PHARMACEUTICAL TRADE POLICIES AND ACCESS TO MEDICINES IN KENYA

by

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Declaration

I declare that this thesis, which I hereby submit for the degree Doctor Legum (LLD), at the University of Pretoria, is my own work and has not been previously submitted by me for a degree at this or any other tertiary institution.

Paul Omondi Ogendi

Signature _____

Dedication

This thesis is dedicated to all access to medicines actors around the world. Your commitment to safeguard access to medicines especially in developing countries is saving millions of lives, which otherwise would be needlessly lost.

God bless you!

Acknowledgement

The process of writing this thesis faced many challenges that seemed insurmountable. At one point, I almost gave up writing this thesis. However, I am deeply indebted to my two supervisors, Professor Magnus Killander and Professor Attiya Waris, for continuously motivating me and closely working with me to resolve the many challenges that I was facing throughout my research process. Without this motivation and close support perhaps, this project would not have been concluded.

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I thank you too.

Acronyms and abbreviations

ACA	Anti-Counterfeiting Agency
ACHPR	African Commission on Human and Peoples' Rights
ACRWC	African Charter on the Rights and Welfare of the Child
AG	Attorney General
AGOA	African Growth and Opportunity Act
ALP	AIDS Law Project
API	Active Pharmaceutical Ingredients
ARVs	anti-retrovirals
AU	African Union
CEDAW	Convention on the Elimination of All Forms of Racial Discrimination
CESCR	Committee for Economic, Social and Cultural Rights
CESR	Centre for Economic and Social Rights
CFTA	Continental Free Trade Agreement
CRPD	Convention on the Rights of Persons with Disabilities
CSOs	Civil Society Organization
DSU	Dispute Settlement Understanding
EAC	East African Community
EALA	East African Legislative Assembly
EC	European Community
EPA	Economic Partnership Agreement
EU	European Union
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
HIA	Health Impact Assessment
HLP	High Level Panel
HRB	Human Rights Budgeting

HRC	Human Rights Council
HRIA	Human Rights Impact Assessment
IAIA	International Association of Impact Assessment
IBP	International Budget Project
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IHRIP	International Human Rights Internship Program
IIAG	Ibrahim Index of African Governance
IPECAC	Intellectual Property and Enforcement Coordination Advisory Committee
JTI	Judicial Training Institute
KAM	Kenya Association of Manufacturers
KIPI	Kenya Industrial Property Institute
KIPO	Kenya Industrial Property Organization
KNCHR	Kenya National Commission on Human Rights
LDCs	Least Developed Countries
MDGs	Millennium Development Goals
MSF	*Medecins sans Frontieres*
NEMA	National Environmental Management Authority
NGOs	Non-Governmental Organizations (NGOs)
OHCHR	Office of the High Commissioner for Human Rights
OPERA	Outcomes, Policy, Efforts, Resources, and Assessment
PETS	Public Expenditure Tracking Survey
RHIA	Right to Health Impact Assessment
RIA	Recognition, Institutionalization and Accountability
SADC	Southern African Development Community
SDGs	Sustainable Development Goals
SERF	Social Economic Rights Fulfilment
SHRC	Scottish Human Rights Commission
SIA	Social Impact Assessment

SSFFC	Substandard, Spurious, Falsely-labelled, Falsified and Counterfeit
TRIPs	Trade Related Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UHC	Universal Health Coverage
UNDP	United Nations Development Programme
UNGA	United Nations General Assembly
UNSG	United Nations Secretary General
US	United States
VLCT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Abstract

The implementation of the World Trade Organization (WTO) Trade Related Intellectual Property Rights (TRIPs) Agreement at the national level via pharmaceutical trade policies may adversely affect access to medicines especially in developing countries. Access to medicines is protected under many international and national instruments on the right to health including the International Covenant on Economic, Social and Cultural Rights, the African Charter on Human and Peoples' Rights (African Charter) as well as the Constitution of Kenya, 2010. The right to health norms on access to medicines require the full and effective use of all TRIPs Agreement flexibilities by developing countries as confirmed by the Doha Declaration on the TRIPs Agreement and Public Health (Doha Declaration), 2001. In this regard, access to medicines is affected by failure to provide for all the TRIPs Agreement flexibilities in pharmaceutical trade policies as well as the incorporation of TRIPs plus standards in trade policies including bilateral and multilateral free trade agreements (FTAs). In order to identify and mitigate on the potential adverse impacts of pharmaceutical trade policies on access to medicines, the mechanism of human rights impact assessment (HRIA) is needed. The HRIA can resolve *beforehand* the adverse impacts of pharmaceutical trade policies on access to medicines. However, the implementation of the HRIA or specifically the right to health impact assessment (RHIA) mechanism by developing countries including Kenya is rare. This study therefore explores, using mixed methodologies including desktop literature review and expert interviews with selected trade policy makers in Kenya, *how* HRIA may be utilised by the government in order to resolve the potential adverse impacts of pharmaceutical trade policies on access to medicines.

Key words

Human rights impact assessment; right to health impact assessment; access to medicines; Trade-Related Aspects of Intellectual Property Rights Agreement; fair trade; free trade agreements; market failure; economic partnership agreement; pharmaceutical trade policies; Kenya; and developing countries.

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CHAPTER ONE: INTRODUCTION TO THE THESIS

1.1 Introduction

Access to medicines is a fundamental element of the right to health protected under Article 25 of the Universal Declaration of Human Rights (UDHR),[1] Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR),[2] Article 16 of the African Charter on Human and Peoples' Rights,[3] and Article 43(1)(a) of the Kenyan Constitution, 2010[4]. Arguably, access to medicines is also necessary in the context of achieving universal health coverage (UHC) under the Sustainable Development Goal (SDG) 3[5].

In relation to pharmaceutical trade policies, access to medicines is mainly about the adverse impacts of the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement in developing countries particularly in relation to the high prices of medicines beyond the reach of the majority poor. *How* to resolve the adverse impacts of pharmaceutical trade policies on access to medicines at the national level is therefore critical for developing countries including Kenya. In this context, the mechanism of human rights impact assessment (HRIA) has emerged as an ideal tool for this purpose.[6] The HRIA is ideal because it can ensure that the implementation of international trade rules

[1] United Nations General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III), http://www.refworld.org/docid/3ae6b3712c.html (accessed 7 March 2016).
[2] United Nations General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993, 3, http://www.refworld.org/docid/3ae6b36c0.html (accessed 3 March 2016). Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966. Entry into force 3 January 1976, in accordance with article 27.
[3] Organization of African Unity (OAU), *African Charter on Human and Peoples' Rights ("Banjul Charter")*, 27 June 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), http://www.refworld.org/docid/3ae6b3630.html (accessed 3 March 2016).
[4] The Constitution of Kenya [Kenya], 27 August 2010.
[5] United Nations Sustainable Development Goals (SDGs), 2030. Goal 3 is about god health and well-being. One of the targets is to '[a]chieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.' http://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being/targets.html (accessed 18 July 2017).
[6] R Mungoven 'Walking the talk: Exploring methodologies and applications for HRIA by the United Nations' (February 2016) 7.

such as the TRIPs Agreement do not prioritize trade imperatives at the expense of the right to health for all.[7]

The HRIA can be employed by developing countries to identify and mitigate *beforehand* the manner in which international trade rules impact on human rights.[8] Consequently, the then Special Rapporteur on the Right to Food, Olivier De Schutter, has argued that the need to conduct HRIA especially in trade and investment treaties in order to avoid inconsistencies in terms of treaty obligations should be a *duty* of the states in accordance with Articles 26 and 30(4)(b) of the Vienna Convention on the Law of Treaties (VLCT).[9] However, despite the strong legal language above, the implementation HRIA is still rare in developing countries even though it is currently being promoted as a routine process worldwide.[10] HRIAs conducted particularly by or on behalf of governments is especially rare if compared to the usage of health impact assessment (HIA) or social impact assessment (SIA).[11] The distinction between RHIA and health or social impact assessment is on the use of human rights norms for HRIA and the *status quo*[12] for HIA and SIA in terms of the reference point. Illustratively, apart from Thailand, no other HRIA has been conducted by or on behalf of the government in developing countries.[13] The HRIA in Thailand was conducted in 2006 to identify and mitigate on the human rights effects of the Thailand-United States (US) free trade agreement (FTA) on agriculture, the environment, intellectual property and services, and investment.[14]

Developing countries have been repeatedly cautioned against negotiating or implementing trade-related intellectual property rights without first assessing their impacts on human

[7] G MacNaughton 'Human rights impact assessment: A method for healthy policymaking' (2015) *Health and Human Rights Journal* 64.
[8] J Harrison & A Goller 'Trade and human rights: What does "impact assessment" have to offer' (2008) 8 *Human Rights Law Review* 592.
[9] Report of the Special Rapporteur on the right to food, Olivier De Shutter, 'Guiding principles on HRIA of trade and investment agreements' 19 December 2011 [UN Doc. A/HRC/19/59/Add.5], para. 1.1.
[10] MacNaughton n 7 above, 64.
[11] L Forman & G MacNaughton 'Moving theory into practice: Human rights impact assessment of intellectual property rights in trade agreements' (2015) 7 *Journal of Human Rights Practice* 122.
[12] According to the Black's Law dictionary, *status* quo means: 'Latin phrase that means without change and in the same situation as it was.' https://thelawdictionary.org/in-status-quo/ (accessed 18 July 2018)
[13] Forman and MacNaughton n 11 above, 117-118.
[14] As above.

rights.[15] This is particularly crucial because of the increasing popularity of intellectual property protection provisions in many bilateral and multilateral trade agreements over the past decade, which means that the pressure on the government to accept more stringent standards of intellectual property protection is higher than before and to their detriment including in terms of access to medicines.[16] The HRIA is therefore an important methodology especially in developing countries in this context.[17]

In Kenya, HRIA has only been conducted by non-governmental organizations (NGOs) in relation to the Convention for the Protection of New Varieties of Plants (UPOV), 1991 with Kenya being one of the cases studies.[18] However, HRIA by either the government or NGO initiative in relation to international intellectual property rules and access to medicines is still absent. This study is therefore important in order to change the current reality.

1.2 Background

This background is divided into four main sections, namely: WTO and the marginalization of the poor; TRIPs and access to medicines; access to medicines in developing countries; as well as pharmaceutical trade policies and access to medicines in Kenya. These four sections have been discussed separately below.

1.2.1 World Trade Organization and the marginalization of the poor

The marginalization of the poor is an inherent problem within the trading system today. The acceptance of obligations by the state within the WTO system in particular has been

[15] As above, 117-118.
[16] L Forman & G MacNaughton 'Lessons learned: a framework methodology for human rights impact assessment of intellectual property protection in trade agreements' (2016) *Impact assessment and Project Appraisal* 1, http://www.dlsph.utoronto.ca/wp-content/uploads/2012/02/Forman-MacNaughton-IAPA-final-.pdf (accessed 30 July 2017).
[17] As above, 111.
[18] New Report: Owning seed, accessing food: A human rights impact assessment of UPOV 1991 based on case studies in Kenya, Peru and the Philippines' *APBREBES* [Monday, 13 October 2014], http://www.apbrebes.org/news/new-report-%E2%80%9Cowning-seed-accessing-food-human-rights-impact-assessment-upov-1991-based-case, (accessed 18 July 2018).

promoted on the basis of special interests and the provision of adjustment assistance.[19] The assumption with this approach is that the state will possess autonomy from dominant groups and is therefore a neutral actor.[20] The reality, however, is different because if you exaggerate or misjudge the extent of autonomy of a state it means that they may not be able to respond to the concerns of the poor and marginal groups adversely affected by the trade liberalization agenda.[21]

Therefore, trade-led growth rates do not automatically translate into the welfare of the poor, which requires the putting into place of appropriate laws and institutions.[22] Since state policy-making is dominated by rich elites it therefore follows that it may be difficult to put in place laws and institutions responsive to the needs of the poor people.[23] Such laws and institutions could be in any area of trade including access to medicines. The problem of access to medicines may therefore be described as a problem of poverty and marginalization of the poor in the trading system.

1.2.2 TRIPs Agreement and the problem of access to medicines

The WTO as currently established is generally insulated from political debates and this partly explains why it is outside the UN system.[24] The WTO pursues a non-political and strictly technical path in its work because of its contractual nature.[25] Therefore, arguably, the WTO as an institution is *ab initio* not properly constituted to deal with the problem of access to medicines in developing countries.

The space for dealing with political problems such as access to medicines especially in developing countries is also currently limited because of the structural barriers in existence

[19] BS Chimni 'Developing countries and the GATT/WTO system: Some reflections on the idea of Free Trade and Doha Round trade negotiations' in C Thomas & JP Tratchtman (eds) *Developing countries in the WTO legal system* (2009) 29-30.
[20] As above.
[21] As above, 30.
[22] As above.
[23] As above.
[24] W Benedek 'The World Trade Organization and human rights' in W Benedek, K de Feyter& F Marrella (eds) *Economic globalization and human rights* (2007) 139.
[25] As above.

within the WTO. The civil society, through its criticisms, have therefore effectively assumed the role of articulating access to medicines and other human rights issues within the WTO in the past decades.[26] Some of the criticism against the WTO include that it has failed to ensure that its rules and agreements are sensitive to human rights norms.[27] Through the work of the civil society it is arguable that an inextricable link between human rights and international trade currently exists.[28]

Perhaps the main reason why the link between human rights and international trade should be acknowledged is because of the structural effects of WTO rules in developing countries as well as the wide disparities of power and capabilities among WTO members.[29] The TRIPs Agreement in particular is highly interventionist, which means that it not only interferes with the sovereignty of a country in terms of deciding on its own patenting regime but also limits the capacity of a country to pursue other important competing public policies such as human rights.[30] The TRIPs Agreement is thus problematic for especially trade policy makers because developing countries joining the WTO have no choice but to cede control of their policy space in favour of implementing trade rules.[31] The scenario that emerges is that the process of deregulation at the national level is currently being complemented by the process of regulation at the international level.[32] Accordingly, international trade rules can very well undermine the capacity of states to comply with their human rights obligations without protecting the policy space necessary to act at the national level in relation to the adaptation of international trade agreements.[33]

[26] As above, 141.
[27] As above 151.
[28] As above, 151.
[29] As above.
[30] S Fredman *Human rights transformed: Positive rights and positive duties* (2008) 49.
[31] C Dommen 'Human rights and trade - Two practical suggestions for promoting coordination and coherence: Commentary on Victor Mosoti' in TS Cottier, J Pauwelyn, & E Burgi (eds) *Human rights and international trade* (2005) 200.
[32] T Mentan *The State in Africa: An analysis of the impact of historical trajectories of global capitalist expansion and domination in the Continent* (2010) 37.
[33] D Ovett 'Making trade policies more accountable and human rights-consistent: A NGO perspective of using human rights instruments in the case of access to medicines' in W Benedek, K de Feter& F Marrella (eds) *Economic globalization and human rights* (2007) 170.

