of a particular drug on saving lives.²³ Other possible approaches to the reward theory could take the form of incentivising pharmaceutical companies by SADC members to conduct research and development in the public interest and then license the invention to the state.²⁴ Another alternative approach to the traditional rewards theory would be for SADC countries to introduce tax incentives in combination with threats to use compulsory licences²⁵ such that producing previously unprofitable drugs can be financially rewarding for pharmaceutical companies.²⁶ In terms of this tax incentive, pharmaceutical companies not doing research and development on diseases of the poor would have to be taxed heavily. While this version of the rewards theory may sound attractive, it is likely to be effective to SADC members with more disposable financial resources and would not be possible to apply in other poorer members, unless donor assistance can be procured. After all, there is some veracity in the submission that “poverty, not patent policies, more often inhibits access to essential medicines in the developing world”.²⁷

To summarise the recommendation based on theories of intellectual property, it is important to reiterate that patents are supposed to provide rewards for innovation but in countries like India, patents are awarded to big multinational companies which strategically restrict competition.²⁸ SADC members are urged to use the social argument and reinvent the rewards theory so that only inventions that contribute to the alleviation of the disease burden peculiar to the region are deliberately incentivised through subsidies and tax schemes. This recommendation can easily be implemented alongside the rights-based approach which is discussed immediately below.

7.3.2 Prospects of the Rights-based Approach

In Chapter Three, the relationship between access to medicines and human rights was contextualised and potential areas of conflict exposed. Many human rights activists allege that TRIPS provisions on pharmaceutical patents violate basic human rights by compromising the

²³ Pogge TW “Human Rights and Global Health: A Research Programme” (2005) 36 *Metaphilosophy* at 189. Admittedly, such a proposal is attractive but quite difficult to implement.

²⁴ Dietsch above at 241.

²⁵ Threats to use compulsory licenses may rattle some big drug companies to lower drugs prices but this is likely to happen with powerful developing countries with a big market for drugs and the purchasing power.

²⁶ Dietsch above at 242.

²⁷ Attaran A “How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?” (2004) 23 *Health Affairs* at 155.

²⁸ Lofgren H “David and Goliath: Novartis Challenges India’s Patent Law” (2012) *The Conversation* at 2.

ability of poor countries to access essential medicines.²⁹ The TRIPS Agreement purports to reflect the needs of the developing countries such as the protection of public health.³⁰ Hence, the developing countries found it easy to accede to the agreement. Therefore, the TRIPS Agreement, specifically Article 8 thereof, must be used by the developing countries and the SADC members to demand that there be an essential right to health, and thus essential medicines should be made available, regardless of patent laws.³¹ Additionally, the TRIPS Agreement provides for public health exceptions to patentability which should allow countries with legitimate health concerns to deny a patent on a particular drug or even all drugs.³² Therefore, the TRIPS Agreement should not act as an impediment to the public health of developing countries,³³ including SADC.

Under international human rights law, access to medicines is a matter of rights, with human rights providing an alternative way of understanding issues relating to the distribution and availability of drugs, as well as providing a workable framework for adjudication of rights.³⁴ Governments do not only have a moral and humanitarian obligation to provide access to medicines, but also have a legal obligation, which enjoins them to make budgetary provisions for access to medicines.³⁵ The legal obligation implies accountability when a state has not met its obligations.³⁶ A human rights framework imposes obligations on states to interpret treaties, trade rules and intellectual property laws in a manner that fully advances public health interests.³⁷ Because states are the primary bearers of human rights responsibilities, they should take actions to ensure that activities of private actors, such as pharmaceutical companies, do not obstruct the realisation of human rights.³⁸

Although Articles 7, 8 and 27 of the TRIPS Agreement do not give WTO Members an unlimited room for exceptions to pharmaceutical patents, the implication, nevertheless, is that TRIPS

²⁹ Seeratan NN “The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry” (2001) 3 *Scholar* at 404.

³⁰ See Article 8 of the TRIPS Agreement.

³¹ Seeratan above at 404.

³² Article 27 of the TRIPS Agreement.

³³ The Doha Declaration on TRIPS and Public health categorically states in paragraph 4 thereof 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.

³⁴ Attaran AE “Not Just a Tragedy: Access to Medications as a Right under International Law” (2003) 21 *Boston University International Law Journal* at 327.

³⁵ *Ibid.*

³⁶ *Ibid.*

³⁷ AE Attaran above at 328.

