

9 INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH: THE CONSTITUTION AND PRACTICE IN MALAWI

Dr Zolomphi Nkowani*

ABSTRACT

The paradox of health care and intellectual property (IP) rights protection provokes strong debates on the utility of protecting one over the other. There is a silent consensus that health and economic development are inseparable factors for improving living standards. Healthy people are better and efficient economic actors. The cost of ill health or occupational injuries has a direct effect on productivity and efficiency¹. However innovation and creativity are at the cutting edge of development and are a catalyst for pioneering breakthrough in medical and health-care sectors that are vital for health-care provision. The dilemma for policymakers is how to balance the two with manageable trade-offs.

This article focusses on Malawi and how it deals with the issues of intellectual property rights and public health. The institutionalization of health as a constitutional right in the 1994 Constitution (Sections 13, 16, 19, and 30) is an acknowledgement that a healthy population is a prerequisite for sustainable human development and increased productivity. Challenges that Malawi faces are similar to those of most least developed countries (LDCs). Currently, Malawi does not have an IP policy. The country's IP policy has been in draft form for some time. Much of the county's IP laws are outdated and ill-suited to 21st century needs and

challenges. In health-care delivery Malawi, like most LDCs, can take advantages of flexibilities under paragraph 7 of the WTO Doha Declaration 2001 until 2016.² Regionally, there are flexibilities³ that Malawi can harness through its regional memberships to ease the challenge of access to medicines and health-care services such as the SADC pooled procurement of essential medicines and health commodities⁴.

Within SADC, under Article 5 of the Treaty, Malawi is obliged to promote the living and working standards of its people. The SADC Protocol on Health reinforces the principle that productivity and efficiency are affected by the health status of economic actors. Healthy populations are better economic actors and without this a functional integration of the region is a dim possibility. Lack of a pharmaceutical manufacturing base in the region is a challenge for countries such as Malawi to take advantage of flexibilities in international IP regimes.⁵

In this article, the author reflects on the symbiotic relationship between intellectual property rights and the right to health as a subset of public health. The context for the discussion is local, but the outlook is regional and international. It is concluded that there are flexibilities under TRIPS, the General Agreement on Tariffs and Trade 1994 (GATT 1994), WIPO frameworks, and regional frameworks such as ARIPO, from which Malawi can benefit. However, this is dependent on internal structural constraints such as lack of an effective IP policy, lack of a pharmaceutical manufacturing base, and low level awareness of IP issues nationally.

Keywords: *Public health, intellectual property rights, TRIPS, SADC, Malawi, and Nkowani*

* **Dr Zolomphi Nkowani** (Malawi) LLB (Hons), Mlw, LLM (IEL), Warwick, ICSA (Cand), (UK), PHD, Salford (UK), Pg. Cert, (DSU), Dip, FRSA, F.R.S.PH (UK), Chief State Advocate, lecturer in law, University of Malawi. Formerly, lecturer in law, Lancashire Law School, University of Central Lancashire, (UK) and Research Fellow, Universities of Liverpool and Manchester (UK), Consultant to the China-Africa Legal Training Base. The interpretations, conclusions, views and opinions expressed here are mine and should not be attributed to any institution with which I am associated or any other agency or individual. I am indebted to all those that read the original draft of this paper for their useful comments. The law in this paper is stated as it stood on 10 November 2014.

¹ Z Nkowani, 'Injury unto Death, Occupational Health and Safety Regulation in Malawi' *Comparative and International Law Journal for Southern Africa* (2008) Vol 41 Issue 1. <<http://www.unisa.ac.za/Default.asp?Cmd=ViewContent&ContentID=21046>> Also see Z Nkowani, 'Occupational Health and Safety in the SADC Region: Exploring an Economic Approach' (2007) *Labour and Development Law Monograph*, University of Cape Town. [ISBN: 978-0-7992-2332-3].

² BK Baker (2003) 'Analyses and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' United Nations Millennium Development Goals Project, Task Force 5: Infectious Diseases and Access to Essential Medicines, Sub-Group Access to Essential Medicines. New York: United Nations.

³ Such as under Article 5 of the SADC Treaty and Articles 16 and 24 of the Protocol on Trade. Article 9 of the Protocol on Trade allows for GATT 94 Article XX (b) Exceptions to the Most Favoured-Nations treatment (MFN) and National Treatment (NT) obligations in the face of health concerns.

⁴ <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CCIQFjABahUKEwi4s6a43_3HAhVKOhQKHWMUCmA&url=http%3A%2F%2Fwww.sadc.int%2Ffiles%2F7614%2F1898%2F8449%2FSADC_Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf&usq=AFQjCNHieNlxFRaxz8qPiXT87EGNs4fTOA&sig2=2KgOyPf-1pxmD9GO0VAgbQ>

⁵ See Fink Carsten, (2005) 'Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective' in Richard Newfarmer (ed.), *Trade, Doha, and Development: Window into the Issues* (The World Bank).

I. BACKGROUND

Recent decades have been marked by policy shifts, reversals, and reconciliation of potentially conflicting social and economic priorities. On the one hand, competition has led to a surge in the urge to stimulate trade and investment to maintain global competitiveness. On the other, the need to cushion against adverse impact of trade has led communities to demand 'something to be done' to guarantee fundamental rights as a prerequisite for sustainable peace and development. This has been more visible in the realm of intellectual property rights⁶ and public health. Whilst states desire to create conducive environments for trade and investment, they need to ensure that they do not race to the bottom⁷ of social standards such as health. Although on the surface the language of multilateral trading texts such as the World Trade Organization (WTO) agreements is economic, the underlying rationale is social. Humans are at the centre. The human rights movement began in part as a protest against a form of trade i.e. 'slave trade' that subordinated humans and their welfare to corporate greed. The goal of trade is to improve people's living and working standards.⁸ Through the GATT 1994⁹, States

undertake to conduct their economic relations with a view to raising standards of living.¹⁰ Intellectual property rights are some of the tools for stimulating growth through creativity and innovation. Intellectual property rights and public health are mutually inclusive and supportive.

Public health refers to measures, whether publicly or privately designed, to prevent disease, promote health, and prolong life among the population as a whole.¹¹ The issue of access to medicines and health care is a vital component of a public health discourse.¹² Its activities aim to provide conditions in which people can be healthy and focus on entire populations. Public health is concerned with the total system and not only the eradication of a particular disease. Often in discussion about health there is a blurring in the usage between 'health' and 'public health'. These refer to two different trajectories with policy implications. Public health refers to a system, while health is a state of human affairs.¹³ The World Health Organization (WHO) defines health as a state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity.¹⁴ Public health is concerned with the assessment and monitoring of the health of communities and populations at risk to identify health problems and priorities. It seeks to

⁶ Intellectual property rights refer to the products of the mind or intellect, which are in the form of ideas and tangible and intangible objects. There are two broad fields of intellectual property: industrial property and copyright and related rights. Industrial property covers patents, trademarks, industrial designs, geographical indications, and trade secrets

⁷ 'Race to the bottom' is a socio-economic phenomenon in which governments deregulate the business environment or taxes in order to attract or retain economic activity in their jurisdictions, resulting in lower wages, worse working conditions and fewer environmental protections. See Z Nkowitz, 'When Elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A Beacon of Hope or Confusion Compounded? Commonwealth Law Bulletin, Volume 33, Issue 1 March 2007, pages 41–54.

⁸ This Commitment is expanded in the Marrakesh Agreement Establishing the World Trade Organization (WTO) to include trade in services and trade and environment. The social base for International Trade is expanded. In the preamble, Member States recognize that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment, and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development <http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm> See <<http://www.sadc.int/>> (accessed November 2014).

⁹ Under Article II of the Marrakesh Agreement Establishing the World Trade Organization and the General Agreement

on Tariffs and Trade 1994 (GATT 1994).

¹⁰ <www.wto.org>

¹¹ Article 1 of the WHO Constitution.

¹² JO Lanjouw and I Cockburn 'Do Patents Matter? Empirical Evidence after GATT' (2000) NBER Working Paper n 7495. See also K Balasubramaniam 'Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives', paper presented at the Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement?, Brussels, 20 March 2001.

¹³ See the preamble of the WHO Constitution for the definition of health. This definition has been adopted in other multilateral treaties and conventions such as the International Labour Organization's (ILO) Occupational Health and Safety Convention C155. For a general discussion of this aspect, see the latter which states that the term 'health', in relation to work, indicates not merely the absence of disease or infirmity, but also includes the physical and mental elements affecting health which are directly related to safety and hygiene at work, R Loewenson, C Nhachi, W Murambiwa and P Gona (1991), 'Epidemiology of the Health Impact of Pesticide Use in Developing Countries': Epidemiological research in Zimbabwe, Mimeo, Harare and Nkowitz 'Occupational Health and Safety in the SADC Region: Exploring an Economic Approach' (2007) *Labour and Development Law Monograph*, University of Cape Town. [ISBN: 978-0-7992-2332-3].

¹⁴ Preamble to the WHO Constitution, as adopted by the International Health Conference, New York, 19-22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the WHO, n 2, p 100; entered into force on 7 April 1948. See WHO (1948) *The Constitution of the WHO* International Health Conference, New York, 2 June 1945. New York WHO.

ensure that all populations have access to appropriate and cost-effective care, including health promotion and disease-prevention services.

Production costs and the cost of medicines are impacted by IP regimes such as patents. Access in the context of the General Comment 14 and the WHO Constitution can be economic (affordability), or legal, informational, or structural.¹⁵ There is a call for a balancing act between the promotion, acquisition, commercialization, and enforcement of intellectual property rights and provisions of public goods, such as health care.

II. CONSTITUTIONAL FRAMEWORK

A discussion about law is preceded by an acknowledgment of law as an abstract and a socio-political construct. The source and validity of law has preoccupied jurists for millennia.¹⁶ As a discussion of the jurisprudence is beyond the scope of this article, it will suffice to contextualize the constitutional threshold for law and policy on intellectual property rights and health in Malawi. Our point of departure is Hans Kelsen's pure theory of law.¹⁷ This is a theory of positive law, whereby a basic norm (grundnorm)¹⁸ underlies a hierarchy of laws.¹⁹ All other norms are related to each other by being either inferior norms, when one is compared to the other, or superior norms.²⁰ Grundnorm is a concept in the *Pure Theory of Law* that denotes the basic norm, order, or rule that forms an underlying basis for a legal system²¹. The theory is based on a need to find a point of origin for all law, on which basic law and the constitution can gain their legitimacy.²²

¹⁵ Ibid.