What is more, WTO rules and the TRIPs Agreement cannot be called 'agreements' properly so-called because of the following reasons. First, a country desirous of becoming a member of the WTO must accept all the treaties including the TRIPs Agreement without exception in what Peerenboom observes is the 'price' developing countries must suffer to join the WTO system.[34] Many countries therefore have no option but to join the TRIPs Agreement and the sole motivation for many of these countries is the promise of accessing markets in developed worlds.[35] The problem with the market access argument however is that the Generalized System of Preferences operated by the US and European Union (EU) has many conditions, which in turn makes its benefits unstable and a waste of assets and therefore they cannot guarantee that poor countries would eventually access the developed countries' markets.[36] This scenario at best may be termed as undue influence as opposed to freedom of contract.

The other reason why the TRIPs Agreement is believed to be imposed is that developed countries have traditionally assumed the role of ensuring that developing countries implement their obligations under the TRIPs agreement without fail by employing various strategies including use of trade sanctions.[37] The US in particular has within its Trade Act of 1974 a section 301, which is the 'statutory authority under which the [US] may impose trade sanctions on foreign countries that either violate trade agreements or engages in other unfair trade practices.'[38] Using this law, countries that violate the TRIPs Agreement are liable for trade sanctions and this has in turn achieved a greater implementation of the TRIPs Agreement by developing countries than perhaps would have been possible.

Lastly, the WTO is so far the only international body that has an enforcement system in terms of its dispute settlement body, which requires all WTO members to frequently adapt their

[34] R Peerenboom *China modernizes: threats to the west or model for the rest?* (2007) 14.
[35] AS Taubman 'TRIPs goes east: China's interests and international trade in intellectual property' in DZ Cass, BG Williams & G Barker (eds) *China and the WTO Trading System: Entering the new millennium* (2003) 345.
[36] C Thomas and JP Trachtman 'Editor's introduction' in C Thomas & JP Tratchtman (eds) *Developing countries in the WTO legal system* (2009) 7 Oxford University Press.
[37] FM Abbott 'The TRIPs-legality of measures taken to address public health crises: Responding to USTR-State-industry positions that undermine the WTO' in Abott FM, Breining-Kaufmann C, & Cottier T (eds) *International trade and human rights: Foundations and conceptual issues* (2006) 342. Abbott notes that perhaps the WTO is a multilateral institution that is only responsive to the hard bargain. Those with power will achieve their aims; those without power will suffer.
[38] 'Section 301' *International Trade Administration,* https://www.trade.gov/mas/ian/tradedisputes-enforcement/tg_ian_002100.asp (accessed 7 June 2017).

domestic laws in order to comply with its decisions.[39] To this extent, the WTO decisions are bound to be prioritized in terms of implementation as opposed to other decisions at the international level including those emanating from human rights bodies, which comparatively lack a robust enforcement mechanism as the WTO.

1.2.3 Access to medicines in developing countries

What then should be the role of human rights in the context of international trade, if at all? In light of the foregoing, some commentators have suggested that the role of human rights should be to provide a mechanism of external social justice.[40] This has been made possible especially during the post-Cold War period, which has seen human rights develop significantly to cover both the taming of state power and advancing social justice ideals on a global scale.[41]

From a global social justice perspective, the adverse impact of the TRIPs Agreement on public health and access to medicines in developing countries is particularly dire.[42] Yamin for instance notes that the untold suffering of people in developing countries due to lack of access to medicines for HIV and AIDS, malaria and tuberculosis is a 'horrific injustice' and should not be treated as a 'tragedy'.[43] Consequently, Yamin further notes that it is therefore crucial to implement TRIPs Agreement flexibilities if it would facilitate the right to health and access to medicines in developing countries.[44]

Illustratively, Grover, the former special rapporteur on the right to health, observes that the issue of the impact of patents on manufacture and importation of generic medicines is crucial

[39] D McRae 'The place of the WTO in the international system' in D Bethlehem, D McRae, R Neufeld, & I van Damme (eds) *The Oxford handbook of international trade law* (2009) 74.
[40] Harrison & Goller n 8 above, 591.
[41] K de Feyter 'Introduction' in W Benedek, K de Feyter & F Marrella (eds) *Economic globalization and human rights* (2007) 3.
[42] Abbott n 37 above, 342. The adverse impact of TRIPs Agreement in developing countries has been tackled separately under chapter three section 3.4.
[43] A Yamin 'Not just a tragedy: Access to medicines as a right under international law' (2006) *Berkley University International Law Journal* 370.
[44] As above.

since patents allow the patentee to set higher prices.[45] He also observes that due to generic medicines notable gains have been achieved in developing countries in terms of lowering of prices of HIV medications from as high as US$ 10,000 per patient per year to US$ 350 per patient per year but the post-2005 TRIPs Agreement period poses unique challenges.[46] In this regard, generic competition is necessary to achieve better medicines' prices including the patented ones.

As a response to the threat posed by the TRIPs Agreement on affordability of medicines, developing countries have succeeded in achieving the following results within the WTO system: the Doha Declaration on the TRIPs Agreement and Public Health, 2001; the Decision of 30 August 2003; and TRIP[s] Agreement Amendment of December 2005.[47] From the above, the problem of unaffordability of medicines in developing countries is therefore not a trivial one and developing countries have been actively engaged at the WTO level to push for appropriate reforms.[48] It is crucial to note that the challenge of access to medicines in developing countries is also currently included as part of the UN Sustainable Development Goals (SDGs) specifically under Target 3b further illustrating its critical nature.

However, the increasing use of bilateral and multilateral FTAs outside the WTO like the EU Economic Partnership Agreements (EPAs) and anti-counterfeiting legislation is representing a new challenge, which is threatening to reverse the gains that have already been registered at the WTO level.[49] These FTAs often include measures beyond what is required by the TRIPs Agreement or TRIPs plus rules (this term means increased levels of protection and enforcement beyond what is provided for under the TRIPs Agreement).[50] As Forman rightly observes higher standards beyond what is provided for under the TRIPs Agreement or TRIPs plus standards only serves to further exacerbate the problem of access to medicines in

[45] 'Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health' A Grover, 31 March 2009, [A/HRC/11/12], para 17-18.
[46] As above, para 20-21.
[47] H Hestermeyer *Human rights and the WTO: The case of patents and access to medicines* (2007) 255.
[48] For a detailed discussion on TRIPs reforms please see the section on WTO, TRIPs Agreement reforms and access to medicines under Chapter three specifically section 3.4.5.
[49] In particular, the EU has been pushing for the ratification of EPA in EAC and so far only Kenya and Rwanda have ratified the EPA with the other countries yet to do so.
[50] L Forman 'From TRIPS-plus to rights-plus? Exploring right to health impact assessment of trade-related intellectual property rights through the Thai experience' (2012) 7 *AJWH* 349.

developing countries.[51] Therefore, the present political climate requires that standards beyond the TRIPs Agreement should be stalled in order to safeguard access to medicines.[52] Despite the conflict in terms of the duties these agreements present to the government and those that are required under human rights law the scenario is that many policy makers tend to ignore their human rights obligations when negotiating and implementing trade-related policy and practice and this must be dealt with.[53] The trend towards greater intellectual property rights protection and enforcement is often justified by the imperative to fight counterfeiting and piracy.[54]

1.2.4 Pharmaceutical trade policies and access to medicines in Kenya

There is a close link between intellectual property rules at the international level and domestic pharmaceutical trade policies. The latter actually implements the former. In Kenya, both the controversial Anti-Counterfeit Act, 2008 and the equally controversial EU EAC EPA have been negotiated on the basis of prevailing international intellectual property rules. The other TRIPs-compliant pharmaceutical trade policy in Kenya is the Industrial Property Act, 2001.[55] The Anti-Counterfeit Act is particularly controversial in Kenya because in 2012 it was declared by the Kenyan High Court to be in violation of the rights to health, dignity and life in the case of *PAO & 2 Others v AG & 2 Others*.[56] Similarly, EU EAC EPA is also controversial since it represents a future threat because parties have yet to agree on specific terms in relation to intellectual property and its negotiation has been suspended pending the ratification of the final agreement.[57] Once the document is ratified and operational, the

[51] As above.
[52] Hestermeyer n 47 above.
[53] Forman n 50 above, 349.
[54] B Mercurio 'Beyond the text: The significance of the anti-counterfeiting trade agreement' (2012) 15(2) *Journal of International Economic Law* 363.
[55] See chapter six, section 6.2 on the relevant laws and policies on intellectual property rights in Kenya.
[56] *PAO & 2 Others v AG & 2 Others* [2012] eKLR.
[57] European Union East African Community Economic Partnership Agreement (EU EAC EPA), http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153845.compressed.pdf (accessed 27 February 2018).

negotiations on intellectual property rights will then have to be concluded within five years.[58]

What therefore can be done to ameliorate the current and future problems? As noted above, access to medicines is currently part of the UN SDGs. In this context, the UN Secretary General High Level Panel (HLP) on access to medicines in its report proposed the utilisation of public health impact assessment at the national level in the context of implementation of international trade rules.[59] This proposal for impact assessment mirrors closely the proposal for HRIA that was introduced in the introduction section. It is argued that countries with enforceable international and constitutional right to health framework like Kenya may take advantage of their legal framework in order to implement the HRIA and specifically the right to health impact assessment (RHIA) in relation to the adverse impact of the TRIPs Agreement on access to medicines.[60]

1.3 Problem statement

Kenya is one of the countries that is currently grappling with the problem of access to medicines and relevant policy makers including those in trade are unable to respond appropriately because the policy space is constrained by obligations arising from the necessity to implement international intellectual property trade rules including the TRIPs Agreement and other FTAs. The trade policy makers are often keen to implement the obligations emanating from international trade rules at the expense of the other obligations of the state including under international human rights and access to medicines. In order to avoid marginalizing other obligations of the state in favour of trade rules, trade policy makers as a necessity should adopt appropriate tools that are able to balance the implementation of international trade rules as well as human rights without sacrificing one to the other. In this context, the utilization of the HRIA has been proposed as a routine process in trade especially in relation to the implementation of the obligations of the

[58] As above. See Article 3 on rendez-vous clause, which has listed among other things intellectual property rights to be negotiated within five (5).
[59] See the United Nations Secretary-General's High Level Panel on Access to Medicines Report, 14 September 2016, http://www.unsgaccessmeds.org/final-report/ (accessed 27 February 2018).
[60] The right to health norms in relation to the TRIPs Agreement has been discussed at length in chapter four.

government in relation to international trade and investment rules locally. The problem however is that many governments including Kenya, with the exception of Thailand, are yet to embrace the HRIA.[61] This is despite the fact that Kenya subscribes to an elaborate right to health frameworks, which can be used as a comprehensive guide for trade policy makers in terms of how to implement their obligations under international trade rules without sacrificing their obligations under human rights and access to medicines. The current apparent lack of implementation of the HRIA mechanism by the Kenyan government is the problem addressed in this study and specifically the study focuses on *how* HRIA may assist in resolving the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya.

1.4 Research questions

The main research question for this study is *how* the mechanism of HRIA could be implemented in order to resolve the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya.

The specific research questions of the study are as follows:

1. How do international intellectual property rights including TRIPs Agreement affect the realisation of access to medicines in developing countries?
2. What theory could best justify the implementation of HRIA in trade as a routine process?
3. What are the right to health obligations of the government in relation to trade and access to medicines that may be used in relation to HRIA?
4. Why are trade policy makers in Kenya not using HRIA in order to resolve the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya?

[61] Forman & MacNaughton n 11 above, 122.

1.5 Literature review

This literature review section provides a brief overview of the theories, methodologies as well as case studies on the subject of HRIA in relation to trade and access to medicines in order to identify the gap addressed in this study.

1.5.1 Theories of human rights impact assessment

The applicable theories in relation to HRIAs in relation to trade can be divided into two main categories, namely: the traditional human rights theories: and the market or trade theories. The human rights theories are: human rights as a source of substantive policy guidance in trade; human rights as a source of political, moral and legal pressure; human rights and fragmentation, coherence and constitutionalisation of international law; and human rights as a trigger for social learning in trade.[62] This review will only focus on human rights as a trigger for social learning in trade due to its popularity. The market theories may include: Rational theory for morality; and semiotics.

1.5.1.1 Human rights theories

In relation to human rights as a trigger for social learning in trade, Harrison notes that the HRIA as a tool is currently more popular in other fields and is outwardly focused and as such it is possible that human rights can affect policy debates in new areas including trade.[63] The idea here is that the HRIA facilitates the process by which human rights-based arguments can be introduced and supported in other sectors where it was previously not possible to do so. This view is shared by Forman who further argues that 'the tool's methodology and approach is best understood through theories of rights as drivers of social change, particularly constructivist theories of socially-driven normative diffusion.'[64] In Forman's

[62] ATF Lang 'The role of the human rights movement in trade policy-making: Human rights as a trigger for policy learning' (2007) 5 *NewZealand Journal of Public International Law* 77. Much of these theories have been discussed in detail under chapter two of this study.
[63] J Harrison 'Human rights measurement: reflections on the current practice and future potential of HRIA' (2011) 3 *Journal of Human Rights Practice* 170.
[64] L Forman 'From TRIPS-plus to rights-plus? Exploring right to health impact assessment of trade-related intellectual property rights through the Thai experience' (2012) 7 *Asian Journal for WTO & International Health Law* 355.

view, the way the tool works is through playing 'a more subterranean normative role by diffusing and internalizing new human rights norms around medicines, so that policy makers are forced to consider their right to health duties when dealing with intellectual property rights.'[65] Lang also argues and notes that unlike the other traditional human rights theories, the social learning theory is transformative in relation to the trading system because of its role of imposing a 'new thinking'.[66] In this manner, human rights rules and principles become the basis of producing new policy ideas to fundamentally question the present assumptions that has hindered progress in trade.[67]

The social learning theory as briefly articulated above is persuasive in relation to HRIA but it suffers from one major weakness, which is legitimacy from a trade policy maker's point of view. This constrain is addressed using market theories discussed below.