³⁸ Hunt P *Neglected Diseases: A Human Rights Analysis* (2012) at 11.

norms are not meant to over-run the pre-existing human rights obligations of WTO Members.³⁹ Article 27 recognises that certain innovative medical procedures may be excluded from patentability because of their value to the global community in saving lives.⁴⁰

For SADC countries, it is important that each provision of the TRIPS Agreement, whether it is used in the context of TRIPS flexibility or not, be read in light of the objectives of the TRIPS Agreement.⁴¹ Such an interpretive approach has a textual basis in the Vienna Convention on the Law of Treaties,⁴² which establishes that a “treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its objects and purpose”.⁴³ Just like the recommendations made under the theories of intellectual property above, Article 7 of TRIPS clearly shows that IP rights do not exist in a vacuum since they are supposed to benefit society as a whole and not merely protect private rights. There is no better way of making IP rights ‘benefit society’ as a whole than providing affordable essential medicines for all as a human right. Therefore, patent rights should be exercised coherently with the objectives of mutual advantage to right holders and the users of patented medicines, in a manner conducive to social and economic welfare and to balance rights and obligations.⁴⁴

In this study, apart from Chapter Three, the rights based approach was echoed in many places particularly in Chapter Six. A violation of the right to health was explicitly alleged and litigated in the Kenyan case of *P.O.A and Other v Attorney General* and the Court ruled that the government of Kenya does have an obligation to protect the right to health in the context of access to medicines by adopting measures and policies that facilitate access to affordable essential medicines. The Kenyan High Court went further and ruled unequivocally that intellectual property rights are subordinate to human rights, specifically the right to health. In the Indian case of *Novartis AG v Union of India and Others*, citing from the historical development of patent law in India, the Supreme Court cited submissions made by Justice Ayyangar (as he

³⁹ Saxlin-Hautamäki E “Establishing Coherence: The Right to Access to Medicines, Pharmaceutical Patents and the WTO Medicines Decision” (2010) 1 *Nordic Journal of Commercial Law* at 7.

⁴⁰ Specifically Articles 27 (2) and 27 (3) of TRIPS. See further and on a related note, Manne C “Pharmaceutical Patent Protection and TRIPS: The Countries that Cried Wolf and Why Defining ‘National Emergency’ will save them from themselves”.

⁴¹ The objectives are spelt out in Articles 7 and 8 of the TRIPS Agreement.

⁴² Concluded in Vienna on 23 May 1969.

⁴³ Article 31 of the Vienna Convention.

⁴⁴ Elbeshbishi AN “TRIPS and Public Health: What Should African Countries Do?” (2007) 49 *ATPC Work in Progress* at 14.

then was) that patent systems must be modelled according to the conditions obtaining in the country, hence the effects of patents on the right to health can only be effectively assessed in the context of the unique needs of the country.⁴⁵ Like in all other instances when the right to health is contextualised to the TRIPS Agreement, the Indian Supreme Court referred to the nature and scope of obligations,⁴⁶ national treatment,⁴⁷ objectives,⁴⁸ principles,⁴⁹ patentable subject matter⁵⁰ and the rights conferred.⁵¹

To conclude this recommendation on the use of the rights-based approach by SADC, it is important to emphasise that it is only by using the language of human rights that it would be possible to carve out and use exceptions to patents that fully take into account access to affordable medicines.⁵² Additionally, rights-based approaches do not only call for the availability of medicines at lower prices but also put pressure on states to provide funds for research and development of drugs that affect the people in the particular country or region.⁵³ Notably, therefore, the rights approach can work as a ‘double edged sword’⁵⁴ in that private pharmaceutical companies can be called to ‘human rights order by the state’, while at the same time benefitting from increased government funding aimed at actualising the right to health.

In closing, the SADC region including civil society groups is hereby urged to adopt a human rights approach because it “offers an alternative vision of the purpose and requirements of intellectual property as well as a set of obligations that place intellectual property in a wider context”.⁵⁵

This human rights approach may be used as a justification for embarking on the development of local pharmaceutical manufacturing capacity and using compulsory licence provisions

⁴⁵ *Novartis AG v Union of India and Others* at paras 36 – 37.

⁴⁶ Article 1 of TRIPS.

⁴⁷ Article 3 of TRIPS.

⁴⁸ Article 7 of TRIPS.

⁴⁹ Article 8 of TRIPS.

⁵⁰ Article 27 of TRIPS.

⁵¹ Article 28 of TRIPS.