¹⁶ Joseph Raz, 'Legal Validity' *The Authority of Law: Essays on Law and Morality* Oxford University Press, 2 August 1979 Oxford Scholarship Online 22 March 2012 (accessed 15 September 2015)

<<http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780198253457.001.0001/acprof-9780198253457-chapter-8>>

¹⁷ Joseph Raz, 'Kelsen's Theory of The Basic Norm' *The Authority of Law: Essays on Law and Morality* Oxford University Press, 2 August 1979 Oxford Scholarship Online. 22 March 2012 (accessed 15 September 2015). <<http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780198253457.001.0001/acprof-9780198253457-chapter-7>>.

¹⁸ A basic norm is something postulated for the purpose of bringing order to our conception of the legal system being examined.

¹⁹ George C Christie, 'The Notion of Validity in Modern Jurisprudence' *Minnesota Law Review* [Vol 48, 1049]

²⁰ See Hans Kelsen *General Theory of Law and State* 11-78 (Wedberg Tranl. 1949).

²¹ See generally HLA Hart *The Concept of Law*, Joseph Raz, and Penelope A Bulloch (eds) Clarendon Press.

²² Ronald M. Dworkin *Law's Empire* (Legal Theory), Clarendon Press; 2nd edition (24 April 1997), *Madzimbamuto v Lardner Burke* (PC) (1969) 1 A.C. 651. See

The Constitution as a basic norm²³ provides a minimum threshold for the validity of public decisions, actions or inactions. The peculiar feature of the Malawi Constitution is that it has both vertical and horizontal application.²⁴ Section 10(1) of the Constitution of Malawi provides that in the interpretation of all laws and in the resolution of political disputes, the provisions of the Constitution shall be regarded as the supreme arbiter and ultimate source of authority. Section 11 provides for a value-based approach to statutory interpretation that promotes fundamental values underlying an open and democratic society. Such interpretation ought to take account the provisions of Chapter III and Chapter IV of the Constitution²⁵. Chapter III deals with the fundamental principles of the constitution, while Chapter IV domesticates the United Nations Universal Declaration of Human as a bill of rights in the constitution.²⁶ Section 11(2)(c) introduces an important aspect in terms of the content and application of domestic laws and policies. Current norms of public international law and comparable foreign case law ought to be taken into account in the interpretation and application of the constitution or any law. Under Section 5, any act of Government or law that is inconsistent with the provisions of the Constitution is, to the extent of such inconsistency, invalid. What this means is that in a contest between the right to health and trade and IP protection, health takes precedence. Malawi is obliged to protect and safeguard the right to health under various international frameworks such as the WHO²⁷, WTO²⁸ and WIPO frameworks.²⁹

Among the fundamental values the Constitution promotes is the right to health in Section 13, as read with Section 16, Section 19, and Section 30. Section 13(n) advocates an economic management

also Lord Alfred Denning, *The Discipline of Law* Lexis Nexis Butterworth.

²³ In Pure Theory of Law, this 'basic norm', however, is often ascribed as hypothetical. The reception of the term has fallen into three broad areas of discernment including: (i) Kelsen's original introduction of the term; (ii) the Neo-Kantian reception of the term by Kelsen's critics and followers; and (iii) the hypothetical and symbolic use of the term through the history of its application.

²⁴ Danwood Chirwa, *Human Rights under the Malawi Constitution* Juta Publishing Press (2011).

²⁵ <<https://www.icrc.org/.../Constitu>>

²⁶ <[https://www.icrc.org/applic/ihl/ihl-at.nsf/0/4953f2286ef1f7c2c1257129003696f4/\\$FILE/Constitution%20Malawi%20-%20EN.pdf](https://www.icrc.org/applic/ihl/ihl-at.nsf/0/4953f2286ef1f7c2c1257129003696f4/$FILE/Constitution%20Malawi%20-%20EN.pdf)> (accessed October 2014)>

²⁷ See Articles 1 and 2 of the WHO's Constitution.

²⁸ Article XX(B) of GATT 1994, Article 31bis of the TRIPS Agreement and the WTO Doha Declaration on TRIPS and Public Health.

²⁹ See M Koivusalo 'Impact of WTO Agreements on Health and Development Policies Globalization and Social Policy Programme' (2003) in B Deacon, E Ollila, M Koivusalo, P Stubbs (eds) *Global Social Governance: Themes and Prospects*. Helsinki: Ministry for Foreign Affairs: 77–129.

regime that strikes a balance between creation and distribution of wealth through the nurturing of a market economy. It also provides for long-term investment in health, education, and economic and social development programmes with the aim of raising living and working standards, a central feature of the multilateral trading system. This section is a call to balance social and economic policy. There is a realization that sustainable development requires stimulation of the economy and social policies that cushion against market externalities such as social costs. Underinvestment in health can wipe out the gains of economic growth through reduced productivity and efficiency besides the cost of providing public services. The Ebola epidemic in West Africa has had a measurable negative effect on the economies of the countries affected³⁰. This is a sad footnote to the need for a balance between social and economic.

The other right relevant to IP and health is provided under Section 29. This is the right to economic activity. The constitution does not define 'property' but entrenches the right to acquire property, either alone or in association with others.³¹ Property in law includes tangibles and intangibles such as intellectual property rights. Section 28(2) protects against arbitrary deprivation of property. Section 29 provides that every person has the right to freely engage in economic activity, to work, and to pursue a livelihood anywhere in Malawi. The combined effect of Sections 28 and 29 is that they provide a seedbed for the acquisition and commercialization of intellectual property rights. In tandem with Section 10 and Section 11, the emerging jurisprudence is that provisions of the Constitution are to be read not to destroy but to reinforce each other.³² Thus government has to balance the quest for stimulation of investment and economic growth through the promotion and protection of intellectual property rights, on the one hand, and the promotion of the realization of the right to health, on the other. Where the trade IP and human rights such as health compete for priority, the right to health as a human right in principle ought to take precedence.

³⁰ For estimating the worldwide economic cost of ebola, see <<http://blogs.worldbank.org/developmenttalk/estimating-economic-cost-ebola>> See also Z Nkowani 'Injury unto Death, Occupational Health and Safety Regulation in Malawi' Comparative and International Law Journal for Southern Africa (2008) Vol 41 Issue 1 <<http://www.unisa.ac.za/Default.asp?Cmd=ViewContent&ContentID=21046>>

³¹ Section 28 (1) of the Constitution.

³² *Fred Nseula v The Attorney General and Malawi Congress Party*, MSCA Civil Appeal no 32 of 1997 (unreported) (See also *Attorney General v The Malawi Congress Party*, LJ Chimango and Dr HM Ntamba, MSCA Civil Appeal no 22 of 1996 (The Press Trust case), *Bakili Muluzi and UDF v Malawi Electoral Commission* Constitutional Case n 1 of 2009, per Justice Chipeta).

Opinion is varied on the status of health under the Constitution of Malawi. The predominant view is that health is not a right under the constitution, but merely a directing or guiding principle.³³ The author questions this rendition of the law in view of principles of interoperation in Section 11 of the Constitution.³⁴ The standard approach to Constitutional interpretation is to render a liberal or generous construction of Constitutional provisions.³⁵ In terms of scope, Section 13(c) ought to be considered in the context of other rights such as the right to life under Section 16, the right to human dignity under Section 19, the right to a clean environment under Section 13, and the right to development under Section 30. Section 11, as read with Section 211, of the Constitution provides that the interpretation should take into account norms of public international law and foreign case law. Section 11 is similar to Section 39 of the South African Constitution, and the courts have (as has been done by Malawi courts) advocated a liberal or generous interpretation. One of the norms of Public International Law in relation to the right to health is contained in General Comment No. 14. General Comment No. 14 is binding on all member States. The definition of the right to health is expansive and includes the right to health as captured under Section 13(c), Section 16, Section 19, and Section 30 of the Constitution of Malawi.

As a national policy, Section 13(c) enjoins the state to promote the welfare and development of the

³³ Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi' Southern and Eastern African, Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007). See also C Namelo and SWD Chavula, 'Aspects of Non-conformity in Malawi's Intellectual Property Legislation vis-a-vis International Agreements Conventions and Treaties on Intellectual Property' (2003). Robert Lewis-Lettington and Chikosa Banda 'A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi' DFID Health Systems Resource Centre (2004).

³⁴ See Hoyt Webb 'The Constitutional Court of South Africa; Rights Interpretation and Comparative Constitutional Law' (1998) *Journal of Constitutional Law*, Vol 1:2, p 207. See also *State v Mak-wanyane*, 1995 (3)SALR 391, 451-52 (CC) (striking down the death penalty in the face of large public support).

³⁵ *Bakili Muluzi and UDF v. Malawi Electoral Commission* Constitutional Case no 1 of 2009 and *Fred Nseulav's The Attorney General and Malawi Congress Party*, MSCA Civil Appeal no 32 of 1997 (unreported). For cogent analyses of theories of constitutional interpretation, see generally Lourens M du Plessis, 'Constitutional Interpretation: Theories and Practice' (1995) (unpublished manuscript, on file with the University of Pennsylvania *Journal of Constitutional Law*); Lourens M du Plessis and JR de Ville, 'Bill of Rights Interpretation in the South African Context (3): Comparative Perspectives and Future Prospects' *Stellenbosch Law Revue* 356, 356-392 (1993).

people of Malawi by progressively adopting and implementing policies and legislation that promote good health and self-sufficiency and adequate health care, commensurate with the health needs of Malawian Society and international standards of health.³⁶ Further, the state needs to put in place policies that enhance the quality of life in rural communities. Public health under the Constitution is a measure of government performance. Section 13(e) recognizes rural standards of living as a key indicator of the success or failure of government policies. Section 13(d)(iii) enjoins the government to manage the environment responsibility in order to provide a healthy living and working environment. This Section links trade to the environment and health and enjoins the state to ensure generational and intergenerational rights for sustainable development.