1.5.1.2 Market theories

The link between trade and human rights has suffered greatly because it often appears as if the two disciplines are inconsistent with each other. The challenge at hand therefore is to try and explain why the two bodies should not be viewed as being inconsistent with each other but compatible. This is the challenge addressed by market theorists discussed in this section. One theorist is Malloy who introduces a concept known as semiotic method, which he contends can 'help us to reflect on the social and cultural consequences of invoking and validating economic assumptions in law and social institutions.'[68] In the semiotic method, Malloy contends that the focus is made not only on 'what might be efficient, but on what the social significance might be of declaring an efficiency criterion to be of primary significance in determining social policy.'[69] The Semiotic method is significant in so far as it allows for the challenging of the dominant efficiency criterion in trade and economics.

[65] As above.
[66] Lang n 62 above, 101. According to Lang 'new thinking' means 'new ideas about the kind of trade policies which are desirable and legitimate, and about the kind of governance structures through which political power is constituted and exercised in the trading order.'
[67] As above, 101.
[68] RP Malloy *Law and market economy* (2000) 26.
[69] As above.

Perhaps the most relevant theory in this study is that propounded by Cole, who argues that in general morality is incompatible with rational behavior but in exceptional circumstances, which is market failure, morality may be compatible with rational behavior, which is the *modus operandi* in trade.[70]

1.5.2 The methodology of human rights impact assessment

Limited scholarship exists in the area of methodology of HRIA and considering the practice and experience of implementing HRIA.[71] There are however a few critical scholars that will be reviewed in this section. Harrison for instance notes that HRIA has developed in at least six main areas including: development; health and human rights; children's rights; multinational companies; international trade; public authorities; and others including anti-trafficking laws and policies and domestic violence.[72] It appears therefore that HRIA has multiple uses and has been used in many contexts including international trade. The immediate problem however is that some actors will abuse the term HRIA to refer to a process that does not resemble any ideal-type instrument as known by human rights actors and commentators.[73] It is therefore crucial to understand the methodology of HRIA in order to distinguish it from other instruments employed by human rights or trade actors. According to Harrison, the ideal-type instrument developed from the practice of HRIA all over the world over a long period of time should have eight main elements as follows:[74]

[70] As above.
[71] Harrison n 63 above, 163.
[72] As above, 168-170.
[73] As above, 171.
[74] As above, 172-179.

screening;[75] scoping;[76] evidence gathering;[77] consultations;[78] analysis;[79] conclusions and recommendations;[80] publication;[81] and monitoring and review[82]. Suffice to note the steps under HRIA are actually similar to most of the other types of impact assessments and as such the methodology of impact assessment is similar across board.[83] Harrison also notes that in order to enhance future practice, there are a number of things that must be addressed including:[84] improving collective understanding of the process;[85] better guidance and support for those undertaking HRIAs;[86] and monitoring performance.[87] In the context of access to medicines, the health impact assessment (HIA), international trade agreements HRIA and right to health impact assessment (RHIA) are instructive. For a detailed discussion about HRIAs in the context of health policy-making, the work of MacNaughton is key.[88] However, since this study is about international trade agreements, the focus of this study is

[75] As above, 172-173. 'Screening is the process of deciding whether a particular policy, practice, or project is suitable for a full impact assessment, and screening out those where an HRIA is not considered appropriate or necessary. It therefore performs a critical step in justifying a decision to undertake an assessment.'
[76] As above, 173-174. 'Scoping refers to the information that is gathered and questions that are asked once the decision to undertake an HRIA has been made (although in some forms of HRIA considerable scoping may be required before a screening decision is taken). Scoping essentially provides a road map for the rest of the assessment (what is being assessed, and how it is to be assessed).'
[77] As above, 174-175. 'This is the collection of information to inform analysis of the policy in question. This is at the heart of an impact assessment methodology. Without gathering evidence about the (potential) impacts of a policy, the conclusions of the decision-maker are likely to reflect simply their own knowledge, experience and prejudices.'
[78] As above, 175-176. 'There need to be procedures for ensuring that the voices of those who are or are likely to be affected by the policy are heard and taken into account in the HRIA process. This requires effective consultations.'
[79] As above, 176-178. '…using human rigs obligations as the basis of impact assessment is not as obvious or as simple as it seems. In some extreme cases, there are assessments in which no real attempt is made to use human rights obligations as the basis for assessment at all…HRIAs must be fundamentally rooted in human rights norms and standards if they are really to be considered HRIAs.'
[80] As above, 178-179. 'If the aim is to have an effect on actual policy and practice, then clearly this step is central – without clear conclusions and recommendations, action in response to the HRIA is highly unlikely.'
[81] As above, 179. 'Publishing HRIA is a vital part of the impact assessment process. It ensures that the body undertaking the assessment can be held to account by rights-holders and other interested actors.'
[82] As above. 'Some form of monitoring process sis vital in order to scrutinize whether recommendations in the original HRIA are properly implemented.'
[83] MacNaughton n 7 above, 66.
[84] Harrison n 63 above, 180-183.
[85] As above, 180-181. Some of the areas he identifies as in need of better understanding includes 'evidence gathering techniques that are appropriate to different forms of assessment, and the development of techniques that are appropriate to different forms of assessment, and the development and application of context-specific indicators that actually drive assessment processes.'
[86] As above, 181-182. This involves using toolkits and other aides including principles.
[87] As above, 12-183.
[88] MacNaughton n 7 above. 69.

mainly on HRIAs and specifically RHIA but not the HIA. The difference between HRIA and RHIA is on the norms that have been used with the latter emphasizing only on the right to health norms as is the case in this study. HIA has a different methodology which does not put human rights at the core and therefore different from HRIA. This author has no technical competence to articulate HIA in such a study since he is only conversant with human rights methodologies including HRIA.

Accordingly, Harrison and Goller observe that HRIA of international trade agreements will depend largely on how best the interlinkages between trade and human rights norms are treated in the methodology.[89] In this regard, they go ahead to develop an appropriate methodology to cover the gap noting that 'there is minimum guidance in relation to the appropriate methodologies from key institutional actor despite the numerous calls to conduct HRIA on trade agreements.'[90] Most importantly the two authors note that

> an HRIA of a trade agreement requires developing a methodological framework for exploring the impact of international legal obligations and how they are implemented at the national level, rather than the impact of a particular actors or set of actors and the impact of their actions on specified third parties as in the case of the activities of a multinational company or NGO.[91]

The above quote is important because the focus of HRIA is on the impact of international trade rules at the national level.

The two authors note that the main value of HRIA is the fact that human rights are at the core of its methodology.[92]

The authors also warn that HRIAs commissioned by governments can be retrogressive if it is not appropriately conceived and implemented because it may be 'utilised in future to short circuit important decision-making by other actors.'[93] Finally, the authors note that

> HRIAs should also facilitate identification of situations where government are not in fact constrained by international trade rules to act in a way that conflict with human rights norms.

[89] Harrison & Goller n 8 above, 592.
[90] As above, 592-593.
[91] As above, 594.
[92] As above, 605.
[93] As above, 613.

> Governments may be making domestic policy choices and regulatory decisions in ignorance of the real ambit of international trade rules or for entirely different reasons at the behest of domestic lobbying groups.[94]

Arguably, the development of FTAs and pharmaceutical trade policies that go beyond the TRIPs Agreement is often motivated by lobbying from the private sector and other interest groups as opposed to a clear obligation under international trade rules. In Kenya, the Kenya Association of Manufacturers (KAM) was responsible for championing the TRIPs plus Anti-Counterfeit Act legislation in Kenya and the East African region.[95]

Apart from HRIA on international trade agreements, there are special types of HRIA based on individual rights as opposed to the whole gamut of human rights norms and principles such as RHIA. Forman and MacNaughton work on RHIA in the context of international trade agreements is particularly important in this study.[96] The two authors note that in order to respond to the challenge of access to medicines in relation to the TRIPs Agreement in developing countries the HIA and RHIA have been utilised.[97] Even so, the government has not been active in utilising these tools.[98]

The two authors also develop some guidance borrowing from various articles as follows. They note that the methodology can be 'flexible, robust and user-friendly and draw on a multidisciplinary team that is independent from executive negotiating the agreement.'[99] The requirement for independence from the government is particularly controversial because as argued in this study HRIA should actually be conducted by states and not external stakeholders. States should therefore view the tool as being useful as opposed to something that can be manipulated and as such market theories of HRIA discussed above may play a role. Also, there is a proposal to use six steps as follows:[100]

> (a) screening or preliminary analysis of the extent of the HRIA necessary; (b) scoping including team selection, development of the methodology, selection of an explicit human

[94] As above, 615.
[95] See http://kam.co.ke/policy-advocacy/counterfeit-goods-illicit-trade/ (accessed 27 June 2018).
[96] L Forman & G MacNaughton n 11 above, 109-138.
[97] As above, 122.
[98] As above.
[99] As above, 129.
[100] As above, 129-130.

> rights framework based upon applicable human rights obligations and identification of data sources and indicators; (c) data collection; (d) analysis, requiring the evidence gathered to be compared against the human rights obligations; (e) reporting the conclusion and recommendations of the analysis at the basis for weighing the options, decision making and holding decision makers accountable; and (f) monitoring and evaluating outcomes as they are implemented.

It should however be noted that Harrison (discussed above) had eight steps in his methodology that should constitute an ideal-type HRIA as opposed to the six proposed by Forman and MacNaughton. However, the methodology proposed by Harrison is not sufficiently different from what Forman and MacNaughton have set out since what appears to be data collection and reporting the conclusions and recommendations for Forman and MacNaughton have been split in the case of the methodology for Harrison. With regards to the former, Harrison has instead evidence gathering and consultation as two separate steps. Similarly, with regards to the latter, Harrison has conclusion and recommendations and publication as two separate steps. Ultimately, therefore, the two methodologies are the substantially the same. Further, HRIA should combine quantitative and qualitative analysis using economic modelling, causal chain analysis, expert opinions and civil society involvement.[101] In this study, it is submitted that economic modelling and causal chain analysis is a best practice and therefore its absence is not fatal to any methodology that may be adopted. However, explicit human rights framework should be integrated into HRIA without fail.[102] Also, broad participation is important since it is required by human rights principles and the imperatives of guaranteeing accountability.[103] Further, HRIAs should not be used in isolation but together with 'existing human rights strategies like mobilization, campaigning, advocacy and research and policy analysis, for achieving human rights friendly trade and investment regimes.'[104] It is submitted that HRIA is not a replacement to other strategies but it is just one of the many strategies available in the human rights and trade context. Lastly, HRIA should be institutionalised within domestic laws and within the

[101] As above, 130.
[102] As above.
[103] As above.
[104] As above.

international system to enhance its effectiveness in promoting and protecting human rights in trade.[105]

1.5.3 Case studies

In terms of case studies, only Thailand has conducted a HRIA on behalf of the government in relation to assessing the human rights impact of international intellectual property rules.[106] The Thailand experience is important because it has been a focus of various other studies and has been referred to in order to promote the use of HRIA in other states.[107] These studies together with the one conducted by Walker have particularly been very influential.[108] Other related studies in impact assessment in sub-Saharan Africa include the Social and Environmental Impact Assessment on Competitive Commercial Agriculture in Africa focusing on cassava, cotton, maize, soybeans, rice, sugar, and cattle in Nigeria, Mozambique, and Zambia.[109] Lastly, some private companies have already integrated the idea of HRIA in their business model and has conducted two HRIAs in Nigeria[110] and Senegal[111] respectively. However, it appears that no RHIA has been conducted yet in relation to international trade rules and access to medicines in sub-Saharan Africa as a whole. More importantly for this study, no study on HRIA in general and specifically in terms of right to health and international intellectual property rules has been conducted in Kenya either on behalf of the government or by an independent institution or civil society yet. This is the gap covered in

[105] As above, 131.
[106] As above, 122.
[107] G MacNaughton & L Forman 'Human rights and health impact assessments of trade-related intellectual property rights: A comparative study of experiences in Thailand and Peru' (2015) 14 *Journal of Human Rights* 1.
[108] SM Walker *The future of human rights impact assessment of trade agreements* (1996).
[109] Competitive Commercial Agriculture in Sub-Saharan Africa, 'Mozambique, Nigeria and Zambia case studies social and environmental impact assessment draft report, Universita degli Studi Roma Tre, Department of Economics, August 2007, http://siteresources.worldbank.org/INTAFRICA/Resources/257994-1215457178567/CCAA_Soc_Env_Impacts_Main.pdf (accessed 16 February 2018).
[110] 'Human Rights Assessment in Nigeria' Arla, Report November 2015, https://www.arla.com/globalassets/arla-global/company---overview/responsibility/human-rights/arla-human-rights-assessment-in-nigeria-november-2015_1.pdf (accessed 16 February 2017).
[111] 'Human Rights Assessment in Senegal' Arla, Report November 2015, https://www.arla.com/globalassets/arla-global/company---overview/responsibility/human-rights/arla-human-rights-assessment-in-senegal-november-2015_1.pdf (accessed 16 February 2018).

this study in relation to the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya.

1.6 Methodology

This section discusses data and data collection as well as the legal analysis employed in this study.

1.6.1 Data and data collection

This thesis is an interdisciplinary mixed method research study.

Data from the following disciplines have been integrated in this study: human rights; international trade law; intellectual property rights; and impact assessment methodology.

Both primary and secondary data have been used in this study. The primary data is sourced mainly from legislation, resolutions, court decisions, and treaties. In addition, primary data has also been sourced from semi-structured interviews with trade policy makers, experts, and civil society organizations working in the area of access to medicines in relation to the issue of the preparedness of trade policy makers in terms of their knowledge and attitudes in relation to HRIA discussed under chapter seven. The secondary data used in this study comes from various sources including journal articles, reports, books, and electronic sources.

In terms of data collection, the human rights websites consulted for information on general comments, concluding observations, resolutions, and case laws on access to medicines include: The Universal Human Rights Index, ESCR-Net, the OHCHR, World Health Organisation (WHO), and the ACHPR. Many books and journal articles were obtained from the physical and online libraries of both the University of Pretoria and United States International University-Africa (USIU-Africa) in South Africa and Kenya respectively.