⁵² Gupta A “Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?” (2004) 2 *Buffalo Intellectual Property Law Journal* at 152.

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ Chapman A “The Human rights Implications of Intellectual Property Protection (2002) 5 *Journal of International Economic Law* at 879.

introduced by Article 31 *bis* of the TRIPS Agreement. The next two recommendations deal with these two important issues.

7.3.3 Prospects of Regional Pharmaceutical Manufacturing of Drugs

This study highlighted the fact that while drugs for the treatment of diseases common in the developing countries and the SADC region do exist, most of them are patented and expensive. This is so notwithstanding the fact that most of the imported and generic versions of the drugs have to be imported using scarce foreign currency resources.

Poverty, which results in an inability to pay for even the cheapest medicines, including generics,⁵⁶ imposes a heavy burden on most SADC governments to procure and subsidise drugs for the poor. In addition, there are other problems unique to developing countries and the SADC region, such as under investment in health infrastructure which leads to the lack of clinics and hospitals, poor distribution networks, low numbers of trained health personnel and high levels of patient illiteracy.⁵⁷ Other factors that are attributable to government action may be high taxes and tariffs which raise prices.⁵⁸

To deal with the problem of high drug prices, it is hereby recommended that SADC explores the possibility of manufacturing some essential drugs in the region, using existing pharmaceutical manufacturing capacity as a starting point.

One major constraint in solving the access to medicines problem in the SADC region is that medicine production capacity is weak.⁵⁹ The African heads of state and government adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) in May 2007 in order to ensure a sustainable supply of affordable medicines and to improve public health and promote industrial and economic development in Africa.⁶⁰ The PMPA lists six priority areas,⁶¹ including developing a pharmaceutical manufacturing agenda and addressing IP issues. Equally, SADC has elaborate

⁵⁶ See GlaxoSmithKline “Intellectual Property and Access to medicines in Developing Countries” at <http://www.gsk.com/responsibility/index.htm> (last visited 16/12/2013).

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ See Machemedze R, Munyuki E and Mulumba M “Literature Review on Cooperation in Essential Medicines Production and Procurement between East and Southern Africa (ESA) Brazil, India and China” (2013) 96 *EQUINET Discussion Paper* at 2.

⁶⁰ Ibid.

⁶¹ The priority areas are mapping productive capacity, situation analysis, developing a manufacturing agenda, addressing intellectual property issues, political and geographical matters, economic considerations and financing.

plans for pharmaceutical self-sufficiency, elaborately spelt out in the Pharmaceutical Business Plan⁶² and the Strategy for Pooled Procurement of Essential Medicines and Health Commodities.⁶³ Therefore, within Africa and the SADC region, the policy goal is to create and sustain reliable pharmaceutical industries whose operations are relevant to local economies and responsive to the disease burdens.⁶⁴

While developing local pharmaceutical manufacturing has advantages for employment, skills, foreign currency savings and developing drugs that are suited for the local environment,⁶⁵ the SADC the reality on the ground is that few countries in the region, with the exception of South Africa, have domestic pharmaceutical manufacturing plants.⁶⁶ There are a number of constraints in the local pharmaceutical production within SADC member states inclusive of the following items on the list:⁶⁷

- (a) Weak policy environment and limited governmental support for the local production of drugs;
- (b) High tariffs on imported inputs, high interest rates on credit, unreliable energy supplies, water and transport infrastructure;
- (c) Lack of qualified personnel such as scientists and industrial pharmacists;
- (d) Limited international linkages and mechanism to overcome IP constraints in technology transfer and the acquisition of active pharmaceutical ingredients;
- (e) Gaps in the pharmaceutical regulatory frameworks which do not ensure quality, safe and efficacious medicines;
- (f) Small markets within individual countries; and
- (g) Weak or non-existent capacities for pharmaceutical research and development.

It is axiomatic that most of the above mentioned barriers are non-IP ones which can be resolved without resorting to the provisions of the TRIPS Agreement. Therefore, this makes it easy and

⁶² SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat in June 2007.

⁶³ Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, published by the SADC Secretariat in September 2012.

⁶⁴ Machemedze, Munyuki and Mulumba above at 2.

⁶⁵ Machemedze, Munyuki and Mulumba above at 5.

⁶⁶ See Equinet “Overcoming Barriers to Medicines Production Through South-South Cooperation in Africa” (2013) 34 *Policy Series* at 1. SADC countries with some pharmaceutical manufacturing capacity are Madagascar, Malawi, Mauritius, Mozambique, Namibia, Swaziland, Tanzania, Zambia and Zimbabwe.