The right to health is also covered under Section 16. This Section provides for a right to life, the most basic of all the rights. In other words, courts have interpreted this right as being broader than mere prohibition of physical acts that denude it.³⁷ The Indian Supreme Court in *PachimBangaKhetMajoor-Samity v State of West Bengal, 1996* held that denial of the right to emergency medical care is a violation of the right to life guaranteed by the Indian Constitution. Related to this is the right to human dignity under Section 19. Human dignity encompasses all aspects of the human physiology.³⁸ The right to health is also linked to the right to life. The ICCPR committee in General Comment No. 6 (1966) gives a wider definition of the right to life and defines the state's role in protecting human life to include obligations to reduce infant mortality, increase life expectancy, and eliminate malnutrition and endemics. The right to health is indivisibly linked to the inherent dignity of the human person³⁹ and is indispensable for the fulfilment of other human rights.⁴⁰

³⁶ The State and the Chief Secretary to the President and Cabinet *Ex parte*, Dr Bakili Muluzi, Miscellaneous Civil Cause n 3 of 2011 (unreported).

³⁷ In *Olga Tellis v Bombay Municipal Corporation, 1985 Supp (2) SCR 51*, a Constitutional Bench of the Court held that the right to life includes the right to livelihood, because no person can live without the means of living i.e. means of livelihood. If the right to livelihood is not treated as part of the constitutional right to life, the easiest way of depriving a person of his right to life would be to deprive him of his means of livelihood to the point of abrogation. Such deprivation would not only denude the life of its effective content and meaningfulness, but it would make it impossible. By the same token, failure to provide health care would abrogate the right to life.

³⁸ UN Human Rights Commission, 1982.

³⁹ Covered under Article 19 of the Republic of Malawi's Constitution.

⁴⁰ Joint fact Sheet WHO/OHCHR/323: Right to Health <http://www.who.int/mediacentre/factsheets/fs323_en.pdf

The right to health has been defined in General Comment No. 14⁴¹ as containing both freedoms and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment, and experimentation. By contrast, entitlements include the right to a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health.⁴²

Under Article 5(1)(a) of the SADC Treaty, the main objective of the Organization is to promote sustainable and equitable economic growth and socioeconomic development that will ensure poverty alleviation with the ultimate objective of its eradication, and enhance the standard and quality of life of the people of Southern Africa. One of the founding principles for the organization is human rights, democracy and rule of law. Health is a human right and is covered under Articles 4 and 5 by the expression 'enhance the standard and quality of life'. Article 2 of the SADC Protocol on Health implements the WHO Constitution and Malawi has commitments under all these regional and international treaties and conventions.

Underinvestment in health care undermines the quality of human life and dehumanizes patients and families affected. The right to life is non-delegable under Section 44(1)(a).

There is also a framework that encompasses the right to health. This is the right to development that presupposes that healthy citizens make better economic actors. Section 30(2) calls upon the State to take measures for its realization. This includes equal opportunity to access basic resources, education and health services, food, shelter, employment, and infrastructure. Intellectual property rights such as patents have a double sword effect. They are an engine for innovation growth and development. However they have a direct impact on prices for pharmaceutical products that affect equality of opportunity to access basic life-saving medicines.⁴³ For a country like Malawi, its ability to

>

⁴¹General Comment No. 14: The Right to the Highest Attainable Standard of Health - UN Committee on Economic, Social and Cultural Rights; see also:

<<http://www.nesri.org/resources/general-comment-no-14-the-right-to-the-highest-attainable-standard-of-health#sthash.7silKENP.dpuf>>

(Accessed November 2014).

⁴²Vide

<http://www.nesri.org/sites/default/files/Right_to_health_Comment_14.pdf (Accessed November 2014)>

⁴³Carsten Fink, Intellectual Property and Public Health: An Overview of the Debate with a Focus on US Policy - Working Paper 146, (2008) <<http://www.cgdev.org/publication/>

provide essential health care is constrained by systemic issues such as lack of a pharmaceutical manufacturing base and donor dependency. Its international commitments under the TRIPS Agreement and WIPO have an impact on its ability to provide requisite health care through the price effect of patent protection.⁴⁴ The international harmonization of the protection of intellectual property rights through the TRIPS Agreement robbed developing countries of their traditional ability to refuse granting patents, in order to address pressing health needs.⁴⁵ However, built-in exceptions to patent protection in defined circumstances such as in Articles 30 and 31 of the TRIPS Agreement provide flexibility for developing countries such as Malawi to address its health-care needs.

The right to health involves two values that can at times be irreconcilable: trade and human rights. Much as the two are mutually supportive, the trend has been in favour of stronger intellectual property right protection and for the foreseeable future this might be the trend. For instance, the United States favours strong protection of intellectual property rights in its bilateral agreements⁴⁶. These provisions

[intellectual-property-and-public-health-overview-debate-focus-us-policy-working-paper](#)> (accessed November 2014). See also Laxminarayan, Over, and Smith (2005) who point to another tension in promoting widespread access to medicines: cheaper prices may encourage drug misuse, leading to a more rapid development of drug resistance and thus a shortened duration of a drug's usefulness. Also F Abbott and J Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' *Journal of International Economic Law*, 2007, 10(4): 921–987.
<http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1025593> and F Abbott and R Van-Puybroeck, 'Compulsory Licensing for Public Health: A Guide of Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision' World Bank, Washington, D.C., 2005
<http://www-wds.worldbank.org/external/default/main?pagePK=64193027&piPK=64187937&theSitePK=523679&menuPK=64187510&searchMenuPK=64187283&siteName=WDS&entityID=0012009_20050830130225>

⁴⁴ Cynthia M Ho, 'A New World for Addressing Patent Rights and Public Health', 82 *Chicago-Kent Law Review*, 1469, [2007], *Ibid.* p 1470; see also Frederick M Abbott and Jerome H Reichmann, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' 10, *Journal of International Economic Law*, 921, December 2007, p 7.

⁴⁵ *Ibid.*, and Mor Bakhom, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicine?' Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series no 10-07 <<http://ssrn.com/abstract=1619215>> (accessed November 2014).

⁴⁶ See Article 4 of the US-Jordan Free Trade Agreement, <<https://ustr.gov/trade-agreements/free-trade->

are often TRIPs-Plus.⁴⁷ The right to health has been enshrined in international and regional human rights treaties, as well as national constitutions all over the world⁴⁸: UN human rights treaties such as the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR); the 1979 Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); and the 1989 Convention on the Rights of the Child (CRC). Regional treaties enshrining the right to health include the SADC Charter of Fundamental Social Rights; the 1961 European Social Charter; the 1981 African Charter on Human and Peoples' Rights; and the 1988 Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (the Protocol of San Salvador).

Multilateral instruments such as the General Agreement on Trade in Goods⁴⁹, recognize that this right provides an exception to the most-favoured-nation and national treatment obligation if measures are taken to protect human, animal or plant life or health.⁵⁰ Under the WTO regime, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is devoted to the regulation of trade and health. For SADC, the SPS Agreement has been domesticated by being annexed to the Protocol on Trade.⁵¹ The Protocol on Trade in Article 16 provides that Member States shall base their sanitary and phytosanitary measures on international standards, guidelines, and recommendations, so as to harmonize sanitary and phytosanitary measures for agricultural and livestock production. Further, under Article 16(2), Member States should, upon request, enter into consultation with the aim of achieving agreements on recognition of the equivalence of specific sanitary and phytosanitary measures, in accordance with the WTO SPS Agreement. Article 24 of the Protocol on Trade calls upon Member States to adopt policies

[agreements/jordan-fta/final-text](#)>

⁴⁷ *Ibid.*

⁴⁸ Graeme B Dinwoodie, William O Hennessey, Shira Perlmutter. Graeme W Austin, *International Intellectual Property Law and Policy*. It is pointed out that the future international framework of intellectual property rights should be shaped in the light of the UN Millennium Development Goals. The Millennium Development Goals should have a strong influence in the future intellectual property framework.

⁴⁹ Cynthia M Ho, *op. cit.* (note 3).

⁴⁹ GATT 1994 Article XX(b).

⁵⁰ Under the WTO and SADC SPS Annex to the Protocol on Trade, 'animal' includes fish and wild fauna; 'plant' includes forests and wild flora; 'pests' include weeds; and 'contaminants' include pesticide and veterinary drug residues and extraneous matter.

⁵¹ <http://www.sadc.int/files/7413/5817/6371/SADC_Sanitary_and_Phyto_Sanitary_ANNEX.pdf> SADC/CMT/20/2008/10 >

and implement measures within the Community for the protection of intellectual property rights, in accordance with the TRIPS Agreement. The regional domestication of the TRIPS and WTO covered agreements recognize the right to health and exceptions under Article XX(b) and Article 31bis of the TRIPS Agreement. It is clear that, in trade terms, the symbiotic relation between intellectual property rights and health is a frontline consideration.

The International Covenant on Economic, Social and Cultural Rights (1966) in Article 12 states that steps for the realization of the right to health include those that reduce infant mortality and ensure the healthy development of the child; improve environmental and industrial hygiene; prevent, treat, and control epidemic, endemic, occupational, and other diseases; and create conditions to ensure access to health care for all. The WHO Constitution⁵² states in the preamble 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. It further states that the extension to all peoples of the benefits of medical, psychological, and related knowledge is essential to the fullest attainment of health.⁵³ States under Article 1 of the WHO Constitution seek the attainment by all peoples of the highest possible level of health.

The right to health contains four elements:

- (a) Availability - this refers to a sufficient quantity of functioning public health and health care facilities, goods and services, as well as programmes;
- (b) Accessibility - this means that health facilities, goods, and services should be accessible to everyone;
- (c) accessibility has four overlapping dimensions - non-discrimination, physical accessibility, economical accessibility (affordability) and information accessibility;

(a) ⁵²The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, which was signed on 22 July 1946 by the representatives of 61 States (Off. Rec. WHO, 2,100), and entered into force on 7 April 1948. Amendments adopted by the Twenty-Sixth, Twenty-Ninth, Thirty-Ninth and Fifty-First World Health Assemblies (Resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively and are incorporated in the present text.

⁵³<http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1>

(d) acceptability - this means that all health facilities, goods, and services must be respectful of medical ethics and culturally appropriate, as well as sensitive to gender and life-cycle requirements; and

(e) quality - this refers to health facilities, goods, and services that must be scientifically and medically appropriate and of good quality.