Furthermore, the study employed semi-structured expert interview targeting various actors working in the trade policy development process in Kenya including government trade officials. The questions used in the interviews were subjected to ethical clearance from the University of Pretoria before being administered to the interviewees through a series of face-

to-face interviews. The responses received from each interviewee were then transcribed and filed. The file is available with the author. There was no compelling need to obtain authorisation from the relevant review board in Kenya because the interviewees who participated in this study were willing expert participants and were not vulnerable or at risk.

1.6.2 Legal analysis

A legal opinion is valued for the expertise and learning that the scholar brings to analysing and answering a problem. However, this is not to suggest there is a lack of rigour in legal analysis or the peer review conducted by legal journals, quite the contrary. A legal scholar is expected to fully analyse all sides of an issue and provide an unbiased well-argued justification as to why their findings are compatible with the current state of the law highlighting both the strengths and weaknesses of this position. The issue of objectivity is relevant in so far as bias can undermine the rigour of the analysis leading to inaccurate or weak conclusions that would fail when challenged in a court of law.

Although legal scholars rarely provide a detailed methodology in their articles, their analysis and interpretation will cite legal principles to establish the legal basis for their conclusion.[112] In international human rights law, the focus of the legal element of this thesis, the analysis is guided by legally grounded interpretative rules related to international law. The sources of international law are generally accepted to include international treaties (binding legal agreements between states), general principles of law and customary law (rules that evolve over time, becoming commonly accepted through continuous practice).[113] My focus is on an international human rights treaty, the ICESCR,[114] and addresses the obligations of states parties to the ICESCR.

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[112] F Coomans, F Gunfeld, and M Kamminga (eds) *Methods of human rights research* (2009).
[113] Statute of the International Court of Justice. 59 Stat. 1055, 33 U. N.T.S. 993; 1945.
Article 38(1) of the Statute of the International Court of Justice states that the primary sources of international law are international treaties and conventions, customary practices of states accepted as law and general principles of law common to most legal systems.
[114]In August 2014 the ICESCR had 162 States Parties.
https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en (accessed 30 October 2018).

As pure legal analysis is not best suited for answering my research questions I employed two complementary social science methodologies, literature review and qualitative case studies, to collect data on the different areas on which my overall thesis rests.[115] Where appropriate I applied both research methodologies, employing human rights based lens for framing my inquiries, a social science based approach to data collection (literature review and key informant interviews) and returning to a human rights based lens for analysing my data using a social constructivist paradigm as is increasingly common in human rights research.[116] I selected a constructivist paradigm because it is congruent with an approach that emphasises the subjective interrelationship between the researcher and the subject (or study participant) and the co-construction of meaning.[117]

1.6.3 Case study of Kenya

In relation to the case study approach, the idea is that the discussions presented in the study should be understood in context as opposed to abstraction. In this regard, the main focus is on the trade policy maker in Kenya and how he or she may be persuaded to take interest in implementing the HRIA as a routine process in trade in order to resolve the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya. Secondly, unlike least developed countries (LDCs), Kenya is required to protect and enforce pharmaceutical patents. Consequently, it is important to ensure that the trade policy makers are adequately equipped to formulate appropriate policies in trade without losing focus on other obligations of the government including in relation to access to medicines.

1.7 Limitations of the study

The key limitation in this study is that due to a lack of resources, financial and time, it was not possible to conduct an actual HRIA in Kenya to be part of the thesis chapters. The inclusion of an actual HRIA study conducted in Kenya would have undoubtedly been of

[115] A Bryman *Social Research Methods* (2008) 3rd edition, Oxford, Oxford University Press.
[116] F Coomans et al n 112 above. For a recent example see P Claeys 'The Creation of Rights by the Food Sovereignty Movement: The Challenge of Institutionalising Subversion' (2012) 46 *Sociology* 5, 844-860.
[117] Hayes R, Oppenheim R. 'Constructivism: Reality is what you make it' in Sexton T, Griffin B. (eds) *Constructivist thinking in counselling practice, research and training* (1997) 19-41 New York: Teachers College Press.

significant value in terms of enriching the findings and conclusions reached in this study. However, the failure to conduct an actual HRIA does not affect the validity of the findings and conclusions of this study as the focus of the study was on trade policy makers as opposed to the methodology of the HRIA mechanism. In terms of methodology, the use of a case study is a good approach because it enables the analysis of this study to be conducted in a particular context as opposed to in abstraction.

1.8 Assumptions of the study

The main assumption made in this study is that economic and political pressure often applied by developed countries to force developing countries to implement international trade rules will not stand on the way of the actual implementation of HRIA. In this regard, trade policy makers may take primary responsibility in implementing HRIA without negative repercussions even though Forman and MacNaughton appear to be suggesting that HRIA should be independent from the executive.[118]

It is also assumed in this study that the executive through its trade policy makers in various ministries and departments are best positioned to implement HRIA as a routine process since these people are directly in charge of developing and negotiating trade rules on behalf of the Kenyan government. Independent actors including UN and NGOs may therefore provide technical or financial support but should not take primary responsibility for the implementation of HRIAs at the national level.

1.9 Definitions of key terms

The following key words have been used extensively in this study and therefore require special definition: pharmaceutical trade policies; access to medicines; adverse trade impact; trade policy makers; HRIA; and market failure and perfect market.

[118] Forman & MacNaughton n 11 above, 129.

1.9.1 Pharmaceutical trade policies

Pharmaceutical trade policies as used in this study mean the national and international rules used to regulate the buying and selling of medicines in the Kenyan market. These policies include trade-related intellectual property rules, procurement rules, and medicine regulation rules. In this study however, the focus is on trade-related intellectual property rules. The reason for not including procurement rules and medicines regulation rules is because these two areas are substantial and may require additional time and resources to comprehensively tackle them in a satisfactory manner. It is therefore proposed that they form areas for future research.

1.9.2 Access to medicines

Access to medicines has been used in this study to encompass the four elements of the right to health, namely: availability; accessibility; acceptability; and quality. In brief, availability connotes a '[f]unctioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity….' Secondly, accessibility connotes '[h]ealth facilities, goods and services must be accessible to everyone without discrimination…' Thirdly, acceptability means '[a]ll health facilities, goods and services must be respectful of medical ethics and culturally appropriate.' Lastly, quality refers to 'health facilities, goods and services must also be scientifically and medically appropriate and of good quality.'[119] The study however focuses on the element of accessibility in order to demonstrate the utility of right to health impact assessment. In particular it focuses on the effects of pharmaceutical patents on prices and therefore affordability of medicines in developing countries, which affects access. It is important to note however that the four elements of the right to health are intertwined and it is impossible to separate them in practice. In this regard, this study discusses access to quality medicines that is available and acceptable in Kenya.

[119] General Comment 14: The right to the highest attainable standard of health (Art. 12), Adopted at the Twenty-second session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4), para 12.

1.9.3 Adverse impact

This term has been used in this study to connote any negative outcome emanating from pharmaceutical trade policies in terms of violating human rights obligations of the government and specifically under the right to health norms. In this regard, any pharmaceutical trade policy that does not comply with the obligations of the government as can be identified under human rights law and specifically the right to health has an adverse impact on the realization of access to medicines in the country.

1.9.4 Trade policy makers

This term has been used in this study to refer to the trade officials, experts and negotiators at the Ministry of Trade in Kenya including other officials in other government departments and agencies whose terms of reference is to participate in the trade policy development process including their advisors. The meaning of this term is therefore not exclusive but rather inclusive and it applies to all actors who influence the process of trade policy development and may therefore include civil society and international organizations working on behalf of the government. However, the term does not include non-state actors working independently including local and international civil society, UN, and independent scholars. The term also does not include members of the other arms of government including the judiciary and the legislature.

1.9.5 Human rights impact assessment

HRIA can be defined as a means of either 'ensuring the human rights implications of a policy are considered when that policy is being developed (*ex ante*); or of assessing the impact of policy or practice on the rights of those affected once the policy is implemented (*ex post*).'[120] The main aim of HRIA is therefore to build attention to human rights in relation to trade.[121]

[120] J Harrison & M Stephenson 'Scottish Human Rights Commission 'Human rights impact assessment: review of practice and guidance for future assessments' (1 June 2010) 14, http://eqhria.scottishhumanrights.com/eqhriapolicyprocess.html (accessed 27 February 2018).
[121] As above.

The main rationale for using HRIA is because it has the potential to change policies and practices so that they align with human dignity and thus improve lives.[122]

1.9.6 Market failure

Market failure means a situation in which a state is unable to realise the benefits of a trade measures and risks dealing with its adverse impacts instead, including the impact on human rights.

1.10 Significance of the study

This study is significant because it analyses *how* the mechanism of HRIA may be implemented in order to resolve the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya thereby providing a deeper understanding of the subject to all stakeholders. This is important because trade-policy-makers are often faced with immense challenges of how to ensure that by implementing their international trade obligations including under the TRIPs Agreements they do not at the same time undermine other obligations of the government including under human rights and access to medicines.

This study is particularly significant in relation to theory, practice and management as discussed below.

In terms of theory, this study will explore market theories that can be used to justify the implementation of HRIAs in developing countries especially in countries with strong free market ideology like Kenya.

In terms of practice, this study may lead to new practices being adopted in Kenya's trade sector in relation to how trade policies are developed and negotiated. In this regard, adopting appropriate methodologies in appropriate contexts such as HRIA may help safeguard some of the interests and commitments of the government and prevent future crises in terms of access to medicines.

[122] As above, 16.

In terms of the management, the study is significant because it will affect the behaviour and attitude of trade policy makers to be mindful about the utility of human rights norms and tools in relation to trade and therefore be able to implement HRIA as a routine practice.

1.11 Overview of chapters

This thesis has eight chapters in total. The contents of each chapter have been discussed separately below.

The present chapter is chapter one, which is the introduction to the thesis. It contains among other things the problem statement, background research questions, literature review and methodology used in this study. The main research question employed in this study is to find out the manner in which HRIA works and how it can identify and mitigate some of the adverse impacts that may be present in pharmaceutical trade policies in relation to access to medicines in Kenya.

The second chapter addresses the theories that underpin HRIA implementation. In particular, it analyses both the human rights and market theories for HRIA in relation to trade. The main argument in the chapter is that market theories may also be used to promote HRIA mechanism.

Chapter three analyses the TRIPs Agreement and its problems in developing countries in relation to access to medicines. The main argument in this chapter is that developing countries have no identifiable interest under the TRIPs Agreement and should therefore not be enthusiastic about its robust implementation.

Chapter four discusses the right to health norms that are applicable in relation to the adverse impacts of the TRIPs Agreement on access to medicines. The right to health norms allows for the implementation of the TRIPs Agreement without necessarily compromising on the obligations of the government to safeguard access to medicines.

Chapter five discusses the practice and methodology of HRIA. It emerges in this chapter that apart from HRIA no other methodology can identify *beforehand* the adverse impact of pharmaceutical trade policies on access to medicines.

Chapter six analyses the Kenyan country context in relation to HRIA and access to medicines. In particular, the section discusses how some pharmaceutical trade policies including Anti-Counterfeit Act, 2008 and EU EAC EPA may adversely impact on access to medicines in Kenya.

Chapter seven discusses the preparedness of trade policy makers in relation to their knowledge and attitude on human rights and trade. It emerges in this chapter that trade policy makers in Kenya are generally deficient in terms of their knowledge in human rights and that their attitude towards human rights is also negative.

Lastly, chapter eight contains the conclusion and recommendations of the study.

CHAPTER TWO: THEORETICAL FRAMEWORK FOR HUMAN RIGHTS IMPACT ASSESSMENT

2.1 Introduction

The previous chapter introduced the thesis by, among other things, providing the problem statement, background, research questions, and literature review. It emerged that the focus of the present study is the implementation of human rights impact assessment (HRIA) in Kenya and specifically *how* it can help resolve the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya. In this chapter, various theories have been discussed in order to demonstrate how HRIA may be relevant in trade especially in countries with a strong free market ideology.

In general, there are at least two approaches that may be used to theorize HRIA in relation to trade, namely: human rights-based theories; and market-based theories. On the human rights side, several theories have been identified and discussed in this study including: Human rights as a substantive policy guidance in trade; human rights as a source of political, moral and legal pressure; human rights and fragmentation, coherence and constitutionalisation of international law; and human rights and social learning theory. On the market theories side, not much direct work has been done in relation to HRIA but there are at least two theories that may be applicable including: semiotic methods; and the rational theory of morality. In this chapter, a case is made for the need to ground the use of HRIA in market theories as opposed to human rights theories in order to motivate trade policy makers to implement HRIA as a routine process. The argument that there is need to motivate trade policy makers is informed by the fact that the HRIA is so far only popular with non-state as opposed to state actors. In Kenya, for instance, it may be argued that the free market ideology is stronger than human rights ideology and consequently linking HRIA to free market ideology may be more attractive to the government or trade policy makers than using human rights ideology.

Both the human rights theories and market-based theories have been discussed separately below.

2.2 Human rights as a source of substantive policy guidance in trade

The first theory in relation to HRIA is the theory of human rights as substantive policy guidance in trade. The claim in this theory is that human rights norms are in fact sources of substantive policy guidance in trade.[1] For this claim to be plausible, at least one of the following two criteria must be met: (a) international law should have a formal hierarchy of sources recognizing the supremacy of human rights over trade; or human rights norms relevant in the context of access to medicines should have attained the *jus cogens* status. It will be demonstrated below that neither of the two conditions pertain and, as such, human rights cannot be a source of policy guidance in trade strictly speaking.