⁶⁷ Equinet above at 2 – 3.

practical to recommend local production as a possible solution to the access to medicines problem in the SADC region.

A range of regional and national measures are, therefore, needed for the SADC region to overcome the above outlined barriers towards the manufacturing of drugs locally. Firstly, the governments must set an enabling policy environment that will facilitate investment in and support of domestic production, such as using tax exemptions, lowering tariffs on imported active ingredients and providing government guarantees on credit applied for by pharmaceutical companies desirous of manufacturing drugs to cure diseases of the poor.⁶⁸

Secondly, there is a dire need for governments to invest in skills development in areas cutting across pharmacology, regulatory functions, management of pharmaceutical manufacturing and negotiation with international firms and governments such as the United States which favours patent protection at all costs.⁶⁹

The third possible solution is legal and administrative in that SADC member states must pass good laws and strengthen enforcement capacities within medicines regulatory bodies. This could work well with well-equipped laboratories staffed with technically competent personnel.⁷⁰

Finally, it is important to negotiate regional and international agreements in order to widen the market size and access technology and investment opportunities while at the same time investing in research and development capacities.⁷¹

It is recommended that should the SADC region consider the above problem-solving approach the issue of regional pharmaceutical manufacturing may see the light of day. To complement the proposals above, there is another dimension to possible regional pharmaceutical production dubbed South-South cooperation.⁷²

In line with the current thinking around South-South cooperation, SADC members are urged to consider partnering with fellow developing countries such as India, Brazil, Thailand and China

⁶⁸ Equinet above at 3.

⁶⁹ Machemdze, Munyuki, Mulumba above at 3.

⁷⁰ Ibid.

⁷¹ Machemedze, Munyuki and Mulumba above at 3.

⁷² See generally Musungu SF, Villanueva S and Blasetti R *Utilising TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks* at 35 -79.

in order to develop local pharmaceutical manufacturing capacity and markets expansion.⁷³ These South-South cooperative frameworks are likely to significantly help developing countries including SADC members to devise ways of effectively dealing with constraints around TRIPS flexibilities.⁷⁴

Good examples of these South-South collaborations are to be found in Mozambique and Uganda. The government of Mozambique is currently in partnership with the government of Brazil to build a plant to produce generic drugs for HIV/AIDS and other diseases.⁷⁵ The initial investment in the project was estimated at about \$23 million⁷⁶ in 2008, when the local office was opened in Mozambique. In 2007, a \$38 million pharmaceutical plant to manufacture antiretroviral and anti-malaria drugs was set up in Kampala, Uganda by Cipla, an Indian pharmaceutical company, upon request for technical assistance by the Ugandan government.⁷⁷ In terms of the cooperative arrangement, Cipla will extend technical assistance to Uganda through a joint venture with a local partner; Quality Chemicals Ltd. Cipla provided the technology and expertise to set up the plant,⁷⁸ which now provides an outlet for Cipla to produce the specific medicines for the African market.

The two examples above reflect different approaches to the South-South approach – the first is largely through government to government development aid while the second is done through the private sector which supports distribution and sale. There are, therefore, prospects of the expansion of pharmaceutical markets in Africa through South-South cooperation and it is hereby strongly recommended that the SADC region explores this possibility vigorously using the Mozambique experience as a starting point.

The foregoing recommendation highlights the importance of the local production of drugs aided either by investments in local pharmaceutical manufacture from within the region or using resources from other sources in the south, in the form of development aid or private joint ventures. The overall aim is to realise the local production of drugs that are suited for the reality

⁷³ Equinet above at 3.

⁷⁴ Musungu, Villanueva and Blasetti above at xiv.

⁷⁵ Machemedze, Munyuki and Mulumba above at 8.

⁷⁶ World Bank “Bridging the Atlantic: Brazil and Sub-Saharan Africa: South-South Partnering for Growth” (2011) at <http://siteresources.worldbank.org/AFRICAEXT/Resources.africa-brazil-bridging-final.pdf> (last visited 16/12/13)

⁷⁷ Machemedze, Munyuki and Mulumba above at 9.

⁷⁸ Machemedze, Munyuki and Mulumba above at 9.

of disease in the region. Another opportunity for a regional solution to the access to medicines problem in the SADC region is presented by Article 31 *bis* of TRIPS. The next recommendation investigates the possibility of using Article 31 *bis*.