The right to health imposes upon States Parties three types of obligations:

- (a) Respect - this means simply not to interfere with the enjoyment of the right to health ('do no harm');
- (b) Protect—this means ensuring that third parties (non-state actors) do not infringe upon the enjoyment of the right to health (e.g. by regulating non-state actors); and
- (c) Fulfil - this means taking positive steps to realize the right to health (e.g. by adopting appropriate legislation, policies or budgetary measures).⁵⁴

Section 13(c) of the Constitution introduces the principle of proportionality to the discourse of right to health. Courts normally take a textual and contextual approach on the interpretation and application of this right. Sections 10 and 11 of the Constitution guide the application and interpretation of the Constitution. In practice, courts will only resort to international case law if there is a lacuna in local principles.⁵⁵

⁵⁴ <http://www.who.int/mediacentre/factsheets/fs323/en/>

⁵⁵ In the words of J Chipeta in *The Public Affairs Committee v Attorney General*, Civil Cause no 1861 of 2003:

I have just advocated for a chance to be given to the Constitution to speak with an uninterrupted voice and to first try and understand what it means before rushing to borrow the influence of decisions in other jurisdictions for the construction of our Constitution. I should think it is only when a direct understanding of the Constitution proves difficult to capture that resort can be meaningful had to such other guiding materials or precedents.

The views of Mr Justice Chipeta are also reflective of the views in Supreme Court Reference no 2 of 1995 and Reference by Western Highlands Provincial Executives (1996) 3 LRC 28. J Mahomme in *Svs Makwanyane* (1995) 3 SA 391 (CC) emphasized the need to place context and text at the centre of interpretation. He had this to say:

What ... is required to do in order to resolve an issue is to examine the relevant provisions of the Constitution, their text and their context; the interplay between the different legal provisions; legal precedent relevant to the resolution of the problem both in South Africa and abroad; the domestic common law and public international law impacting on its possible solution;

In health-care rights, the courts' approach has been to apply the principle of proportionality by considering the wider context in which individual health-care rights interface with community health-care rights. In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁵⁶, the court stated:

Health-care rights by their very nature have to be considered, not only in a traditional legal context structured around the ideas of human autonomy, but in a new analytical framework based on the notion of human interdependence. A healthy life depends upon social interdependence: the quality of air, water, and sanitation which the state maintains for the public good; the quality of one's caring relationships, which are highly correlated to health; as well as the quality of health care and support furnished officially by medical institutions and provided informally by family, friends, and the community.⁵⁷

In the words of Minow:

Interdependence is not a social ideal, but an inescapable fact; the scarcity of resources forces it on us. Who gets to use dialysis equipment? Who goes to the front of the line for the kidney transplant?⁵⁸

Traditional rights analyses accordingly have to be adapted so as to take account of the special problems created by the need to provide a broad framework of constitutional principles governing the right of access to scarce resources and to adjudicate between competing rights bearers. When rights by their very nature are shared and are interdependent, striking appropriate balances between the equally valid entitlements or expectations of a multitude of claimants should not be seen as imposing limits on those rights (which would then have to be justified in

factual and historical consideration bearing on the problem; the significance and meaning of the language used in the relevant provisions of the content and sweep of the ethos expressed in the structure of the Constitution; the balance to be struck between different and sometimes potentially conflicting considerations reflected in its text; and by a judicious interpretation and assessment of all factors to determine what the Constitution permits and what it prohibits.

⁵⁶ (CCT32/97) [1997] ZACC 17, at p 28.

⁵⁷ Minow, participating in an interdisciplinary discussion held at Harvard Law School in 1993, 'Session I: Applying Rights Rhetoric to Economic and Social Claims' *Economic and Social Rights and the Right to Health* (Harvard Law School Human Rights Programme Cambridge MA 1995) 1 at 3.

⁵⁸ *Ibid.*

terms of Section 36), but as defining the circumstances in which the rights may most fairly and effectively be enjoyed.

Section 13(c) of the Constitution obliges the state to actively promote the welfare and development of the people of Malawi by progressively adopting and implementing policies and legislation that aim to provide adequate health care, commensurate with the health needs of Malawian society and international standards of health care. It introduces the principle of proportionality in the provision of health care to Malawian society. This principle is internationally recognized as demonstrated by the South Africa case of *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁵⁹ and English cases such as *Re J (a minor)*⁶⁰ [1992] 4 All ER 614 (CA) at 625g; *Airedale NHS Trust v Bland*⁶¹, and *R v Cambridge Health Authority, ex parte B.*⁶² This is also reflected in UNESCO's position on the issue.⁶³ The Social and Economic Council in General Comment No. 14 alludes to the proportionality principle when it states that the notion of 'the highest attainable standard of health' in Article 12.1 takes into account both the individual's biological and socioeconomic preconditions and a state's available resources.⁶⁴

There are a number of aspects that cannot be addressed solely by the relationship between States and individuals; in particular, good health cannot be ensured by a state, nor can states provide protection against every possible cause of human ill health. Genetic factors, individual susceptibility to ill health, and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services, and conditions necessary for the realization of the highest attainable standard of health. These cases show that the principle of proportional allocation of limited state resources and the realization of the right to life

⁵⁹ (CCT32/97) [1997] ZACC 17.

⁶⁰ [1992] 4 All ER 614 (CA) at 625g.

⁶¹ [1993] 1 All ER 821 (CA) at 857b.

⁶² [1995] 2 All ER 129 (CA) at 137d-f.

⁶³ Brody, *Biomedical Technology and Human Rights* (UNESCO, Paris 1993) at 233. South Africa is a middle income country where 'despite their high profile, modern lifesaving medical treatments are only available on a limited scale', Benatar 'History of Medical Ethics: Africa' *Encyclopaedia of Bioethics Vol 3*, Revised (Macmillan, New York 1995) 1465 at 1467.

⁶⁴ General Comment No. 14: The Right to the Highest Attainable Standard of Health - UN Committee on Economic, Social and Cultural Rights.

See more at: <<http://www.nesri.org/resources/general-comment-no-14-the-right-to-the-highest-attainable-standard-of-health#sthash.7siKENP.dpuf>>(accessed November 2014).

and health for everyone by the state requires rationing and setting of criteria.

In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*,⁶⁵ the court stated:

The hard and unpalatable fact is that, if the appellant were a wealthy man, he would be able to procure such treatment from private sources; he is not and has to look to the state to provide him with the treatment. But the state's resources are limited and the appellant does not meet the criteria for admission to the renal dialysis programme. Unfortunately, this is true not only of the appellant, but of many others who need access to renal dialysis units or to other health services. There are also those who need access to housing, food and water, employment opportunities, and social security. These too are aspects of the right to:

" human life: the right to live as a human being, to be part of a broader community, to share in the experience of humanity".⁶⁶

The state has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society, rather than to focus on the specific needs of particular individuals within society.

J O'Regan in *State v Makwanyane and Another*⁶⁷ and J Combrinck in *R v Cambridge Health Authority, ex parte B*⁶⁸ equally offer guidance in approaching health-care rights as opposed to other rights. Emphasis is placed on context, and our Constitution in Section 13(c) is in tandem with this approach. The learned Judge in that case had this to say:

I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court

were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonizing judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make.

The jurisprudence emerging from authorities and Section 13(c) of the Constitution is a holistic approach to health-care rights anchored on the principle of proportionality. The right to health under Section 13(c), like all rights, is not an absolute right. It is limited through the principle of proportionality by the availability of resources and its allocation must be proportionate to the greater needs of society. Thus, access to essential medicines, though constitutionally guaranteed, is constrained by resources. For Malawi, intellectual property rights are an opportunity to stimulate growth in the economy and biotech innovations that will expand the resource base for the actualization of the right to health. There is need to ensure that preconditions for such capacity building in the pharmaceutical manufacturing base, modernization of laws on intellectual property rights, and pooled procurement mechanisms are in place. Thus, there is a business case for the promotion, protection, and enforcement of intellectual property rights, as well as a social imperative for utilizing flexibilities in intellectual property right regimes for raising the living and working standards of people in Malawi and the SADC region.

In Section 44(1), the Constitution provides a list of rights from which there can be no derogation, restriction, or limitation. The right to health is not one of them. This gives efficacy to the proportionality principle in Section 13(c), because if it were non-derogable it would be in conflict with the proportionality principle, as well as norms of public international law referred to in Section 11. However, two of the related rights to health are non-derogable; there is the right to life (Section 16) and the right not to be subjected to torture and cruel, inhuman, or degrading treatment (Section 19). Without prejudice to Section 44(1), Section 44(2) allows restrictions or limitations prescribed by law, which are reasonable, recognized by international human rights standards and necessary in an open

⁶⁵See, *supra* P Chaskalson, at p 16.

⁶⁶Per O'Regan J in *S v T Makwanyane and M Mchunu* (CCT3/94) [1995] ZACC 3; 1995 (6) BCLR 665; 1995 (3) SA 391; [1996] 2 CHRLD 164; 1995 (2) SACR 1 (6 June 1995) at para 326.

<http://www.saflii.org/za/cases/ZACC/1995/3.html> (accessed November 2014).

⁶⁷1995 (3) SA 391 (CC); 1995 (4) BCLR 665 (CC) in relation to the right to life.

⁶⁸See *supra*.

and democratic society. In *Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal)*⁶⁹, P Chaskalson had the following observations to make:

The Constitution is forward looking and guarantees to every citizen fundamental rights in such a manner that the ordinary person-in-the-street, who is aware of these guarantees, immediately claims them without further ado – and assumes that every right so guaranteed is available to him or her on demand. Some rights in the Constitution are the ideal and something to be strived for. They amount to a promise, in some cases, and an indication of what a democratic society aiming to salvage lost dignity, freedom and equality should embark upon. They are values which the Constitution seeks to provide, nurture and protect....

The learned Judge then turned to the issue of limitation of such rights at paragraph 43 on page 22 and had this to say:

However, the guarantees of the Constitution are not absolute, but may be limited in one way or another. In some instances, the Constitution states in so many words that the state must take reasonable legislative and other measures, within its available resources 'to achieve the progressive realization of each of these rights'. In its language, the Constitution accepts that it cannot solve all of our society's woes overnight, but must go on trying to resolve these problems. One of the limiting factors to the attainment of the Constitution's guarantees is that of limited or scarce resources.