2.2.1 Formal hierarchy of sources under international law

Under international law there does not seem to be a formal hierarchy of sources in terms of treaty obligations.[2] Unlike section 3 of the Kenyan Judicature Act, Article 38(1)(a) to (c) of the Statute of the International Court of Justice is not about the hierarchy of sources under international law.[3] According to Pauwelyn, the Statute of International Court of Justice therefore does not set out a *priori* hierarchy.[4] Due to lack of a formal hierarchy of sources, it is not directly possible to resolve any conflict that may arise in relation to treaty obligations at the international level.[5]

As alluded to above, the situation may be different at the municipal level in that unlike the international level at the domestic level the hierarchy of law may exist, the structure of which varies depending on the legal system of a country.[6] Consequently, in many countries, the

[1] ATF Lang 'The role of the human rights movement in trade policy-making: Human rights as a trigger for policy learning' (2007) 5 *New Zealand Journal of Public International Law* 57, 90.
[2] J Pauwelyn *Conflict of norms in public international law: How WTO Law relates to other rules of international law* (2003) 94. The Article identifies treaties, customary law and general principle of law as sources of international law.
[3] As above.
[4] As above, 94.
[5] As above, 95.
[6] As above, 96.

constitutional norms usually rank higher than legislation in the domestic context. In Kenya, this position is reflected under section 3(1) of the Judicature Act.[7]

In this regard, what is the position of international law in Kenya in terms of hierarchy of sources since it appears to be currently unaddressed by the Judicature Act. This inquiry is important because Articles 2(5) and 2(6) of the Constitution provides that the general rules of international law and that any treaty or convention ratified by Kenya shall form part of the laws of Kenya respectively. The problem at hand therefore is that all international law treaties ratified by Kenya currently form part of the Kenyan laws without clarity on the question of hierarchy. The present domestic situation in Kenya therefore also fails to answer the question as to whether there exists a formal hierarchy of sources in relation to international law applicable in Kenya to, for example, establish a clear supremacy of international human rights norms over international trade norms. So far, this question has only been addressed at the theoretical level as discussed below.

Scholars in Kenya tend to address the issue of international law as though it is homogenous. For instance, Orago only focuses on the hierarchy of human rights treaties in Kenya without referring to trade treaties and others.[8] In his view, there are three main options, which are that human rights treaties can be interpreted: one, at the same level as the constitution; two, at a level below the constitution and the legislation; and three, at a level below the constitution and above the legislation.[9] Consequently, Orago argues that the best interpretation for human rights treaties is to adopt the third approach which will then make human rights treaties attain a supra-legal status in Kenya so as to insulate such treaties from democratic processes at the domestic level.[10] In this regard, Orago posits that the supra-legal status will ensure that

> important democratic governance standards as well as human rights and fundamental freedoms contained in international law are sufficiently entrenched in the Kenyan domestic

[7] Judicature Act, Cap 8 Laws of Kenya.
[8] NW Orago 'The 2010 Kenyan Constitution and the hierarchical place of international law in the Kenyan domestic legal system: A comparative perspective' (2013) 13 *African Human Rights Law Journal* 437.
[9] As above.
[10] As above.

> legal system, and are not left to the whims of the ruling majority of the day to change at their own convenience through legislative amendments.[11]

The implication of Orago's proposal without addressing the issue of other treaties is that if human rights treaties are supra-legal in nature then it follows that WTO treaties will have to comply with the human rights norms recognized in Kenya as a matter of domestic law. To this extent therefore a formal hierarchy of sources under international law may be argued to exist in Kenya. It is therefore important to see how the courts in Kenya have treated this issue if at all.

The jurisprudence from the courts according to Kabau and Osogo is still incoherent with respect to the position of international law within the hierarchical norms.[12] It should be noted that Kabau and Osogo are addressing international law as a homogenous category of laws and no distinction is made between human rights and trade norms. Notwithstanding this analytical deficiency in Kabau and Osogo's work, they observe that monist countries have been reluctant to endorse unrestricted supremacy of international legal instruments over domestic laws including its progressive aspects such as human rights.[13] Suffice to note Kenya is a monist country. It therefore emerges that the subject of hierarchy of sources under international law needs to be developed further by the legislature and the judiciary in order to have a much clearer position.[14] In this regard, pending the contribution by the judiciary and parliament as proposed above it is argued that the status of hierarchy of norms in Kenya in relation to international human rights law and trade treaties is still unclear. Trade policy makers therefore cannot authoritatively act as if human rights norms especially emanating from the international level are superior to trade norms. This brings us to the second option, which is human rights should be at the level of *jus cogens* in order to provide substantial policy guidance in trade.

[11] As above.
[12] T Kabau & O Ambani 'The 2010 Constitution and the application of international law in Kenya: A case of migration to monism or regression to dualism' (2013) 1 *Africa Nazarene University Law Journal* 50.
[13] As above, 51.
[14] As above, 55.

2.2.2 The *jus cogens* argument

Under international law, in accordance with Article 53 of the Vienna Convention on the Law of Treaties (VCLT), human rights can only override WTO rules including TRIPs Agreement if human rights is considered peremptory and the WTO rules are not.[15] Article 53 of the VCLT thus provides that

> [a] treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law. For the purposes of the present Convention, a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.

From the above, it appears from the text that an ordinary treaty cannot violate peremptory norms of general international law.

The question that arises is whether states can overrule Article 53 through exercising their sovereign authority. The argument here is that since states have powers to make an illegality legal, the invalidation of a treaty under Article 53 cannot be overruled simply because of the will of the states since this illegality falls under a special category called *objective* illegality.[16] Consequently, it requires an objective as opposed to subjective criteria in order to assess whether a treaty is in conflict with *jus cogens* for it to be invalidated.[17] In this regard, the objective sense applies even if all states are against it or do not agree with it and the treaty will stand nullified. As such,

> [i]f the views of the parties as to whether a conflict occurs-e.g. whether a norm in question is peremptory and whether a treaty clashes with it-is decisive, the purpose of Article 53 would be frustrated. If only the parties were to determine whether a treaty is illegal, this would be an implicit recognition of their faculty of actual derogation from peremptory norms.[18]

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[15] J Sellin *Access to medicines: Interface between patents and human rights. Does one size fits all?* (2014) 245. Article 53 of the Vienna Convention on the Law of Treaties reads as follows: 'A treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of a general international law. For purposes of the present Convention, a peremptory norm of general international law is a norm accepted and recognized by the international community of states as a whole as a norms from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.'
[16] A Orakhelashvili *Peremptory norms of international law* (2006) 134.
[17] As above.
[18] As above.

Consequently, human rights norms that have achieved peremptory status can be a source of substantive policy guidance. In relation to access to medicines it is critical to find out the status of rights to life and health before one can make such a conclusion.

Since peremptory norms go against the general principle of international law which is based on consent, peremptory norms therefore have to be agreed upon by the whole of the international community.[19] To this extent peremptory norms may be subjected to contestation of *realpolitik* and political and cultural bias since the international community has to decide which norms should have a peremptory character.[20]

The idea that a general multilateral treaty can be a source of peremptory norms is supported by the reference to the rules of general international law under Article 53 of the VCLT.[21] This suggestion is however in contravention of Articles 34-36 of the VCLT because it would mean that a treaty can bind non-parties in at least those provisions that have attained *jus cogens* status.[22] An alternative interpretation is that if one rejects the idea of binding non-parties then one would be endorsing the idea that some peremptory norms only bind parties to multilateral treaties, which is by itself a contradiction to the idea of *jus cogens.*[23]

It is possible therefore to interpret the right to health as a peremptory norm of international law because it is inextricably linked to the rights to dignity, life, and bodily integrity.[24] However, it is doubtful whether the right to life in a comprehensive manner including its positive elements will still qualify as a peremptory norm.[25] What is more because of *realpolitik* or the controversial nature of socio-economic rights it is unlikely that the current restrictive list of peremptory norms include the right to health and access to medicines in particular.[26] However, from international law including in the context of the Genocide Convention and the 1951 Advisory Opinion, it emerges that the peremptory status of a norm

[19] Sellin n 15 above, 246.
[20] As above.
[21] Orakhelashvili n 16 above, 111.
[22] As above.
[23] As above, 112.
[24] Sellin n 15 above, 247.
[25] As above, 247.
[26] As above, 248.

is not conferred to it by a treaty provision, which means that it is an independent process.[27] In this regard, 'even if a multilateral humanitarian treaty embodies *jus cogens,* it cannot be a direct source of *jus cogens,* but merely its reaffirmation and codification.'[28]

Consequently, Sellin notes that because of the requirement of consensus among the international community, it is unlikely that in the near future the right to health will be considered as a peremptory norm of international law despite the recent developments in the area of socio-economic rights.[29] Fortunately, there is another avenue that could be exploited which are Article 103 of the UN Charter but even this cannot elevate the right to health above WTO rules.[30] It seems therefore the primacy of right to health over WTO rules is not yet supported under international law. In the absence of a solid legal basis, human rights and specifically the right to health at the current moment is not sufficiently supported under international law to provide substantive policy guidance in trade. Illustratively, the almost 30,000 pages of the WTO Agreement and its annexes and schedules of concessions do not mention '[h]uman rights and the need for constitutional safeguards to protect human rights against abuses of government powers'.[31] It is also telling that despite the robust relationship between WTO and the specialized agencies and other bodies of the UN system as well as regional economic arrangements, human rights is not contemplated in this relationship.[32]

2.2.3 Some updates on efforts towards primacy of human rights

The UN High Commissioner for Human Rights (High Commissioner) is on record as urging WTO members to take their obligations under human rights seriously when 'negotiating and

[27] Orakhelashvili n 16 above, 112-113.
[28] As above, 113.
[29] Sellin n 15 above, 249.
[30] As above, 249-252. Article 103 of the UN Charter states that in the event of a conflict between the obligations of the members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail.
[31] EU Petersmann 'Constitutionalism and WTO law: From a state-centered approach towards a human rights approach in international economic law' in DLM Kennedy & JD Southwick (eds) *The political economy of international trade law: Essays in honour of Robert E. Hudec* (2002) 32.
[32] D McRae 'The place of the WTO in the international system' in D Bethlehem, D McRae, R Neufeld, & I van Damme *The Oxford handbook of international trade law* (2009) 61-66.

designing international trade law'.[33] What human rights arguably does is to provide broad guidelines through which trade rules can and should be developed or implemented. To begin with, the UN Guiding Principle on Business and Human Rights, 2011 (UN Guiding Principles)[34] addresses the issue of human rights in trade and investment treaties. With regards to policy coherence, the document states that

> states should ensure that governmental departments, agencies and other State-based institutions that shape business practices are aware of and observe the State's human rights obligations when fulfilling their respective mandates, including by providing them with relevant information, training and support.[35]

The presumption from the above quote is that there are two separate regimes of trade and human rights, which may potentially affect each other. In addition, the UN Guiding Principles provides that 'states should maintain adequate domestic policy space to meet their human rights obligations when pursuing business-related policy objectives with other states or business enterprises, for instance through investment treaties or contracts.'[36] Again, it is clear in this example that the role played by human rights in business is not about providing detailed guidelines about how trade should be conducted but about preserving the state capacity to respond to competing obligations under international law using policy. In this regard, trade should not restrict that space and to the extent it does so then there is a problem.

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[33] Lang n 1 above, 90.

[34] Human Rights Council resolution 17/4 of 16 June 2011, A/HRC/RES/17/4.

[35] As above, para 8. 'There is no inevitable tension between States' human rights obligations and the laws and policies they put in place that shape business practices. However, at times, States have to make difficult balancing decisions to reconcile different societal needs. To achieve the appropriate balance, States need to take a broad approach to managing the business and human rights agenda, aimed at ensuring both vertical and horizontal domestic policy coherence. Vertical policy coherence entails States having the necessary policies, laws and processes to implement their international human rights law obligations. Horizontal policy coherence means supporting and equipping departments and agencies, at both the national and subnational levels, that shape business practices – including those responsible for corporate law and securities regulation, investment, export credit and insurance, trade and labour – to be informed of and act in a manner compatible with the Governments' human rights obligations.

[36] As above, para 9. Economic agreements concluded by States, either with other States or with business enterprises – such as bilateral investment treaties, free trade agreements or contracts for investment projects – create economic opportunities for States. But they can also affect the domestic policy space of Governments. For example, the terms of international investment agreements may constrain States from fully implementing new human rights legislation or put them at risk of binding international arbitration if they do so. Therefore, States should ensure that they retain adequate policy and regulatory ability to protect human rights under the terms of such agreements, while providing the necessary investor protection.

Apart from the Principles and Guidelines on Business and Human Rights discussed above, the issue of trade and human rights has also been discussed at the Human Rights Council level in terms of elaboration of an international legally binding instrument. This effort, if successful, will be the most authoritative statement of the relationship between human rights and trade in terms of the human rights supremacy rhetoric.[37] In 2014 through resolution 26/9, the Human Rights Council (HRC) established an open-ended intergovernmental working group to work on an the elaboration of a legally binding international instrument that will regulate the activities of transnational corporation and other enterprises in accordance with international human rights law. In particular, the working group has discussed in its the first and second sessions of the intergovernmental working group in 2015 and 2016 on how to ensure that the treaty ensures the primacy of human rights in trade and investment policies.[38] Already the discussions around this issue envisages in addition to a multilateral treaty an international implementation mechanism and possibly an international tribunal to assist states regain the policy space for the protection of human rights.[39] Consequently, the fact that that a treaty on trade and human rights is currently under development is the most authoritative indicator that human rights norms do not in fact supersede WTO rules.

The political import of the above efforts cannot be ignored and in fact they may lead to a consolidation of international law either through a treaty or state practice in the future. Because of this potential development in terms of the consolidation of international law there are still problems that are inherent in the human rights framework in the context of trade. First, what is required is for human rights norms to be sufficiently elaborated so that it can define the acceptable boundaries for trade policy choices through providing a viable

[37] Currently, there is established an open intergovernmental working group at the UN level to discuss this matter.
[38] M Krajewski 'Ensuring the primacy of human rights in trade and investment policies: Model clauses for a UN treaty on transnational corporations, other business and human rights' CIDSE (2017) 4, http://www.cidse.org/publications/business-and-human-rights/business-and-human-rights-frameworks/ensuring-the-primacy-of-human-rights-in-trade-and-investment-policies.html (accessed 18 November 2017).
[39] Report of the second session of the open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights, Maria Fernanda Espinosa, [A/HRC/34/47], 4 January 2017, para 20, https://documents-dds-ny.un.org/doc/UNDOC/GEN/G17/000/94/PDF/G1700094.pdf?OpenElement (accessed 15 February 2018).

framework which policymakers may rely upon to arbitrate between competing trade policy agendas and priorities.[40] In other words, the human rights norms and standards should be clear enough to guide policy-makers to be able to reject the implementation of certain trade policies if they are in violation of existing human rights obligations.[41] Suffice to note there are some progress on this front as can be discerned from the following facts. The first one is that there has been an elaboration of the normative and legal content of the relevant human right in the recent past especially in relation to trade.[42] This work has mainly been undertaken by UN and others in terms of the adoption of several resolutions, expert reports and general comments. In the area of right to health for instance, the HRC has been able to adopt resolution 23/14, which has elaborated the norms applicable in the area of access to medicines. It is hoped that these norms will in the future be codified into substantive legal rules under international law either in form of treaty or otherwise. Secondly, there have been more and more analyses being conducted focusing on the different trade policies and their practical effects on human rights.[43]

These kinds of analyses are important in terms of establishing a clear relationship between trade and human rights. Secondly, it is also important in shedding light on the adverse impacts of trade rules including in the context of human rights. Thirdly, a comparison in terms of the effects and the desired outcomes in relation to human rights has also been undertaken.[44] This comparison is important in order to ensure that the trade agenda is not achieving conflicting objectives. Lastly, a set of proposals have been generated for changes to either trade policies or WTO rules to make them conform more closely to what human rights obligations require.[45] These proposals are clear indication of the need to order the WTO system in line with the dictates of human rights. It is only a matter of time before this can become the rule rather than exception. The Doha Declaration on the TRIPs Agreement

[40] Lang n 1 above, 90.
[41] As above.
[42] As above, 91.
[43] As above. A good example is C Dommen 'Raising human rights concerns in the World Trade Organization: Actors, processes and possible strategies' (2002) 24 *Human Rights Quarterly.*
[44] Lang n 1 above, 91.
[45] As above. A good example discussing this is the article by A Sajo 'Socioeconomic rights and the international economic order' (2002) 35 *New York University School of Law Journal of International Law and Politics.*

and Public Health and well as the amendments on the relevant provisions of the TRIPs Agreement on compulsory licensing clearly shows the active role being played by human rights even though it is rarely acknowledged.