7.3.4 Use of the Paragraph 6 System and Article 31 *bis* of TRIPS

From a holistic reading of various sections of this study, it is not in dispute that WTO members can issue compulsory licences for domestic production as well as importation.⁷⁹ Impediments to the use of compulsory licences may be the unavailability of sources of supply and the fact that by virtue of the principle of territoriality of patents, members cannot grant a compulsory licence directly to a foreign manufacturer.⁸⁰ The last mentioned of the two concerns is no longer relevant in light of the August 2003 Decision and the 2005 TRIPS waiver which introduced Article 31 *bis*, thus taking care of the ‘paragraph 6 problem’ identified by the Doha Declaration in 2001.⁸¹

The Paragraph 6 problem has now been solved and developing and least developing countries, including SADC members can now take full advantage of compulsory licences under TRIPS for both domestic use and export subject to certain conditions. Paragraph 6, now Article 31 *bis* of TRIPS, is very relevant for regional trade blocks like SADC.⁸²

Paragraph 6 permits developing countries or LDCs that are part of a regional bloc 50 % of whose membership are LDCs to produce or Import products under compulsory licensing both for domestic use and for export to other members with similar health problems.⁸³ Since Paragraph 6

⁷⁹ See generally Article 31 of TRIPS.

⁸⁰ Van Eeckhaute JC “The Debate on the TRIPS Agreement and Access to Medicines in the WTO: Doha and Beyond” (2002) 5 *Pharmaceuticals Policy and Law* at 17.

⁸¹ Paragraph 6 of the Doha Declaration bemoaned the fact that in terms of Article 31 (f) of TRIPS, compulsory licenses can only be granted for the predominant supply of the domestic market, thus leaving members with little or no pharmaceutical manufacturing capacity in a catch 22 situation – they can issue compulsory licenses but will not be able to manufacture pharmaceuticals in terms of the license due to the lack of capacity. This issue was addressed by the August 2003 Decision which introduced a waiver to Article 31 (f) which became effective in 2005.

⁸² Decision of the General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 1 September 2003 (hereafter August 2003 Decision). For an assessment of the potential impact of the Decision for developing countries for a broad array of diseases, see Abbot FM “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *The American Journal of International Law* at 322 – 323 and at 358, where he submits that although the Decision shows WTO sensitivity to social concerns, the effectiveness of the Decision will be felt when developing countries actually use it to address their public health needs.

⁸³ The pertinent provision provides as follows:

“With a view to harnessing economies of scale for the purpose of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products;

(i) where a developing or least-developed country WTO member is party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More

provides that if half of the members of a Regional Trading Agreement (RTA) is made up of LDCs, the requirements of Article 31(f) of TRIPS shall be waived,⁸⁴ the SADC region, which qualifies as a targeted RTA in terms of the specified criteria, should make use of the paragraph 6 window of opportunity.⁸⁵

It is hereby strongly recommended that SADC members ratify Article 31 *bis* of the TRIPS Agreement in order to be able to effectively issue compulsory licences for the manufacture and export of generic drugs within the region, at least the enabling provisions, namely, the August 2003 Decision waiver and Article 31 *bis* of TRIPS allow such conduct. Using a compulsory licence to reduce the disease burden in the SADC region can be used in conjunction with the local regional pharmaceutical manufacturing capacity building proposal outlined above together with South-South collaborations. This is a very viable proposal which is very TRIPS-compliant but is currently unused due to unexplained reasons.

It is conceded that the paragraph 6 solution will not be easy to implement.⁸⁶ It is also noted that viewed from a broad developing country perspective, it is not an equitable solution because out of all RTAs in which developing and LDC WTO members are members, only the SADC region and other African RTAs would qualify.⁸⁷ The fact that the SADC region is the only RTA qualifying in terms of the criteria set by Article 31 *bis* does not imply that the solution is not viable. The SADC region faces the largest disease burden than all other regions of the world and

Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made of countries presently on the United Nations list of least-developed countries, the obligation of the member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that member to be exported to the markets of those developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patents rights in question...”

⁸⁴ See Kingah SS, Smis S and Soderbaum F “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* at 19.

⁸⁵ The SADC region qualifies because 8 out of 15 member countries (about 53%), namely, Angola, Malawi, Democratic Republic of Congo, Lesotho, Madagascar, Mozambique, Tanzania and Zambia are LDCs. There are strong opinions in the region that Zimbabwe, which has been dogged by political and economic instability since the late 1990s, should also be included on the LDC list.