Thus, the right to health in constitutional terms is limited by the principle of proportionality. However, in the case for Malawi, the fact that related rights, such as the right to life and the right against subjection to degrading and inhuman treatment (lack of access to medicines degrades and dehumanizes patients by diluting the quality of life), are non-derogable points to the heightened duty of the State to safeguard this right. The status of intellectual property rights and their protection and enforcement have a bearing on this. The need to review laws on intellectual property rights and the symbiotic relationship between these and health need no emphasis. Within intellectual property right legal frameworks there exist flexibilities that can be utilized to address the challenges of access to essential medicines and health-care. One example is to use valuable TRIPS flexibilities under Article 31*bis* of the TRIPS agreement, as well as under Article XX

⁶⁹ *Supra* page 22.

exceptions of GATT 1994. Within SADC, Malawi can participate in the pooled procurement and ease its current problem on the health-care bill.

III. LEGAL FRAMEWORK

The legal framework for intellectual property rights and public health consists of a number of laws, much of which were received during colonial interaction from Britain and have become obsolete. It also includes Malawi's international obligations under various multilateral agreements. As a WTO Member, Malawi assumes obligations both under GATT 1994 and TRIPS in Annex 1C. Thus Malawi has intellectual property right obligations not only under the TRIPS Agreement, but also under the covered agreements, as defined under Article 1.1 of the Understanding on Rules and Procedures Governing the Settlement of Disputes.⁷⁰ The scope of obligations under Article 1.3 includes obligations under the Paris Convention (1967), the Berne Convention (1971), the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits.⁷¹ Article 2.2 of the

⁷⁰ In *Brazil — Desiccated Coconut*, the Appellate Body defined the term 'covered agreements' as follows:

The 'covered agreements' include the *WTO Agreement*, the Agreements in Annexes 1 and 2, as well as any Plurilateral Trade Agreement in Annex 4 where its Committee of signatories has taken a decision to apply the *DSU*. In a dispute brought to the DSB, a panel may deal with all the relevant provisions of the covered agreements cited by the parties to the dispute in one proceeding.

In *Guatemala — Cement I*, the Appellate Body examined the Panel's interpretation of the relationship between Article 17 of the Anti-Dumping Agreement and the rules and procedures of the DSU. In this context, the Appellate Body made the following general statement about Article 1.1 of the DSU:

Article 1.1 of the DSU establishes an integrated dispute settlement system which applies to all of the agreements listed in Appendix 1 to the DSU (the 'covered agreements'). The DSU is a coherent system of rules and procedures for dispute settlement which applies to 'disputes brought pursuant to the consultation and dispute settlement provisions of the covered agreements. The *Anti-Dumping Agreement* is a covered agreement listed in Appendix 1 of the DSU; the rules and procedures of the DSU, therefore, apply to disputes brought pursuant to the consultation and dispute settlement provisions contained in Article 17 of that Agreement."

⁷¹ In the TRIPS Agreement, the 'Paris Convention' refers to the Paris Convention for the Protection of Industrial Property; 'Paris Convention (1967)' refers to the Stockholm Act of this Convention of 14 July 1967. 'Berne Convention'

TRIPS Agreement provides that nothing in the Agreement shall derogate from existing obligations that Members have to each other under the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits. Although Malawi is a signatory to those WIPO conventions, their incorporation under the TRIPS Agreement brings a new dimension in terms of enforcement and dispute settlement. Article 64.1 of the TRIPS Agreement provides that provisions of Articles XXII and XXIII of the GATT 1994, as elaborated and applied by the Dispute Settlement Understanding, apply to consultations and the settlement of disputes under it, except as otherwise specifically provided therein.⁷²

Under Sections 10 and 11 of the Constitution, the content, application, and interpretation of our domestic laws and policies include a number of international treaties and conventions. Courts are enjoined to take into account principles and norms of public international law. For intellectual property rights they include the Trademarks Act (Cap. 49:01), the Patents Act (Cap. 49:02), the Copyright Act (Cap. 49:03), the Trade Descriptions Act (Cap. 49:04), and the Registered Designs Act (Cap. 49:05) of the Laws of Malawi. In addition, there are the Competition and Fair Trading Act and the Environment Management Act (Caps. 48:09 and 60:02) respectively, of the Laws of Malawi. The industrial property statutes (trademarks, patents, and industrial designs), which are administered by the Department of the Registrar, were enacted during the Federation of Rhodesia and Nyasaland. The Patents and Trade Marks Act came into force on 1 April and the Registered Designs Act on 1 December 1958. These laws have never been amended except for the Patents and Registered Designs Acts in 1985. The Competition and Fair Trading Act was enacted in 1998 to regulate and monitor monopolies and concentrations of economic

refers to the Berne Convention for the Protection of Literary and Artistic Works; 'Berne Convention (1971)' refers to the Paris Act of this Convention of 24 July 1971. 'Rome Convention' refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. 'Treaty on Intellectual Property in Respect of Integrated Circuits' (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. 'WTO Agreement' refers to the Agreement Establishing the WTO. See:

<http://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm>

⁷² *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, 2 Jan. 2002 ('*US – Havana Club*'), WT/DS176. Also see *United States – Section 110(5) of the US Copyright Act*, WT/DS160, 15 June 2000. ('*US – Copyright Exemption*').

power, as well as to prohibit anti-competitive trade practices. The Trade Descriptions Act was promulgated in 1987 to criminalize certain uses of trade descriptions and trademark forgery. In addition, the Environment Management Act (1996) is being repealed by another statute of a similar title, to take into account the protection of genetic resources. The main legal framework for public health is the Public Health Act, Cap.34:01. This is complemented by other pieces of legislation such as the Mental Treatment Act, the Pharmacy, Medicines and Poisons Act, the Dangerous Drugs Act, the Pesticide Act, and the Occupational Safety, Health and Welfare Act.

Malawi is a member of the WTO, the World Intellectual Property Organization (WIPO), and the United Nations Educational, Scientific and Cultural Organization (UNESCO). Among the WTO Agreements that bind Malawi, the most important in the field of intellectual property is the TRIPS Agreement. Malawi has not acceded to some treaties such as the Washington Treaty on Intellectual Property in Respect of Integrated Circuits and the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. In the area of copyright and related rights, Malawi is also a party to the Berne Convention for the Protection of Literary and Artistic Works and the Universal Copyright Convention, which is administered by WIPO and UNESCO respectively. An important additional dimension to Malawi's IP regime is the country's adherence to the Convention on Biological Diversity (CBD) adopted in 1992.

Malawi is a founding member of ARIPO. Within the framework of ARIPO, Malawi is a party to ARIPO's Protocol of Patents and Industrial Designs, 1984, and the Banjul Protocol on Marks of 1993. Malawi is also a founding member of both the Common Market for Eastern and Southern Africa (COMESA) and the Southern Africa Development Community (SADC). The constitutive texts establishing these economic groups' intellectual property rights have provisions that are binding on Malawi.⁷³ For instance, the SADC Protocol on Culture, Information and Sports also

⁷³For example, the COMESA Treaty obliges member states to:

jointly develop and implement suitable patent laws and industrial licensing systems for the protection of industrial property rights and encourage the effective use of technological information contained in patents.

The SADC Treaty is a little robust in this respect. Article 24 of the Protocol on Trade in the SADC, entitled 'Intellectual Property Rights, states that 'Member States shall adopt policies and implement measures within the Community for the protection of Intellectual Property Rights, in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.'

calls on Member States to provide effective copyright and related rights protection and to fight against piracy. At the continental level, the African Union Heads of State and Government have decided to establish the Pan African Intellectual Property Organization.

There are a number of intellectual property service providers in the country, which range from the two main national intellectual property offices, the Registrar General and the Copyright Society of Malawi (COSOMA), to the judiciary, police, Malawi Revenue Authority, Malawi Law Society and the Institute of Patent and Trademark Agents of Malawi. Apart from a loose cooperation framework between the two main national intellectual property offices, there is virtually no coordination among the intellectual property service providers.

IV. CHALLENGES

For Malawi, an apparent lack of a sustainable innovation culture is a huge challenge toward utilization of available flexibilities in laws on intellectual property rights. This is manifested in the state of legal frameworks for intellectual property rights in the country. The state of the laws is indicative of the country's inability to see things differently.⁷⁴ Drivers for innovation include production, organization, and consumption. To innovate there must be a need to see the need for new production methods and new ways of organizing the production and products to satisfy new forms of consumption. Malawi is stuck in an agro-based economy and has yet to shift to the new order. The state of the policy on intellectual property rights and laws is an indicator of policy delusion. For as long as the preconditions for utilizing available flexibilities are not in place, the country will struggle to manoeuvre its way through its international obligations and meet pressing health-care needs.

Malawi has assumed international obligations for intellectual property rights. It also enjoys some flexibility such as compulsory licensing and parallel importation as an LDC. The challenge is that these flexibilities require that Malawi have in place TRIPS-compliant legislation. In the area of access to medicines, the principal act is the Malawi Patent Act (1992). Section 29 of the Act grants protection on the first-to-file principle for 16 years with a possibility for extension and renewal fees payable from the fourth year. This is not consistent with TRIPS, which provides a 20-year patent protection period.⁷⁵ Further biological materials and

biotechnology processes are not patentable in Malawian law, in conflict with TRIPS provisions.⁷⁶ Malawi's patent legislation does not take advantage of key flexibilities available under TRIPS, the subsequent Doha Declaration (2001) or the Paragraph 6 Implementation Agreement, although it does have some potential flexibility built in. Malawi's entire patent regime can be described as TRIPS-Plus because it prematurely provides patent protections for medicines. This is unhelpful. Malawi needs to review its patent laws to take advantage of the flexibilities.

Malawi's major public health challenge is malaria and infant mortality. Malaria kills more Malawians than HIV-AIDS. However, the publicity around HIV-AIDS overshadows other public health issues. For a national budget that is 40 per cent donor funded, this creates donor bias in funding. Faced with financial and institutional challenges, such as lack of local capacity for pharmaceutical manufacturing, Malawi needs to turn to regional and international mechanisms. One example is to use TRIPS flexibilities such as compulsory licensing.⁷⁷ There are both economic and legal prerequisites for compulsory licensing. A compulsory licence is a business transaction between the importer and the new producer. The compulsory licence will only attract a regular for-profit company if it can expect reasonable returns on the investment. The importer, on the other hand, will only conclude a deal if the new producer can offer a price below the patent holder's price. Legally, the rules on compulsory licensing can only be used if they are legally implemented and not contradicted by other international commitments. It may become impossible to use the new rules if the countries in question have implemented provisions that go beyond TRIPS (so-called 'TRIPS-Plus').