While some work has been done as described above there is still more issues that should be tackled. To begin with, it has been argued that human rights arguments are not fundamentally different from other analyses such as health or social analyses.[46] Consequently, there exists no necessity of invoking a human rights language when it is possible to have similar discussions in a different context.[47] Illustratively, it is not necessary to rely on the right to health to identify and remedy the limitations of the TRIPs agreement in relation to access to essential medicines.[48] Because of this weakness therefore it can be argued that human rights do not in fact provide substantive policy guidance even though it is usually assumed to do so.[49] The reason for this, Lang claims, is because human rights analysis is neither a source of new policy ideas nor can it provide a means of choosing between competing ideas.[50]

As a matter of fact many analyses have been undertaken without reliance on human rights and '"ultimate policy prescriptions" for a more "human rights friendly" trading system are usually drawn from, and justified by reference to, policy ideas already in widespread circulation.'[51] Human rights is therefore rarely consulted when important rules are being put in place in the trade sector.[52] Accordingly, it is 'illusory' to think that human rights can derive or arbitrate alternative visions of the global trading order.[53] The above analysis makes one point, which is that human rights do not matter in trade matters and as a matter of fact it is usually ignored when serious studies are conducted to reform the trading system.

[46] Lang n 1 above, 93.
[47] As above.
[48] As above.
[49] As above.
[50] As above.
[51] As above.
[52] As above.
[53] As above.

The main message here is therefore that there is a lot of effort currently ongoing to establish the primacy of human rights over trade and investment treaties. Suffice to note, until the conclusion of the treaty on human rights and trade and investment agreements, there is no formal requirement under international law that international human rights law should trump WTO trade rules since all rules of international law enjoy what is essentially referred to as formal equality.[54] Petersmann however is optimistic that the dynamic evolution and globalization of intellectual property rights since the Second World War is enough to suggest a progressive extension of human rights through public interest legislation and international law.[55]

In the absence of an appropriate international framework to establish the primacy of human rights, it is still possible to exploit the flexibilities within the WTO and WIPO to act in the public interest in what can be described as 'the right of national legislators to balance competing interests and "human rights" as long as there is no guarantee to define the human rights dimensions through substantive international rules'.[56] Since human rights revolution often reflects a struggle against power-oriented discrimination, economic globalization including in the context of WTO offers an opportunity 'for another "human rights revolution" liberating citizens from arbitrary, welfare-reducing government restrictions and extending individual freedom and mutually beneficial citizen cooperation across frontiers.'[57]

2.3 Human rights as a source of political, moral and legal pressure

The second model that is relevant in relation to HRIA is human rights as a source of political, moral and legal pressure.[58] The relative success of human rights movements is directly dependent on the success of universal human rights as a normative framework. Donnelly therefore observes that the universality of human rights and specifically its functional

[54] There is an exception with regards to the EU trade rules and specifically the Cotonou Agreement, 23 June 2000, which integrated human rights as a key in trade matters involving the EU.
[55] EU Petersmann 'Human rights, markets and economic welfare: Constitutional Functions of emerging UN Human Rights Constitution' in F Abott, C Breining-Kaufmann, & T Cottier (eds) *International trade and human rights: Foundations and conceptual issues* (2006) 59.
[56] As above.
[57] As above, 58.
[58] Lang n 1 above, 93.

universality is important to respond to the threat posed to human dignity in the context of market economies and bureaucratic states. In this regard, human rights are the most effective response in safeguarding the threat of human dignity including as a result of the spread of market economies and bureaucratic states across the globe.[59]

2.3.1 The attractiveness of human rights framework over other forms of politics

The remedies available under human rights framework appear to be the main driver of human rights acceptance for 'a growing number of people of all cultures in all regions.' According to the UN, victims of gross violations of international human rights law and serious violations of international humanitarian law have the following remedies as provided under international law: '(a) equal and effective access to justice; (b) adequate, effective and prompt reparation for harm suffered; and access to relevant information concerning violations and reparation mechanisms.'[60] Out of these, reparation is perhaps the most important form of remedy. Full and effective reparation therefore requires 'restitution, compensation, rehabilitation, satisfaction and guarantees of non-repetition'.[61] Reparation is therefore important in the context of this study because '[w]hatever our other problems, we all must deal with market economies and bureaucratic states. Whatever the other religious, moral, legal and political resources, there is need for equal and inalienable universal human rights to protect us from those threats.'[62]

Human rights have also penetrated other areas beyond elite interstate level including in social justice and for political opposition movements.[63] Apart from non-state actors, state actors like China are increasingly finding it fashionable to use the human rights language as an 'inescapable precondition to its full recognition as a great power.'[64] The power of human

[59] J Donnelly 'The relative universality of human rights' (2007) *Human Rights Quarterly* 8-9.
[60] UN 'Basic principles and guidelines on the right to a remedy and reparation for victims of gross violations of international human rights law and serious violations of international humanitarian law, Adopted and Proclaimed by General Assembly resolution 60/17 of December 2005, para VII, https://www.ohchr.org/EN/ProfessionalInterest/Pages/RemedyAndReparation.aspx (accessed 28 June 2018).
[61] As above, part IX, para 18.
[62] As above, 9.
[63] As above, 10.
[64] As above

rights over other forms of political legitimacy however depends on the extent to which states hold it in high regard.[65]

As noted before, virtually every state today recognizes human rights. Therefore, it is clear that human rights is the contemporary form of political expression expressing the deepest ethical, cultural, and political values and aspirations of the people and even governments.[66] Human rights advocates should however understand that what is required apart from treaties is: bold and imaginative activism; domestic, political and economic progress; the support of sympathetic states; and other outside forces and time.[67] In this regard, the promotion of human rights should not stop simply because it is currently popular.

Because of the reasons stated above, arguments framed in human rights language tend to enjoy more privilege than others for instance if one argues that developed countries' agricultural markets should be opened as a matter of human rights this can be of relative significance than if it was just an argument standing on its own.[68] To this extent, the agency of human rights is a useful political tool that can be used strategically to pursue a particular policy agenda.[69] The same political technology based on human rights language can be deployed by various actors in order to achieve a desirable trade policy outcome.[70] This means that people can argue different trade outcomes by relying on human rights framing. For instance, protecting the public health systems of developing countries can be linked to the right to health for more strength and political legitimacy. This approach is more likely to work than relying on any other framework.

[65] As above.
[66] As above, 12.
[67] E Massimino 'The power of human rights law' (2015) 41 *American Bar Association human rights magazine* 2, https://www.americanbar.org/publications/human_rights_magazine_home/2015--vol--41-/vol--41--no--2---human-rights-at-home/the-power-of-human-rights-law.html (accessed 19 July 2017).
[68] Lang n 1 above, 93.
[69] As above, 94.
[70] As above.

2.3.2 Human rights bodies and political mobilization

At the center of this conceptual framework is the role of human rights bodies. Human rights bodies are capable of setting in motion several processes including political mobilization for change by developing norms.[71] Accordingly,

> to the extent that the human rights movement can mobilize actors and interest groups presently marginalized in trade debates, and provide effective tools to augment their political influence, it follows that the human rights movement may be able to achieve real change. Even though it is difficult to measure the precise impact, there is at least some indication already of such effectiveness [for example in the context of the implementation of the paragraph 6 decision of the Doha Declaration].[72]

There are however concerns that the present approach of using human rights bodies to achieve political consensus may not have such a significant impact in the long term and therefore there is no need to be hasty.[73] Some have argued that the available techniques currently utilized for political mobilization rely mainly on the moral legitimacy of human rights language, which is yet to achieve significant authority and legitimacy.[74] This is particularly true in the context of trade. Illustratively, human rights persuasion and normative socialization is still ineffective because trained trade experts rarely refer to human rights norms to arbitrate trade matters.[75]

Moreover, assuming the processes employed by human rights movements were highly effective in producing change, another limitation is that the role set out for the 'human rights movement is very limited and constrained.'[76] Accordingly, the present model is highly problematic because it does not provide a clear understanding in relation to how human rights movements may participate in policy debates in a productive way. [77] Ultimately the 'human rights movement is still figured as a passive recipient of policy knowledge, and is seen as being deployed in the service of policy agenda still defined in the context of

[71] As above.
[72] As above, 95.
[73] As above.
[74] As above, 95-96.
[75] As above, 96.
[76] As above.
[77] As above. Lang explains that this means how human rights movements can generate new ideas about desirable and appropriate trade policy, or alternative visions of the international trading system.

traditional trade policy debates.'[78] In other words, 'to the extent that the international trading system is already structured and informed by prevailing expert knowledge – and in my view this is a very significant extent – the human rights movement has in this model no critical or transformative power at all.'[79] The main argument to discredit the present model of human rights as a source of legal, political and moral pressure is that it is not capable of achieving any meaningful transformation in trade. Those human rights movements rarely bring forth any alternative policy vision that can fundamentally contribute in terms of how trade should be conducted.

This however is not to refuse the importance of human rights movements. On the contrary, the presence of human rights movements in poor countries such as South Africa and Kenya has meant that the corporate greed has been checked somehow but it is agreeable that the fundamental or the underlying structures that are responsible for the marginalization of the poor have not been transformed yet. It is debatable whether human rights could achieve this kind of transformation.

Another plausible argument is that through the consistent challenging of the pharmaceutical companies at the national level, a national consciousness about the dangers of the trading system is slowly being awakened in a manner that will fundamentally create a difference including the complete overhauling or reforming of the current TRIPs system as has been already being advocated through the United Nations Development Programme (UNDP) 2003 report. The UNDP suggested that '[a]n alternative to TRIPs, either within or outside the ambit of the WTO, ought to be debated at the highest level.'[80] In this regard, it has called for thinking around this issue since 'replacing or fundamentally altering TRIPs will not be easy or sudden, given the differences in national positions on this issue.'[81]

Another result of human rights advocacy movement is arguably that the issue of access to medicines in developing countries is now firmly amongst the SDGs agenda specifically under

[78] As above.
[79] As above.
[80] United Nations Development Programme *Making global trade work for people* (2003), 221, http://ctrc.sice.oas.org/trc/Articles/UNDP_FULL.pdf (accessed 19 April 2016).
[81] As above, 222.

SDG 3b, which will be implemented in the period 2015 to 2030. The inclusion of SDG 3.8 and 3b means that access to medicines is now not just a trade issue but a poverty issue or a global development challenge and as time goes by new models will have to be adapted in order to solve the challenge at hand. Already, the access to medicines movements have influenced the report of the UN Sustainable Development Goal (SDG) High Level Panel (HLP) on access to medicines constituted by the UN Secretary General (UNSG) and some concessions were achieved.[82] The next step will be to engage with the HLPF in order to monitor how countries implement the SDG 3b. For Kenya, the main framework for political mobilization including in the trade sector will remain arguably the right to health framework.

From the foregoing, it is important to establish a clear role for human rights in terms of moral, legal and political pressure. This process should however be promoted in the trade sector where its impact is still low compared to other areas such as health or labour in which human rights has played critical roles.

The mechanism of right to health impact assessment (RHIA) however does not lend itself to this theoretical framework especially at the national level for the simple fact that it is to be used by the government itself and it is absurd if the government was to pressure itself. Because of this reason, this theoretical model is not to be part of this study. It is argued here that this model applies best in the context of the right to health impact assessment conducted by social movements or civil society around the world including at the national level working on trade and human rights issues.