⁸⁶ For example, countries that qualify will have to overcome administration impediments, such as coordination of the system, distribution to associate members and avoiding diversion and corruption that industrialised countries like the United States fear so much. See for this and other specific impediments Gumbel M “Is Article 31 *bis* Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System” (2008) 22 *Temple International and Comparative Law Journal* at 181.

⁸⁷ Gumbel above at 189.

if the waiver favours it, then it is only equitable and just that SADC takes full advantage of the waiver.

Practically speaking, the situation on the ground supports the use of Article 31 *bis* in the SADC region. South Africa has very good and advanced pharmaceutical manufacturing infrastructure, while Zimbabwe has a WHO-approved drug manufacturing plant. Additionally, through South-South collaboration with the government of Brazil, Mozambique, an LDC SADC member, will soon have pharmaceutical manufacturing capacity that may be very useful to the region. What, therefore, is required is that the SADC region identify which of the LDC members will do what according to present factor endowments and then proceed to pool resources together and organise regional production of generic drugs using a compulsory licence issued in terms of the permissive provisions of Article 31 *bis*.

Because the use of regional compulsory licences implies regional solidarity in dealing with access to medicines, it is appropriate to continue with this theme of pooling resources together for the SADC regional good by focusing on a recommendation that urges the use of pooled procurement. The next recommendation, therefore, appropriately proposes that SADC must actualise its Strategy on Pooled procurement in order to improve access to medicines.

7.3.5. Prospects of Pooled Procurement in the SADC Region

Pooled procurement, also known as joint procurement or procurement cooperation occurs when part or all of the procurement processes of different procurement entities are jointly executed by one of those procurement entities or a third party procurement entity.⁸⁸

The reason why the SADC region decided to embark on the strategy on pooled procurement was that studies conducted in the region between 2009 and 2011 found considerable differences in pharmaceutical procurement practices of member states as well as in the application of regulations and other procedures such as quality assurance.⁸⁹

The region, therefore, agreed that through the establishment of the SADC Pharmaceutical Procurement Services, pooled procurement will be used as a vehicle *to improve sustainable availability and access to affordable, quality, safe, efficacious medicines* (emphasis in the

⁸⁸ SADC Draft Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017 (2012) at viii.

⁸⁹ SADC Draft Strategy for Pooled Procurement above at v.

original).⁹⁰ The Strategy includes sharing information and work among member states, so that countries can learn and benefit from each other.⁹¹ The Strategy is one of the options for reducing the costs of medicines by creating economies of scale⁹² through collaboration in procurement by SADC members.⁹³ Should the Strategy be fully operationalized, there will be harmonisation in pharmaceutical registrations to the benefit of the members who will adopt similar approaches in future, theoretically cutting costs in registration and inspection of pharmaceutical facilities, thus creating savings across the region.⁹⁴

With savings made through information and work sharing by procurement agencies in member states, more funds will become available for procurement, which will in turn increase availability of and access to essential medicines and health commodities.⁹⁵

In August 2011, the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM) which is funded by DFID and managed by Re-Action (South Africa) was appointed by the SADC Secretariat on a consultancy basis to help the region with among other things, the development of a Pooled Procurement strategy.⁹⁶

The goal of SARPAM is to increase access to affordable essential medicines in the Southern Africa Development Community (SADC) region through supporting the development of a more efficient and competitive regional pharmaceutical marketplace.⁹⁷

While pooled procurement is strictly speaking not an IP issue, its scope for improving access to affordable essential medicines is very high, hence it is highly recommended that the SADC region actualises its implementation in line with the broad objective of ensuring access to medicines for all. Using pooled procurement would complement local pharmaceutical production and the use of regional compulsory licences in terms of Article 31 *bis*. Pooled procurement is

⁹⁰ *SADC Pharmaceutical Business Plan 2007* at 4.

⁹¹ Potsanyane M “Southern African Regional Programme on Access to Medicines to Medicines (SARPAM): a Key Partner in SADC’s Pharmaceutical Sector (2013) 80 *South African Pharmacy Journal* at 59.

⁹² See on a related note a discussion of the possible use of paragraph 6/Article 31 *bis* above.

⁹³ Government of Botswana “The Implementation of Trade Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities in the National Intellectual Property Legislation for Strengthening Access to Medicines in Botswana” (2013), A UNDP-SAPARM-Botswana Government Workshop held in Gaborone, Botswana from 25-27 March 2013 at 12.