Other challenges include inadequate institutional and infrastructure capacity, lack of awareness at all levels of the benefits of the intellectual property system, outdated intellectual property statutes, and inadequate intellectual property human resource cadre at almost all national, sectoral and organization levels. These problems are not unique to Malawi, but are symptomatic of the challenges LDCs face. Malawi, like most developing countries,

2000 ('Canada – Patent Term').

⁷⁶ Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi and Southern and Eastern African' Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007).

⁷⁷ J Love, 'Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord' (prepared for the United Nations Development Programme), (2001), <<http://www.cptech.org>> (accessed November 2014).

⁷⁴ See generally:

<<http://www.newandimproved.com/newsletter/2120.php>> (accessed November 2014).

⁷⁵ Canada – Term of Patent Protection, WT/DS170, 18 Sept.

has many problems relating to public health and access to essential medicines.

The problem of capacity can be addressed by a policy of local manufacturers patterning manufacturers in the West and elsewhere, such as in India, China, and Brazil.⁷⁸ However without an effective legal framework, the country is ill-positioned for this. For now it will have to rely on buying branded drugs from manufacturers in the West.

The country policy response has been to draft policy that aims at ensuring that intellectual property contributes to public health and access to medicines. The policy allows for the exploitation of flexibilities in domestic intellectual property legislation and international treaties, such as those under Article 31*bis* of the TRIPS Agreement. The policy advocates the development of guidelines for the exploitation of these flexibilities in the domestic legislation and various treaties. It advocates the dissemination of information that outlines flexibilities in the protection of intellectual property rights under the TRIPS Agreement. Crucially, it seeks to explore the grant of compulsory licences to manufacture essential medicines. The basic premise of this policy is that intellectual property has a symbiotic relationship with socioeconomic development in that it improves the quality of life through technological advancements and enjoyment of literary and artistic works. Malawi cannot, therefore, effectively implement its development agenda without a comprehensive and clear policy on how an intellectual property system can play this vital role.

The Malawi Government, in its desire to be a technologically driven middle-income economy, intends to reduce poverty through sustainable economic growth and infrastructure development. Just as information and communication technology and science and technology are critical for socioeconomic development, it is imperative that intellectual property be prioritized as it forms part of the basis of development in the key sectors of Malawi's economy such as trade, industry, agriculture, health, culture, and natural resources management.

V. REGIONAL DIMENSION

Malawi is a member of the Southern African Development Community. SADC is a treaty-based

Regional Economic Community-based inter-governmental organization. The SADC Treaty (The Treaty)⁷⁹ and its protocol⁸⁰ provides an all-encompassing framework⁸¹, for countries in the region to coordinate, harmonize, and rationalize⁸² their socioeconomic policies⁸³ and facilitate the movement of factors of production in the region. It commits Member States to fundamental principles of sovereign equality of members⁸⁴, solidarity, peace and security⁸⁵, human rights⁸⁶, democracy and rule of law⁸⁷, equity, and balance and mutual benefit⁸⁸, as well as peaceful settlement of disputes.⁸⁹ SADC's objectives⁹⁰ include the achievement of development and economic growth, alleviation of poverty, enhancement of the quality of life of the peoples of Southern Africa⁹¹ and supporting the socially disadvantaged⁹² through regional integration.⁹³ SADC seeks to build a region with a high degree of harmonization and rationalization⁹⁴,

⁷⁹ SADC is an inter-governmental organization comprising Angola, Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. It was established by Treaty in 1992 and seeks to foster closer economic and political relations among its membership as a step towards the creation of an economic community.
<<http://www.sadc.int/index/browse/page/120>> (accessed November 2014).

⁸⁰ The definition of 'protocol' in Article 1 of the Treaty refers to a protocol as an instrument of implementation of the treaty, having the same legal force as the treaty. See <http://www.sadc.int/files/6213/2808/8365/CONSOLIDATED_PROTOCOL_ON_TRADE_vers_30-01-2012.pdf> (accessed 12 September 2012).

⁸¹ Article 1 of the Treaty.

⁸² Article 21(2).

⁸³ Chengetai C Madziwa 'Social Charter: Towards People-Centered Development' SADC Today Southern African Development Community Vol 6 no 4 October 2003 p 10.

⁸⁴ Article 4(a).

⁸⁵ Article 4(b).

⁸⁶ Article 5(1) of the Treaty. One instrument made hereunder for implementation is the SADC Charter of Fundamental Social Rights (the Charter), which spells out SADC's social policy. The charter embodies recognition by stakeholders in the region of the universality and individuality of basic human rights proclaimed in instruments such as the United Nations Universal Declaration of Human Rights, the African Charter on Human and People's Rights, and the Constitution of the ILO. See Article 3 of the Charter.

⁸⁷ Article 4(c).

⁸⁸ Article 4(d).

⁸⁹ Article 4(e).

⁹⁰ Generally contained in Article 5 of the Treaty.

⁹¹ Article 5(a) of the Treaty as read with Article 11 of the Charter.

⁹² Article 5(a) of the Treaty as read with Article 10(2) of the Charter. This Article provided for social security for persons that have been unable to re-enter the labour market and have no means of subsistence.

⁹³ Similar objectives are aspired to by COMESA, to which a majority of SADC States are members. See Article 3 of the Treaty of COMESA, below.

⁹⁴ Article 5(2)(a).

⁷⁸ See S Chaudhuri, 'Indian Generic Companies, Affordability of Drugs and Local Production in Africa with special reference to Tanzania' IKD Working Paper no 37 Milton Keynes, Open University Research Centre on Innovation Knowledge and Development 2008.
<<http://www.open.ac.uk/ikd/documents/working-papers/ikd-working-paper-37.pdf>>

enabling pooling of resources (such as medicines) to achieve collective self-reliance⁹⁵ and improve the living standards⁹⁶ of the people of the region.⁹⁷

SADC's objective is to promote sustainable and equitable economic growth and socioeconomic development in the region⁹⁸ through efficient productive systems⁹⁹, deeper cooperation and integration¹⁰⁰, good governance, and durable peace and security.¹⁰¹ The understanding is that through this formula the region would emerge as a competitive and effective player in the global economy.¹⁰² The attainment of these objectives is premised on principles of sovereign equality of Member States, solidarity, peace and security, human rights, democracy, rule of law, and peaceful settlement of disputes among others.¹⁰³ In furtherance of these goals, SADC focusses on key enablers for deeper regional integration¹⁰⁴ such as good governance.¹⁰⁵ There is a shared understanding that the convergence of the region's economies and deeper integration will not be attained in the absence of sound macroeconomic management and harmonization and rationalization of socioeconomic policies.¹⁰⁶

Article 5(1)(a), Article 5(i), and Article 5(2)(g) of the Treaty provide a foundational base for health care

⁹⁵ Article 5(d).

⁹⁶ The Social Charter contains the region's blueprint on social policy designed to improve living and working standards of people in the region.

⁹⁷ Marius Olivier 'Social Security for Migrants: Does the EU Framework Provide Lessons for Developments in SADC?' sub-theme: 'Immigration and promoting social security abroad' Paper presented at symposium in the Hague, Netherlands (2001).

⁹⁸ Article 5 1)(a) of the Declaration and Treaty as amended (the Treaty).

⁹⁹ See Article 2 of the SADC Protocol on Trade.

¹⁰⁰ Article 2 of the Trade protocol seeks to further liberalize intra-regional trade in goods and services on the basis of fair, mutually equitable and beneficial trade arrangements.

¹⁰¹ Article 5(1)(a) of the Treaty.

¹⁰² Z Nkowni 'When Elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A beacon of Hope or Confusion Compounded?' Commonwealth Law Bulletin, Volume 33, Issue 1 (2007) 41.

¹⁰³ Article 4 of the Treaty. The ongoing boarder dispute between Malawi and Tanzania is a litmus test of the region's capacity and resolve for peaceful resolution of disputes between states in the region.

¹⁰⁴ The importance of financial service to poverty eradication is reiterated in the recent SADC Declaration on Poverty Eradication and Sustainable Development. In particular paragraphs 2(iii) and 2(vii)

<http://www.sadc.int/conference/content/english/SADC%20Declaration%20on%20Poverty%20Eradication%20and%20Sustainable%20Development.pdf> (accessed 18 February 2009).

¹⁰⁵ Article 5(2)(g) of the Treaty.

¹⁰⁶ Article 5 of the Treaty.

and public health. The treaty places cooperation at the heart of its methodology.¹⁰⁷ Member States are to coordinate, rationalize and harmonize their macroeconomic policies, strategies, programmes, and projects.¹⁰⁸ The Treaty sets out priority areas for cooperation that include health, infrastructure, services¹⁰⁹, trade, industry, finance, and investment.¹¹⁰ The Treaty is implemented by protocols.¹¹¹ For intellectual property rights, the first package comes under the Consolidated Protocol on Trade (1996)¹¹² (the Protocol), the Protocol of Trade in Services, and the Protocol on Health. Article 23(2) of the Protocol encourages Member States to facilitate cross border investment. Members commit to adopting policies in line with their multilateral obligations such as the TRIPS Agreement.¹¹³

SADC's quest for harmonization of economic laws, such as intellectual property right laws, to facilitate free movement of goods, services, capital, and people in the region stems from the organization's economic foundation. It seeks to promote sustainable and equitable economic growth and socioeconomic development in the region¹¹⁴ through efficient productive systems¹¹⁵, deeper cooperation and integration¹¹⁶, good governance and durable peace and security.¹¹⁷ The goal is for the region to emerge as a meaningful player in the global economy.¹¹⁸ The attainment of these objectives is premised on principles of sovereign equality, solidarity, peace and security, human rights, democracy, rule of law, and peaceful settlement of disputes among others¹¹⁹ in line with Article 2(3) of the Charter of the United Nations. In furtherance of these goals, SADC focusses on key enablers for deeper regional integration¹²⁰, such as good

¹⁰⁷ Article 21 of the Treaty.

¹⁰⁸ Article 5(2)(a) and (d).