2.4 Human rights and fragmentation, coherence and constitutionalisation of international law

The third model is the fragmentation, coherence and constitutionalisation or 'coherence' model. The unique aspect of this model is how it characterizes the problem between trade and human rights from the notion of 'policy "trade-offs"'.[83] The argument is that several

[82] FM Abbott 'Reflections on the report of the UN Secretary General's High Level Panel on Access to Medicines' (August 2017) 22(8) *Cienc. Saude coletiva,* http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1413-81232017002802440 (accessed 23 July 2018).
[83] Lang n 1 above 96.

social goods like prosperity in economy, distributive justice, and/or the protection of environment can arise at the same time thus imposing competing demands on policy-makers which must be balanced.[84] At the international level, this poses unique challenges because the processes that are supposed to coordinate actors and institutions doing different things in the trade sector are still at nascent stages.[85] Therefore, directly at issue in this model is that very few coordinating and coherence mechanisms exist at the international level to resolve conflicting demands emanating from various spheres of political life including trade, human rights, environment, labor, finance, development, health, security and others.[86]

With regard to trade and human rights, there is yet to be established an appropriate structure that can help resolve the conflict between the creating and sustaining a liberal trading order under WTO and the equally important obligation to promote and protect human rights in accordance with international law.[87] A coherent policy-making environment as opposed to the current fragmentation of the international legal and political order is thus required.[88] Human rights is thus treated as an object of study in this model in order to be resolved with its trade counterpart.[89] Various solutions to resolving conflicts have developed in this regard including the principle of deference, which requires that trade regimes should defer to specialized institutions where appropriate depending on the subject matter at hand to be resolved.[90] In addition, there are efforts for the constitutionalisation of the trade regime complete with overarching normative and institutional framework for managing its interfaces with various other regimes including human rights.[91]

2.4.1 Human rights revolution and normative superiority argument

In the context of the WTO, '[t]he state-centred focus and numerous "protectionist biases" of WTO rules illustrate that trade policies and the WTO rule-making processes are not

[84] As above.
[85] As above, 96-97.
[86] As above, 97.
[87] As above.
[88] As above.
[89] As above.
[90] As above, 98.
[91] As above, 98-99.

sufficiently "constitutionalised" in order to protect individual freedom and other human rights more effectively.'[92] It is because of this reason that Petersmann has called for a human rights-centred approach of the trading system to cure this deficiency.[93]

The first issue that must be addressed is the issue of the normative superiority of human rights over trade rules. Are human rights normative standards superior to trade rules at the international level? The normative superiority of human rights norms is therefore critical if human rights norms should form the basis of constitutionalisation of international law. Already, from a historical perspective, there are pointers towards what can be termed as a 'human rights revolution' even though some would argue that its time has passed. It is believed that a 'human rights revolution' is currently taking place because unlike in 1947 when the General Agreement on Tariffs and Trade (GATT) was being negotiated, today, almost all the members of the UN recognize human rights as part of general international law and, in part, of international *jus cogens*.[94] In this regard, the proponents of this view argue that the near universal acceptance of human rights globally means that subsequent treaties should at least be interpreted in a manner that takes into account the substance of international human rights law. This model in effect will elevate the role of human rights as being constitutional in relation to other treaties. However, the key challenge for proponents of human rights constitutionalism is the legal basis.

Accordingly, proponents of "human rights revolution" point at the customary rules of international treaty interpretation as reflected under Article 31 of the 1969 Vienna Convention on the Law of Treaties. They argue that this provision requires the interpretation of subsequent treaties including the 1994 Agreement establishing the WTO with due regards to 'any relevant rules of international law applicable in the relations between the parties' which includes international human rights law.[95] The idea here is that since many parties already recognize international human rights law, Article 31(3)(c) of the Vienna Convention

[92] Petersmann n 55 above, 64.
[93] As above.
[94] Petersmann n 31 above, 32.
[95] As above.

requires that the obligations created under human rights law should not be undermined by other obligations arising from subsequent treaties including those emanating at the WTO.

However, the challenge of achieving a harmonious interpretation is undermined because of one reason, which is that '[t]he universal recognition of human rights is not yet accompanied by universal agreement on the optimal *policy instruments* for promoting human rights.'[96] To remedy this problem, Petersmann suggests that

> [t]he necessary *human rights approach to international law* must go beyond power politics, interest-group politics, and legal positivism so as to protect human rights through progressive 'constitutionalisation' of national and international legal systems on the basis of mutually coherent principles of constitutional democracy. Overcoming the contradiction between power-oriented international law and rule-oriented national law requires 'interdisciplinary' approaches beyond the ivory towers of traditional international law doctrine.[97]

The idea advocated by Petersmann is that powerful states should stop exerting their influence over the international trade system and accept a fair system of trade, which should be based on international law and international human rights law in particular.

2.4.2 Some other critical perspectives in support of harmonious or coherent interpretation of international law

The main proposal for constitutionalisation is harmonious or coherent interpretation. Mutua and Howse have engaged with the issue of constitutionalisation of international law in general and their analysis may provide useful insights for the coherence approach. The main question according to Mutua and Howse is whether international law can develop a body of rules that advances 'free' trade and promote and protect human rights at the same time?[98] They proceed to identify how this can be achieved. Their first argument is that GATT Article XX incorporated supervening non-trade public values which can be elevated above trade rules in the event of a conflict.[99] More progress can thus be made through the re-

[96] As above, 46.
[97] As above, 34.
[98] R Howse & M Mutua 'Protecting human rights in a global economy: Challenges for the World Trade Organization' https://www.iatp.org/files/Protecting_Human_Rights_in_a_Global_Economy_Ch.htm (accessed 19 July 2017).
[99] As above.

interpretation of Article XX in light of the norms of international human rights law in WTO dispute settlements.[100] Another means to achieve harmony under international law based on human rights can be found in the preamble of the WTO Agreement or the Marrakesh Agreement through its use of the terms raising the "standards of living" and the need for "sustainable development" which could be interpreted in favor of other values beyond free trade.[101]

The role of human rights in interpretation of international law is also critical. Some authors have argued that Article 103 of the UN Charter may be read broadly to impose an obligation that universal human rights obligation should always prevail over other obligations arising under other international treaty laws in case of conflicts.[102] It should however be noted that the above sentiments is merely a non-binding opinion as they are yet to be reflected in any official jurisprudence at the international level or any treaty document ratified by states. In conclusion, internationalization of law can occur with the emergence of global legal values. It does not depend on any treaty but is the result of an expansion of values, in a normative intercrossing logic. Through different processes for the constitutionalisation of new values, states incorporate into their constitutions similar provisions that are motivated by a single concern.[103] The approach suggested by Mutua and Howse seems to suggest that it is possible to evolve a unitary international system without having to negotiate a treaty. The problem is that as observed above, many international institutions still operate in silos presenting a major challenge in this regard.

In line with the above views, Hestermeyer observes that there is a strong presumption against conflict under international law, which means that it is possible to interpret WTO norms in a manner that avoids conflict or tension with other international rules including human rights law in line with the provisions of Article 31(3)(c) of the VCLT.[104] Already, this

[100] As above.
[101] As above.
[102] As above.
[103] MD Varella 'Central aspects of the debate on the complexity of international law' 27 *Emory International Law review* 1, http://law.emory.edu/eilr/content/volume-27/issue-1/recent-developments/aspects-debate-complexity-international-law.html (accessed 19 July 2017).
[104] Sellin n 15 above, 251-253.

has led to discussions about the meaning of TRIPs Agreement objects and purpose as well as its flexibilities including in various human rights documents including General Comment 15.[105] What is more the concept of balancing private and public rights is also present in intellectual property law because of the limited monopoly period granted for inventions in return for public disclosure which is beneficial in the long term.[106] However, despite the existence of overwhelming 'soft law' supporting harmonious interpretation of WTO rules and human rights rules under international law, there is still no legal obligation on the State or the WTO to do so.[107]

2.4.3 The critical issue of functional versus normative hierarchy

The trade and human rights matter is perplexing since the normative hierarchy between trade and human rights is very different from the factual hierarchy of trade and human rights since the latter clearly favours the WTO regime with its strong adjudication and enforcement mechanism.[108] It is because of this factual hierarchy that trade enjoys over human rights that other scholars have argued for the direct enforcement (as opposed to harmonious interpretation) of human rights within the WTO system to promote coherence. According to Hestermeyer, the question of applying human rights within the WTO system can arise in two different procedural constellations:

> (1) a Member could invoke its human rights obligations in its defense against a claim that it does not provide for (sufficient) protection of pharmaceutical patents in violation of the TRIP[s] Agreement; or (2) a Member could commence a WTO dispute settlement proceedings against another Member that does grant pharmaceutical patents, alleging a violation of that Member's human rights obligations.[109]

From the above, there are two ways in which human rights can be raised within the WTO system. The first is through a member state defending itself before the dispute settlement tribunal. The second option is by way of another state complaining about another member

[105] As above, 252-258.
[106] As above, 255.
[107] As above, 257.
[108] H Hestermeyer *Human rights and the WTO: The case of patents and access to medicines* (2007) 207-292.
[109] As above, 208.

state's neglect or violation of its human rights obligations within the dispute settlement tribunal.

The above issue according to Hestermeyer has been discussed in five different ways as follows: the WTO as a stand-alone independent institution with its own rules and way of doing things independent from other international institutions and norms; minimal application of non-WTO to interpret WTO rules; WTO rules take precedence over non-WTO rules in case of conflict; the application of general international law governing conflict of norms in dispute settlement in case of conflict; and the need for Dispute Settlement Understanding (DSU) to enforce other norms over and above WTO rules.[110]

Consequently, there is still no consensus as to how human rights can be entertained within the WTO system. However, since options exists through which human rights can be introduced within the WTO a lot will depend on the innovation of the judges sitting at the dispute settlement tribunal. Hestermeyer concludes along these lines by observing that the decision to enforce human rights law within the WTO system is entirely in the hands of the judges and especially the members of the WTO Appellate Body to courageously hold members accountable for their legal obligations.[111]

As a first step therefore it would be crucial to reform the influential WTO dispute settlement mechanism because it is made up of trade experts and lawyers with no broad training on human rights or judicial training and therefore incompetent to decide on the conflict between human rights and trade.[112] The result is that the coherence approach cannot achieve far reaching radical transformation of the trading system and instead a more subtle 'cross-pollination' is preferred.[113] Yet, coherence can also be achieved if the WTO dispute settlement bodies were in a position to interpret WTO rules in a manner consistent with human rights

[110] As above, 209-210.
[111] As above, 292.
[112] S Fredman *Human rights transformed: Positive rights and positive duties* (2008) 53. Another potential challenge relates to the lack of transparency of the WTO dispute settlement process.
[113] G Marceau 'WTO dispute settlement and human rights' (2002) 13 *European Journal of International Law* 4, https://academic.oup.com/ejil/article/13/4/753/362707/WTO-Dispute-Settlement-and-Human-Rights (19 July 2017).

norms.[114] The Doha Declaration on TRIPS and Public Health is a good example of such a possible content reading of WTO provisions taking into account relevant human rights law.[115]

The WTO therefore opened a Pandora's box when it begun engaging into issues of intellectual property rights and therefore there is no justification for leaving out human rights and labour rights.[116] Indeed, the task at hand is not an easy one. According to Kong, the adoption of a 'human rights approach to any particular multilateral trade agreement will amount to amending the agreement. Unless a consensus is reached among WTO members, the idea of a human rights approach to trade is a non-starter, and its enforcement is simply out of the question.'[117]

2.5 Human rights and social learning theory in trade

The model of human rights as a trigger of social learning in trade is currently being propounded by various actors especially in the context of HRIA.[118] The present model is believed to be a solution to some of the weaknesses mentioned in other models and especially in relation to the transformative role that human rights should achieve in the trading system by imposing a 'new thinking'.[119] Human rights rules and principles in the context of trade should therefore form the basis of producing new policy ideas to fundamentally question the present assumptions that has hindered progress in society.[120] Consequently, human rights should play an important role in the ongoing revolution in the trading system because 'even if human rights are at present not a source of new policy ideas but its intervention into the trade policy debates perform the crucial function of providing a trigger for policy learning, and help to create the conditions in which learning is more

[114] As above.
[115] As above.
[116] P Alston 'Resisting the merger and acquisition of human rights by trade law: A reply to Pertersmann' (2002) 13 *European Journal of international Law* 818.
[117] Q Kong 'A human rights approach to trade? Some reflections: Commentary on Joost Pauwelyn' in T Cottier, J Pauwelyn, & E Burgi *Human rights and international trade* (2005) 235.
[118] Lang n 1 above, 101.
[119] As above. According to Lang 'new thinking' means 'new ideas about the kind of trade policies which are desirable and legitimate, and about the kind of governance structures through which political power is constituted and exercised in the trading order.'
[120] As above.

likely.'[121] The continued engagement of human rights in trade is therefore the only realistic avenue through which the ideas can evolve in order to achieve 'rational and desirable' policies in the trade sector.[122] The way human rights may achieve this is by targeting the causal beliefs of policy makers.[123] In addition, it may be necessary to also target the causal understandings of the dynamics of the politics in the trading system.[124] Learning therefore involves a change in both of the above set of beliefs or it may involve changes in policy beliefs.[125] With regards to the change in policy beliefs, this can be discussed at various levels including the following levels: 'lowest, deeper and deepest'.[126] With regards to the 'lowest level' the idea is that one changes the dominant views prevailing policy goals.[127] With regards to the 'deeper level' this involves a change to 'strategic policy beliefs' such as the belief that in order for liberalization to be most effective then there must be also reciprocal trade concessions.[128] Lastly, at the 'deepest level', learning involves a change of the goals that underpin decision-making in trade.[129]

The current trading regime at the international level has a number of features which may inhibit learning, which should be the focus of human rights movements in terms of helping to overcome.[130] One of the barriers in the trading system at the international level is the lack of appropriate monitoring mechanisms to assess the outcomes of a particular policy choice in order to feed into the policy formulation and re-formulation procedure.[131] Human rights actors can therefore help overcome this weakness by gathering and compiling relevant

[121] As above.
[122] As above.
[123] As above, 102. Here, Lang notes that '[c]ontemporary ideas about desirable trade policy rest on particular understandings of the economic dynamics of the trading system[.]'
[124] As above.
[125] As above.
[126] As above.
[127] As above. At the WTO level, this involves changing ideas about the appropriate bargaining positions to take within multilateral trade rules. In a domestic context, it may involve refining the nature, scope and sequencing of programs of liberalization as well as the broader policy environment in which liberalization is carried out.
[128] As above.
[129] As above. Lang noted that a variety of different overarching goals of the post-war trading regime have been given different emphases at different times. These include, among others, the reconstruction of post-war Europe, the maintenance of international and domestic economic stability, the generation of a global market in goods and services, and the efforts to drive global economic growth.
[130] As above, 103.
[131] As above.

information of the outcomes being registered under the international trading system and presenting this information coherently to trade policy makers who may then get the impetus to learn from it.[132] Another way human rights movement may facilitate learning is by questioning the broad values and beliefs that underpin the trading system and the responsibilities that trade policy makers are supposed to play.[133] Human rights may aide in thinking about the means and ends of policy in trade by using ethical criteria to justify trade policies and activities.[134] In this regard, if trade is supposed to increase wealth perhaps the 'success' of trade needs to be examined by looking at measures of income distribution rather than overall economic growth.