⁹⁴ Potsanyane above at 59.

⁹⁵ Government of Botswana above at 13.

⁹⁶ Spivey PD Kashi and Carasso KB *SARPAM Annual Review Narrative Report* (2012) at 2.

⁹⁷ *Ibid*.

therefore recommended for the SADC region because it will protect the right to life, human dignity and health by ensuring that members benefit from economies of scale and mitigate the impact of medicines prices on access.

This study focussed on how SADC members can take advantage of TRIPS flexibilities without falling foul of the tenets of IP law, especially the law of patents. The common thread running through this study is that some SADC patent laws require fixing in order for them to be conducive for the accessing of affordable essential medicines. It is now appropriate to focus on the last but not least recommendation that touches on law reform.

7.3.6 Suggestions for Law Reform and Enhanced Role of Civil Society Groups

In chapters four and five of this study, TRIPS flexibilities, including compulsory licences, parallel imports, bolar exceptions, research and experimentation exceptions, the use of anti-competitive procedures, government use of patents, exceptions to patentability, the Doha Declaration and the 2003 August Decision/Article 31 bis were discussed and contextualised to the situation obtaining in the SADC.

In the discussion of TRIPS flexibilities, recommendations relating to the specific TRIPS flexibilities were discussed in Chapter Four and Five above in the proximate context. It is important to reiterate that with specific reference to compulsory licensing, it is recommended that the provisions be expanded and clarified in the individual countries' legislation.

In the context of IP law reform, it is important to repeat here, that the lessons learned from the Indian, Thai and Kenyan experiences in Chapter six must be heeded. The SADC member states must seriously consider introducing robust patent examination systems and patent opposition in amended IP legislation. Incremental patenting and evergreen patents are a major problem in the region because they delay the entry of generic drugs. India's section 3(d) is very informative in this specific regard and it is recommended that no SADC IP law reform project must ignore the importance of provisions similar to section 3 (d) in the context of pharmaceutical patents. IP law reform must, therefore, be given a priority list status on the SADC legislative reform agenda in the future.

Apart from IP issues and TRIPS flexibilities, this study revealed that civil society organisations are important partners in the quest for access to medicines in the developing world and in the

SADC region in particular. Except for South Africa, there is not robust civil society activism in the SADC region and this does not augur well for access to medicines and the holding of governments and pharmaceutical companies to account. In the case studies/cases discussed in Chapter Six above, civil society groups and NGOs enriched the arguments submitted to the courts in the respective jurisdictions. For example, in the P.A.O Kenyan case, the judge thanked the parties for the well-researched submissions⁹⁸ while at the same time acknowledging that the petition revolved around critical issues of great public interest and, therefore, there was no need to make an order as to costs.⁹⁹ Similarly, in *Novartis AG v Union of India and Another*, the court did acknowledge the illuminating and refreshing contributions of all the parties including interested parties.¹⁰⁰ The Thai Didanosine case is set apart from the other two by the fact that the complaint was brought by HIV/AIDS sufferers and a foundation fighting for their rights.

In all the three cases discussed in Chapter Six above, the importance of an empowered civil society was highlighted and it is, therefore, recommended that SADC countries must involve members of civil society in policy formulation in the context of using TRIPS flexibilities to improve access to medicines. Some civil society groups will have to be empowered with knowledge relating to the TRIPS Agreement and public health matters, while some of them, such as the Treatment Action Campaign, MSF and Section 27 in South Africa are more empowered than government departments and may in actual fact bring experts to help the relevant government departments deal with IP and public health matters.

7.4 Areas for Further Research

This study only explored the extent of the domestication of TRIPS flexibilities in the SADC region and the possible benefits for the region should each member state incorporate the minimum flexibilities in its laws. The premise of the study was that patents negatively affect the prices of drugs and using the rights-based approach in the context of a hybrid theoretical framework that contextually applies the rewards theory, exceptions to patents may actually be used to improve access to medicines. However, the study did not examine in any meaningful detail the likely impact of non-IP issues and other political matters allied to the SADC countries' membership to WIPO and the WTO. Most importantly, the South African experience showed

⁹⁸ P.O.A case at para 89.

⁹⁹ P.O.A case at para 90.

¹⁰⁰ *Novartis AG v Union of India and Another* at para 196.

that civil society organizations have an important role to play in access issues but the true extent of this role is currently not very clear. In light of the above observations, the subjects categorized below are suggested as areas for further research and possible empirical exploration.