¹⁰⁹ Article 21(3)(b) of the Treaty.

¹¹⁰ Article 21(3)(c) of the Treaty.

¹¹¹ Article 22 of the Treaty.

¹¹²

http://www.sadc.int/files/6213/2808/8365/CONSOLIDATE_D_PROTOCOL_ON_TRADE_vers_30-01-2012.pdf

¹¹³ Article 23(2).

¹¹⁴ Article 5(1)(a) of the Declaration and Treaty, as amended (the Treaty).

¹¹⁵ See Article 2 of the SADC Protocol on Trade.

¹¹⁶ Article 2 of the Trade protocol seeks to further liberalize intra-regional trade in goods and services on the basis of fair, mutually equitable and beneficial trade arrangements.

¹¹⁷ Article 5(1)(a) of the Treaty.

¹¹⁸ Z Nkowni 'When elephants Dance, FDI and the SADC Charter of Fundamental Social Rights; A beacon of Hope or Confusion Compounded?' Commonwealth Law Bulletin, Volume 33, Issue 1 (2007) 41.

¹¹⁹ Article 4 of the Treaty. The ongoing boarder dispute between Malawi and Tanzania is a litmus test on the region's capacity and resolve for peaceful resolution of disputes between states in the region.

¹²⁰ The importance of financial service to poverty eradication is reiterated in the recent SADC Declaration on

governance and international rule of law.¹²¹ The understanding is that the convergence of the region's economies and deeper integration will not be attained in the absence of harmonization and rationalization of socioeconomic policies such as intellectual property rights and health.¹²²

With cooperation at the heart of its methodology¹²³, the Treaty seeks to achieve this through deeper integration such as infrastructure, services¹²⁴, trade, industry, health, finance, and investment.¹²⁵ Relevant protocols have been adopted in areas such as health, trade in goods¹²⁶, trade in services¹²⁷, and finance and investment.¹²⁸ In terms of dispute settlement they mimic the GATT/WTO regime on dispute settlement. This flows from the fact that regional trade agreements such as SADC are authorized under the GATT/WTO regime, in particular under Article I of GATT 1947, Article XXIV of GATT 1947, and Article V of the General Agreement on Trade in Services (GATS) as building blocks for deeper and faster trade liberalization.¹²⁹ Regional trade agreements are subject to the criteria of transparency, commitment to deep intra-region trade liberalization, and neutrality *vis-à-vis* non-parties' trade.

Under Article 29(b) of the Protocol on Health, Member States are required to cooperate and assist one another in the production, procurement, and distribution of affordable essential drugs. This is the mechanism under which Malawi participates in the pooled procurement of essential drugs. However, the jury is still out on how well this mechanism has been utilized. The reality on the ground, at least for Malawi, suggests that not much joy is coming from this facility. There are operational challenges, but as a policy tool for improving access to health care it is a great incentive. The role of intellectual property rights in health is not limited to patents, but extends to traditional knowledge. The Protocol on Health in Articles 1, 20 and 29 is clear on the link and role of intellectual property rights in public health. Article 29(f) of the SADC Protocol on Health

Poverty Eradication and Sustainable Development. In particular paragraphs 2(iii) and 2(vii) <<http://www.sadc.int/conference/content/english/SADC%20Declaration%20on%20Poverty%20Eradication%20and%20Sustainable%20Development.pdf>> (accessed 18 February 2009).

¹²¹ Article 5(2)(g) of the Treaty.

¹²² Article 5 of the treaty.

¹²³ Article 21 of the Treaty.

¹²⁴ Article 21(3)(b) of the Treaty.

¹²⁵ Article 21(3)(c) of the Treaty.

¹²⁶ <<http://www.sadc.int/>>

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ Z Nkwani 'The EU-ACP Development Cooperation - Governance Challenges for Non-State Actors: the Case of Malawi' *Commonwealth Law Bulletin*, 36: 4, 679—689; visit <<http://dx.doi.org/10.1080/03050718.2010.524289>>

recognizes the role of traditional knowledge in health care and provides for the establishment of a regional databank of traditional medicine, medicinal plants, and procedures in order to ensure their protection in accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology.¹³⁰ The challenge for Malawi is true for most LDCs in a weak intellectual property regime and outdated legislation that result in poor enforcement of intellectual property rights. With poor enforcement there is less incentive from innovation and commercialization of intellectual property rights with a negative impact on health. The draft intellectual property policy for Malawi seeks to respond to this problem by repositioning intellectual property rights and having a frontline for economic development. Malawi, through the draft intellectual property policy puts technology and innovation at the cutting-edge of its growth and strategic agenda. In recognition of this year, the Malawi University of Science and Technology has opened its doors to sow seeds for an economy in which intellectual property rights are a catalyst.

VI. FLEXIBILITIES

The objective of intellectual property rights is to grant its beneficiaries a monopoly by means of an exclusive right.¹³¹ However, the system undertakes a balancing act between private and public interests.¹³² The law provides this in the form of limitations and exceptions to general obligations.¹³³ For instance, Article 9.2 of the Berne Convention provides a three-step test exception in relation to copyrights.¹³⁴ Also, Article 13 of the TRIPS Agreement contains limitations and exceptions to exclusive rights in copyrights in general. Unlike the Article 9.2 exception of the Berne Convention that relates to reproduction, the Article 13 exception of TRIPS is expansive in application and covers the right of reproduction, the right of communication and the right of rental among others.¹³⁵ Article 17 of TRIPS provides exceptions and limitations to trademarks, while Article 26.2 provides for exceptions and

¹³⁰ For the text of the protocol vide <<http://www.sadc.int/>>

¹³¹ Bruno de Vuyst et al, (Exceptions to the Intellectual Property Rights : Lessons from WTO-TRIPs Panels 2003) available at

<<http://www.austlii.edu.au/au/journals/MurUEJL/2003/31.html>> (accessed November 2014)

¹³² *Ibid.*

¹³³ In *A&M Records v Napster, Inc.*, 239 F.3d 1004 (9th Cir. 2001), the 9th Circuit Court of Appeals decided that free downloading of music qualified as an infringement of copyrights.

¹³⁴ See Sam Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986*, London, Kluwer, 1987, p 477 ff.

¹³⁵ Mihály Ficsor, *The Law of Copyright and the Internet*, Oxford, University Press, 2002, 301-302.

limitations to industrial designs.¹³⁶ Exceptions and limitations for patents are provided under Article 30. Overall the scheme is one of striking a balance between private and public interest. As the scope of our discussion is in relation to access to essential health care, I will limit my discussion to patents.

One of the flexibilities Malawi can use to enhance access to medicines is Article 31*bis* of the TRIPS Agreement. The article stipulates that countries that intend to manufacture pharmaceutical products targeting countries with insufficient or no manufacturing capacity need not comply with TRIPS Article 31(f), which only legalizes compulsory licensing, where the target market is predominantly local and allows exporting only on a limited scale. The Article 31(f) obligation does not apply where a Member State grants a compulsory licence in favour of domestic generic manufacturers who intend to export large quantities of pharmaceutical products to countries with little or no manufacturing capacity.¹³⁷ Article 31*bis* creates a formal waiver of the domestic use requirement in Article 31(f).

However, Article 31*bis*(2) obliges exporting Member States to ensure that patent holders are given adequate remuneration in the event that a compulsory licence is issued against them. But this compensation is supposed to be calculated in reference to the market value of the product in the importing country. The article further provides that, where the patent holder has been remunerated under this provision, he will not be entitled to further remuneration in the importing country, even if the importing country issues a compulsory licence on the product.¹³⁸

Article 31*bis* endeavours to solve the problem of 'insufficient manufacturing capacity' by attempting to harness economies of scale using regional trade blocs. The article does this by waiving certain TRIPS obligations in favour of developing or LDCs for WTO Members that are parties to regional trade agreements such as SADC. Article 31*bis* allows these Members to authorize the manufacture of pharmaceutical products both for their own domestic use and for export to other regional group member states that have health problems targeted by the pharmaceutical product in question. The waiver attempts to achieve the following: harnessing economies of scale, enhancing purchasing power in the regional bloc, and facilitating local production of the pharmaceutical products. Malawi can take

advantage of the TRIPS Article 31*bis* waiver through the mechanism of the SADC Protocol on Health under Article 29(b). However, there is need for Malawi to review its intellectual property laws incorporating the flexibilities provided for under Article 31*bis* to import products from countries that produce generic pharmaceutical products. Given that the system requires compulsory licences to be issued by both the exporting and importing states, there is need for Malawi to domesticate the system within our laws and regulations in order to comply with the requirements of Article 31*bis*.

The other measure would be for Malawi, as a part of SADC, to explore the possibility of using the Article 31*bis* system, in order to harness economies of scale, enhance purchasing power, and facilitate local production of pharmaceutical products within their territories. Given that the Article is flexible enough to allow both developing countries and LDCs to manufacture or import pharmaceuticals, the SADC should explore the possibilities of harnessing the R&D and procurement capabilities of some of its Member States such as South Africa, in order to achieve this objective. In terms of building a manufacturing base for pharmaceuticals, Malawi needs to explore the possibility of collaborating with other countries that have a manufacturing base either in the region, such as South Africa, or internationally, such as China, India, the European Union, or the United States. Achieving the objectives of Article 31*bis* is premised on the fact that respective Member States will respect patents and modernize their patent systems. It is imperative that SADC promotes the development of systems for granting regional patents and harmonizing patent systems within the regional bloc.

A number of rationales for a regional policy on health as contained in the Protocol on Health¹³⁹ could be advanced. The starting point is the impact of globalization and liberalization of the international economy, which has brought about increased trade and investment mobility.¹⁴⁰ Globalization is having both positive and negative effects to public health. On a positive note, increased trade has been beneficial to Sub-Saharan economies.¹⁴¹ On the negative side, the increased trade and foreign

¹³⁶ Generally see Robert Howse, 'The Canadian Generic Medicines Panel - A Dangerous Precedent in Dangerous Times' *Journal of World Intellectual Property*, July 2000, n 4, Vol 3, 493.

¹³⁷ Article 31*bis*(1).

¹³⁸ Article 31*bis*(2).

¹³⁹ ILO convention 155 on Occupational Health and Safety states that the term 'health' in relation to work, indicates not merely the absence of disease or infirmity; but also includes the physical and mental elements affecting health, which are directly related to safety and hygiene at work.