To complement and strengthen the findings and recommendations of this study, it is hereby proposed that a follow up study, in the form of a research project covering the issues outlined below be conceived, followed up and executed.

7.4.1 Why have SADC members whose laws incorporate TRIPS Flexibilities been unable or reluctant to use them for access to medicines?

It must be axiomatic from the findings in this study that incorporating all the TRIPS flexibilities will not necessarily result in improved access to medicines. If that was the case, then India and Thailand would deal with HIV/AIDS better than any other developing country in the world. India has the most developed generics industry in the world, and yet it is grappling with access to ARVs for those who need them, in a manner that is arguably more desperate, and probably no better than in Africa. There is, therefore, a need for an empirical investigation into the reasons for not using TRIPS flexibilities by SADC members with relatively good IP laws, such as Mauritius, South Africa, Botswana and Zimbabwe.

7.4.2 What is the role of non-IP matters in access to Medicines?

While this study did acknowledge that non-IP matters, such as drug regulatory activities, discordant coordination between government departments, bureaucracy, lack of economic development, political factors and poor infrastructure influence access to medicines negatively, from the information gleaned while researching for the study, there is no clear ranking of the influence of these factors when weighed against IP issues, especially in the SADC context. These non-IP matters are likely to provide fertile ground for the propagation of a research topic on the role of non IP-matters. This is closely related to the issue canvassed immediately below.

7.4.3 What is the extent and Influence of other forms of IP such as trademarks, designs and copyright on access to medicines?

This study focussed on access to medicines and the use of TRIPS flexibilities with particular reference to patent law in the SADC context. Except in the discussion of the Kenyan case in Chapter Six, wherein there was a veiled reference to copyright law, no reference was made to other forms of IP and how they influence or are likely to influence access to medicines. The other IP forms must surely be important and will in all likelihood influence access to medicines. This may be an interesting follow up study area.

7.5 Valedictory Note on Recommendations

Admittedly, if some or all of the above recommendations are implemented, the current access to medicines legal regime in the WTO, SADC region and in the individual countries may be subjected to a culture shock since some of the proposed reforms may appear to be contentious and revolutionary. Since the intention in this study is to introduce orderly reform in sympathy with access to medicines in the SADC region, the reform process must be marshalled to generate a momentum for the transformation of SADC law and pharmaceutical policy reform that will usher in an era of access to affordable essential medicines coupled with a culture of respect for the right to life, human dignity and health. Therefore, it follows that there must be a focal point for the management of reforms in the region and the SADC Secretariat will be the most suitable driver of such reforms. The buy in from influential SADC members such as South Africa will of course be a prerequisite.

7.6 Chapter Summary

Perhaps the best way to begin summing up this chapter is to revive the question of how SADC countries can take advantage of TRIPS flexibilities to their mutual advantage without falling foul of WTO and TRIPS tenets. Although a complete impact analysis of the human rights implications of TRIPS flexibilities in the context of SADC access to medicines may call for a multi-disciplinary project of titanic proportions, this study has attempted to address the weaknesses in current SADC IP law practice against a comparative perspective from within the region and other comparable developing countries.

The study did show that human rights approaches and a SADC context-specific application of IP theories may yield positive results for access to medicines in the region. In the final analysis, the study recommends that in addition to adopting the rights approach, and revolutionising the rewards theory, the region must consider manufacturing essential drugs locally and also take advantage of pooled procurement. Further, the study recommends that IP law reform efforts currently going on in the SADC region, some of them at the behest of civil society organisations and NGOs must be complimented by reforms in the specific areas of patent examination, tightening requirements for patentability and introducing meaningful pre- and post-grant opposition to patents. Apart from the specific recommendations, this study does also suggest three areas of further research along the lines of examining the role of non-IP matters and other forms of IP on access to medicines in addition to enquiring into why those SADC members with

laws incorporating almost all the TRIPS flexibilities have been reluctant to take advantage of these.

As a parting shot, one must repeat the point that the recommendations outlined here are important and the SADC member states must seriously consider implementing them in the medium to long term. However, to implement the recommendations would require many adjustments in members' policies and other practices relevant to access to medicines. These changes cannot materialise as soon as the researcher would like them to. A lot of planning, consultation and evaluation of financial and other resources will have to be factored in before any SADC wide legal and policy reform is embarked upon in order to improve access to affordable essential medicines. As the adage goes, only time, the magician will tell.

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