¹⁴⁰ R Loewenson, C Nhachi, W Murambiwa and P Gona *Epidemiology of the Health Impact of Pesticide Use in Developing Countries: Epidemiological research in Zimbabwe*, Mimeo, Harare (1991).

¹⁴¹ See Article 1(C) of the Constitutive Act of the African Union. See also the NEPAD Objectives at <http://www.nepad.org/>

investment brings about new health hazards and risks that SADC economies are ill equipped to handle.¹⁴² The technological gap between pharmaceutical manufacturing countries and SADC states means there are intellectual property right issues that the region has to deal with, in order to provide access to essential medicines.¹⁴³ Faced with serious institutional limitations in the area of social protection and the impact of health on integration, it is in SADC's interest to improve its record on health if its economic gains are not be nullified or impaired by adverse social effect of ill-health.¹⁴⁴

Other reasons can be given why public health is crucial to SADC. These include the integrationist rationale. This is premised on the fact that harmonization of laws and social values are the cornerstone of any integration agenda. For the integration process to move forward, Member States need to find common ground in their national policies and plans.¹⁴⁵ Emerging health problems with a regional dimension¹⁴⁶ stimulate intergovernmental cooperation, as envisaged in Articles 21 and 22 of the SADC Treaty¹⁴⁷, and as read with Articles 20 and 29 of the Protocol on Health. Secondly, common health standards assist economic integration.¹⁴⁸

VII. CONCLUSION

There is a symbiotic relationship between intellectual property rights and public health. Intellectual property rights are a catalyst for economic development and can contribute to a reduction of poverty and improvement in access to essential medicines. However, intellectual property rights can impinge on access to medicines and health-care through their impact on prices for pharmaceutical products. Within the legal framework for intellectual property rights there are

flexibilities that can be utilized to improve access to medicines and enhance the right to health for the population. The preconditions for this include modernization of intellectual property right laws that incorporate TRIPS flexibilities.¹⁴⁹ There is need for Malawi, within the SADC context, to build capacity for pharmaceutical manufacturing. This has to be guided by a policy framework for intellectual property rights to attract technologically based foreign direct investment (FDI). The WTO Doha Declaration on Public Health points to the opportunity for LDCs, where need arises, to use the flexibilities to provide public health services; however, the prerequisite for this is a legal framework that enables a country to take advantage of such flexibilities and, in the absence of such a legal framework, as is the case in Malawi, this is unattainable.¹⁵⁰ Intellectual property rights and public health are mutually supportive and complementary.¹⁵¹ Malawi needs to reposition itself to take advantage of existing flexibilities and fulfil its constitutional mandate of improving the living standards of the people through, among others, safeguarding the right to health, whilst protecting the right to economic activity through effective protection and enforcement of intellectual property rights. The current state of affairs does not encourage investments in intellectual property rights and utilization of flexibilities for the provision of access to essential medicines and health services.

BIBLIOGRAPHY

Abbott Frederick M, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) *American Journal of International Law*, n 99, pp 317

Abbott Frederick M, 'Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of US Federal Law' IC TSD-UNCTAD Project on IPRs and Sustainable Development, Issue Paper n 12 (2006)

Abbott Frederick M and Jerome H Reichman, 'Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union'

¹⁴² Alberto López-Valcárcel (Dec. 2001) 'New Challenges and opportunities for Occupational Safety and Health (Occupational Health and Safety) in a Globalized World' *The African Newsletter of Occupational Health and Safety*.

¹⁴³ See Memorandum on The Economic Viewpoint in Occupational Safety and Health Supervision, Ministry of Social Affairs and Health Department for Occupational Safety and Health ampere, Finland 1999 International Publications.

¹⁴⁴ Ali Taqi, 'Globalization of Economic Relations: Implications for Occupational Safety and Health An International View' XIVth World Congress on Occupational Safety and Health Madrid, 23 April 1996.

¹⁴⁵ Article 21 of the Treaty.

¹⁴⁶ See our discussion on the effects of globalization on occupational health and safety.

¹⁴⁷ In Article 12 of the treaty, as amended, social and human development is one of the core areas for integration. Poor living and working conditions would not advance the case for social and human development.

¹⁴⁸ Section 29(a) of the Protocol. See also Frank B Wright *Law of Health and Safety at Work*; Sweet and Maxwell, (London, 1997) pp 32-33.

¹⁴⁹ Leslie London and Aulline H Mabika 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi and Southern and Eastern African, Information and Negotiation Institute (SEATINI) School of Public Health and Family Medicine, University of Cape Town (UCT) (2007).

¹⁵⁰ C Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO, Geneva (2002).

¹⁵¹ See generally, the World Health Organization 'Public Health, Innovation and Intellectual Property Rights' Report of the Commission on Intellectual Property Rights, Innovation and Public Health. (Geneva: WHO 2006).

Report to the Directorate General/External Policies of the European Union (2007)

Abbott Frederick M, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' Occasional Paper 14, Quaker United Nations Office (2004)

Amin Tahir, 'India's Patent Act on Trial' Bridges Weekly, February-March 2007 (available at <http://www.ictsd.org/>)

Baker BK, 'Analyses and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' United Nations Millennium Development Goals Project, Task Force 5: Infectious Diseases and Access to Essential Medicines, Sub-Group Access to Essential Medicines. New York: United Nations (2003)

Balasubramaniam K, 'Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives', paper presented at Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement? Brussels, 20 March 2001

Conference, New York, 2 June 1945. New York: WHO

Correa C, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO Geneva (2002)

Cynthia M Ho, 'A New World for Addressing Patent Rights and Public Health' (2007) 82 Chicago-Kent Law Review, 1469, Ibid. p 1470; see also Abbott Frederick M, and Reichmann Jerome H, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' 10, Journal of International Economic Law, 921, December 2007

Equinet, Seatini 'Policy Series 12: The WTO Global Agreement on Trade in Services (GATS) and Health Equity in Southern Africa' Equinet Policy Series Harare (2003)

Fink Carsten, 'Entering the Jungle of Intellectual Property Rights Exhaustion and Parallel Importation' in Fink Carsten and Maskus Keith E, *Intellectual Property and Development: Lessons from Recent Economic Research* (The World Bank and Oxford University Press 2005)

Fink Carsten, 'Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective' In Richard Newfarmer (ed), *Trade, Doha, and*

Development: Window into the Issues (The World Bank 2005)

Government of Malawi Patents Act 6 of 1992 Lilongwe: Government of Malawi (1992)

Government of Malawi Malawi Constitution Act 7 of 1995 Lilongwe: Government of Malawi (1995)

Government of Malawi 'Competition and Fair Trading Act 43 of 1998' Lilongwe: Government of Malawi in Sub-Saharan Africa (IPI) (1998)

Government of Malawi Public Procurement Act 8 of 2003 Lilongwe: Government of Malawi (2003)

London Leslie and Mabika Aulline H, 'Implications of the GATS and TRIPS Agreements for the Right to Health in Malawi and Southern and Eastern African' Information and Negotiation Institute (SEATINI), School of Public Health and Family Medicine, University of Cape Town (UCT) (2007)

Ministry of Finance, Malawi Growth and Development Strategy, Lilongwe

Ministry of Finance, (2002), Malawi Poverty Reduction Strategy Paper

Bakhom Mor, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicine?' Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series no 10-07 31 January 2009 <http://ssrn.com/abstract=1619215>

Namelo C and Chavula SWD, 'Aspects of Non-Conformity in Malawi's Intellectual Property Legislation vis-a-vis International Agreements, Conventions and Treaties on Intellectual Property' (2003)

Lewis-Lettington Robert and Banda Chikosa, 'A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi' DFID Health Systems Resource Centre

UNCTAD-ICTSD *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* <http://www.ictsd.org/iprsonline/unctadictsd/ResourceBookIndex.htm> (accessed November 2014)

World Health Organization, The Constitution of the WHO. International Health

REGIONAL FRAMEWORKS

African Regional Intellectual Property office

SADC Protocol on Trade

SADC Protocol on Trade in Services

SASDC Protocol on Health

The SADC Treaty

International Framework

Constitution of the World Health Organization (WHO)

Patent Cooperation Treaty Convention

The General Agreement on Tariff on Trade in Goods 1994

The General Agreement on Trade in Goods

The WTO Agreement on Sanitary and Phytosanitary Measures

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

WTO Doha Declaration on the TRIPS Agreement and Public Health

Domestic legislation

Copyright Act (Cap. 49: 03)

Dangerous Drugs Act

Patents Act (Cap. 49: 02)

Registered Designs Act (Cap. 49: 05) of the Laws of Malawi

The Occupational Safety, Health and Welfare Act

The Pesticide Act

The Pharmacy, Medicines and Poisons Act

The Competition and Fair Trading Act Caps. 48:09

The Environment Management Act 60:02

The Mental Treatment Act

The Public Health Act, Cap.34:01

The Republic of Malawi Constitution, 1994

The Trade Descriptions Act was promulgated in 1987

The Trade Marks Act (Cap. 49: 01)

Trade Descriptions Act (Cap. 49: 04)

Cases

Airedale NHS Trust v Bland [1993] 1 All ER 821 (CA)

Dr Bakili Muluzi and UDF v Malawi Electoral Commission Constitutional Case no 1 of 2009

Fred Nseulavs The Attorney General and Malawi Congress Party, MSCA Civil Appeal No. 32 of 1997 (unreported)

Attorney General v The Malawi Congress Party, L.J Chimango and Dr HM Ntaba, MSCA Civil Appeal no 22 of 1996

Madzimbamuto v Lardner Burke (PC) (1969) 1 A.C, 651

Olga Tellis v Bombay Municipal Corporation, 1985 Supp (2) SCR 51

Pachim Banga Khet Majoorsamity v State of West Bengal, 1996

R v Cambridge Health Authority, ex parte B [1995] 2 All ER 129 (CA)

Re J (a minor) [1992] 4 All ER 614 (CA)

Re Reference by Western Highlands Provincial Executives (1996) 3 LRC 28

State v Makwanyane (1995) 3 SA 391 (CC)

The Public Affairs Committee v Attorney General, Civil Cause No. 1861 of 2003

Thiagraj Soobramoney v Minister of Health (Kwazulu-Natal) (CCT32/97) [1997] ZACC 17