Lastly, the human rights framework can help overcome cognitive frameworks that are resistant to change by for instance providing an alternative environment to discuss the current trade framework.[135] Human rights actors as such can create knowledge.[136] This knowledge created by human rights actors can afterwards be used to influence the trade sector and if successful redefine it.[137] When human rights actors engage in the analysis concerning the human rights impact of the trading system as done in this study, among others, they also facilitate the 'production of social knowledge; generating shared narratives; synthesizing some kind of consensus about how certain aspects of the trading system operate; and selecting, reframing and imparting new meaning to information produced by various kinds of trade policy experts.'[138] At the heart of this model therefore is the generation of knowledge that is new about the trading system, which can create an impact in either of the following ways:

> The knowledge thereby produced can, of course inform the actions of policy-makers directly, helping them to reformulate their strategies and their policy preferences. Just as important, however, is the destabilizing role it can play in respect of traditional trade debates. New frameworks facilitate the reconsideration and renewal of contemporary trade policy knowledge by highlighting its (inevitable) cognitive limitations, and by demonstrating that

[132] As above.
[133] As above, 104.
[134] As above, 105.
[135] As above, 106.
[136] As above, 107.
[137] As above.
[138] As above.

> traditional trade experts do not have monopoly on the truths which can be told about the trading system.[139]

As noted above, the proper theoretical framework suggested for HRIA is human rights as a trigger for social learning in trade. Forman observes that HRIAs should be 'best understood through theories of rights as drivers of social change'.[140] She further observes that the constructivist theories of socially driven norm diffusion is appropriate for HRIAs because they 'suggest similar processes whereby norms are advanced by norm entrepreneurs and transnational networks, leading to the emergence of new rules and their internalization as they are adopted as collective understanding.'[141]

The interpretation of this is arguably that human rights ideas must be advanced by various stakeholders including norm entrepreneurs and transnational networks in order for them to be implemented. In other words, norms cannot implement themselves. In this regard, HRIA should play 'a more subterranean role by diffusing and internalizing human rights norms around medicines.'[142] This means that HRIAs can be used as tools for implementing human rights norms by various stakeholders. Policy makers should ideally then be forced to adhere to the relevant human rights obligations of the state especially where there is a danger of being sidelined.[143]

The role of right to health impact assessment as explained above is to therefore ensure that when trade policy makers are making their decisions, they should be made aware of the implications including in the context of human rights. To the extent that the target is policy makers, then right to health impact assessment (RHIA) is a trigger of policy learning in trade. As stated above, in Kenya, human rights are not mere suggestions (as a state party to numerous human rights treaties these are legal obligations, which are also included in the Constitution, 2010) but they are indeed fundamental building blocks of the Kenyan society

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[139] As above.
[140] L Forman 'From TRIPS-plus to rights-plus? Exploring right to health impact assessment of trade-related intellectual property rights through the Thai experience' (2012) 7 *Asian Journal for WTO & International Health Law* 355. According to Forman, the constructivist theorists 'suggest similar processes whereby norms are advanced by norm entrepreneurs and transnational networks, leading to the emergence of new rules and their internalization as they are adopted as collective understanding.'
[141] As above.
[142] As above.
[143] As above, 355.

and HRIA are therefore not an option but a fundamental part of decision-making tools available for all policy-makers. The tragedy today is that many policy-makers are yet to adjust to the new constitutional order and do the right thing and thus the need to think creatively about the issue at hand.

Lastly, the impact of human rights knowledge goes beyond just creating new thinking but also extends to challenging and disrupting existing ways of doing things in trade including the way thinking in trade happens. The fact that this study proposes the utilization of the right to health impact assessment in the context of pharmaceutical trade policies may be a trigger of new thinking in Kenya amongst trade policy-makers. Whether or not it will create change is yet to be seen. However, since the trade policy makers are yet to consider HRIA there is need to explore more theories to strengthen the case for the implementation of HRIA. One way to do this is to refer to market theories as discussed below.

2.6 Market theories of Human rights impact assessment

The study has explored the human rights-based theories in relation to HRIA. It is argued in this study that not all theories there are inherently defective but it may not motivate a trade policy maker or government that has practiced a strong free market ideology in its trade sector. For a long time, Kenya has practiced and applied free market ideology and it is still arguable that the 2010 Constitution has succeeded in changing that. In this section, the study therefore considers two market-based theories that could be applied in the context of HRIAs, namely: semiotic methods; and rational theory of morality. It should be noted that linking market theories to HRIA is a unique contribution of this study and is therefore one of the original contributions of this thesis. The main argument here is that in a strong free market society, one of these two market-based theories may be more convincing to the authorities than human rights-based theories.

2.6.1 Semiotic methods

One of the market theories that could work to support the HRIA in the trade context is the semiotic method. The semiotic method allows actors to reflect on the social and cultural consequences in the context of invoking and validating economic assumptions in law and

social institutions.[144] The semiotic method goes beyond efficiency as an end in itself and proposes the consideration of the social significance of a particular policy proposal in the economic sector. In this regard, this method focuses not only on 'what might be efficient, but on what the social significance might be of declaring an efficiency criterion to be of primary significance in determining social policy.'[145] The semiotic approach to law and market theory requires one to consider the significance of an interpretive shift away from the critical theorists that offer a radical critique of current market exchange networks.[146] Consequently, in a semiotic approach to law and market theory

> it is important to consider the significance of such an interpretive shift. As a rhetorical strategy for reforming the patterns and networks of exchange, critical theory presents an alternative system for allocating scarce resources and access to political authority. It does this by grounding the critical frame of reference in values that support subjectivity, instinct, inequality, exclusion, and group identification.[147]

In essence therefore, the semiotic method of analysis is purposive in that it aims at addressing some of the gaps available in market methods. While this model can be modified to fit the purposes of this study, it is not based on human rights or morality. It fails to provide a clear explanation as to when it may be suitable for instance to invoke morality or virtues in a market context. The theory is only good in so far as it is used to evaluate economic policies in relation to the social impact in society. Because of the weaknesses stated above, this study considers the second market theory, which is the rational theory of morality in the next section.

2.6.2 Rational theory of morality

The rational theory of morality is advanced by Coleman. Coleman begins by acknowledging that there seems to be an inherent conflict between rationality and morality defined as utility maximization and constrained utility maximization respectively.[148] Using these definitions,

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[144] RP Malloy *Law and market economy* (2000), 26.
[145] As above.
[146] As above, 27. According to Malloy, these theorists do so using an interpretive framework that rejects the ideas of objectivity, neutrality, rationality, equality, reciprocity, and self-interest.
[147] As above.
[148] J Coleman *Markets, morals and the law* (1998), 311. According to Coleman, the rational actor seeks to maximize his net (expected) utility and the moral actor sometimes acts so as to constrain the utility-maximizing behavior.

one can easily see the contradiction between morality and rationality in that 'a purely rational individual, at least sometimes, must act immorally; the purely moral individual, at least sometimes, must act irrationally.'[149] Notwithstanding this, in recent literature it has been shown that rationality and morality are not only compatible but that it is also possible to derive morality from rationality.[150] To the extent that this is possible then this study could benefit from such a theory without imposing it on trade policy makers who are predisposed to acting rationally as opposed to irrationally.

Coleman argues that in order for one to derive morality from rationality 'the theory of rationality must generate both the substantive and motivational components of moral theory.'[151] Accordingly, the substantive aspects of a moral theory specifies the content of the principles of morality whilst the motivational aspects explains why a rational person would comply with the principles specified by a substantive theory. The substantive part will be tackled in the next section dealing specifically with the right to health whilst the motivational aspect of the morality theory will be explained in this section below.

Coleman uses contractarian terms to explain that 'under conditions of perfect competition, the individually rational, self-interested behavior of all agents induces a Pareto-efficient outcome…in optimal equilibria, therefore, each actor does as well as he can – that is, his utility is maximized subject to the utility maximization of others.'[152] It will be irrational to impose restrictions if all individuals are performing at an optimum level.[153] Consequently, it follows that '[u]nder conditions of perfect competition…the rational actor has no incentive to adopt constraints, moral or otherwise, on his utility-maximizing behavior. Compliance with moral principles would be irrational.'[154]

Coleman further argues that in situations of market failures where conditions of perfect competition are non-existent, the reverse is true.[155] In this situation, 'the self-interested, utility-maximizing behavior for each individual leads to a Pareto-*inefficient* outcome – that

[149] As above.
[150] As above.
[151] As above.
[152] As above, 312.
[153] As above.
[154] As above.
[155] As above.

is, one in which at least some individuals could be made better off without worsening the conditions of others.'[156] Constraining the utility-maximizing behavior may lead to better results for the individual than if he continues pursuing the unrestrained path.[157] Cole further observes that

> [b]y introducing constraints on the utility-maximizing behavior of individuals, it may be possible to secure Pareto-*efficient* outcomes in which an individual fares better than she would were she to act as an unconstrained utility maximizer. There would then be a rational motivation for compliance with normative, possibly even moral, principles which requires constraint.[158]

The above quote is relevant because it demonstrates that norms and morality can become a rational motivation for actors when their utility-maximizing behavior becomes Pareto-*inefficient*.

Accordingly, Coleman notes that morality is a potential solution to the problem of market failures because it is introduced to govern social interactions only under conditions of market failure, in which it is rendered fundamentally instrumental.[159] Morality must be both individually and collectively rational if it is to be a viable solution to the problem of market failure.[160] The contingency upon which this solution relies on is that markets are never perfectly competitive.[161]

In addition to the market model of morality, market failure can also be addressed using political coercion.[162] In this regard, Hobbesian political contractarianism just like market model of morality characterizes the state of nature as a failed market.[163] Consequently, morality and politics are supposed to be alternate solution to the problem of failed markets.[164] This is done by way of bridging 'the gap between the inefficient equilibrium of the state of the nature and the potential Pareto-efficient equilibria unavailable if individuals'

[156] As above.
[157] As above.
[158] As above.
[159] As above, 313.
[160] As above.
[161] As above.
[162] As above.
[163] As above.
[164] As above.

do not cooperate.[165] In the context of failed markets, it is only when individuals act to constrain their utility maximizing behavior that efficient, mutually beneficial gains will be available.[166] The difference however is that

> while political contractarianism endorses a political or coercive remedy, moral contractarianism offers a moral one. Where political contractarians claim that state coercion is necessary to prevent individuals from unrestrained pursuit of their self-interest, moral contractarianism claims that individuals rationally and voluntary will choose to constrain their behavior, thus rendering a political solution otiose.[167]

The crux of Coleman's thesis is that in the context of market failure, two solutions are often made available, namely: politics; and morality. However, the difference is that political solutions will require coercion but a moral solution will only need that individuals 'rationally and voluntarily choose to constrain their behavior'.[168] In other words, the moral solution to the market failure does not require the use of state coercion to correct the failure.

The above theory is relevant in this study because it allows for the application of moral or human rights norms in an environment where rational behavior or free market ideology is highly valued. In this regard, the theory of morality and rational choice is sufficient motivation to rational actors to constrain their utility-maximizing behavior because such behaviors will only lead to the opposite of what they intend to achieve, which is Pareto-*efficient* outcomes. Therefore, to achieve the outcome they desire, trade policy makers should adopt morality, which is an inefficient but necessary solution to market failures.

The question that remains to be answered however is whether it is possible to introduce moral principles in law. In explaining how moral principles can enter the law, Kramer observes that any Rule of Recognition must be able to instruct officials to handle all cases 'by applying moral norms that produce the optimal result in the circumstances.'[169] This would

[165] As above.
[166] As above.
[167] As above.
[168] As above.
[169] MH Kramer *Where the law and morality meet* (2004) 29.

therefore mean that trade policy makers should be able to apply moral standards when it is optimal to do so including in relation to the TRIPs Agreement.

2.7 Conclusion

The theories that can underpin the use of HRIAs can either emanate from human rights theories or the market theories discussed above. In terms of human rights theories, the human rights as a trigger for social learning theory appears to be appealing in relation to HRIA in trade but it has failed to attract many governments, including Kenya, that has practiced free market ideology for a long time. Therefore, market theories are equally useful in terms of motivating policy makers to implement human rights or morality in relation to trade by clearly explaining circumstances when it is consistent with rational behaviour and when it is not, which is in sync with free market ideology. In this regard, HRIA is a tool that may be used to respond to specific challenges in relation to international trade rules such as the adverse impacts of pharmaceutical trade policies on access to medicines. It should therefore not be used in generic terms for instance in countries without serious access to medicines problems. It is therefore apt to use in developing countries for this reason.

CHAPTER THREE: THE TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT AND ACCESS TO MEDICINES IN DEVELOPING COUNTRIES

3.1 Introduction

The previous chapter discussed the relevant theories in relation to human rights impact assessment (HRIA) in relation to access to medicines. In addition to human rights theories, it emerged that market theories could be used to underpin the utilization of HRIA and specifically in relation to HRIA conducted by or on behalf of the government. Market theories including rational theory of morality as expounded by Coleman is particularly suitable in the context of a strong free market as opposed to human rights ideology in trade affairs. Kenya is arguably a country that has conducted its trade affairs on the basis of free market ideology and may therefore be more receptive to market theories of HRIA as opposed to human rights-based theories. Consequently, in order to be able to rely on the rational theory of morality, a situation of market failure must exist. In this chapter, the study explores whether the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement may qualify as a situation of market failure and therefore justify the use of HRIA by assessing its adverse effects on access to medicines in developing countries. If the answer emerges that the implementation of the TRIPs Agreement is indeed beneficial to developing countries in terms of its impacts then it may be difficult to argue for the use of HRIA, which is utility-restraining and therefore inefficient. However, if the answer is that the TRIPs Agreement indeed adversely impacts on access to medicines in developing countries then the utilization of HRIA by trade policy makers may be justified and defended as a rational behavior in line with free market ideology. Acting inefficiently in such contexts minimizes the adverse impacts while at the same time safeguards other state interests including human rights and access to medicines.

This chapter has the following key sections discussed separately below: globalization; intellectual property trade rules in developing countries; international trade rules and access to medicines; as well as the available options for resolving the problem of access to

medicines in developing world. From these sections, it emerges that the implementation of the TRIPs Agreement does not serve the interests of developing countries as much as it does rich countries but rather produces many adverse impacts that developing countries must deal with whether they like it or not.

3.2 Globalisation and World Trade Organization

Before discussing TRIPs Agreement, it would be important to put everything into perspective first. The current discourse on international intellectual property rights rules implementation via the TRIPs Agreement is not happening in a vacuum but in the context of globalisation and trade liberalization as mainly championed by the WTO.

3.2.1 Globalisation and pharmaceutical market failure in developing countries

At the foundation of this study is the phenomenon of globalisation, which has many definitions. In this study, globalisation is 'the process by which the globe is rapidly becoming single, fused economic unit-driven partially through the formation of regional trading blocs but increasingly across the globe.'[1] This definition presupposes the elimination of barriers to market access. Hughes notes that globalisation may take different unique qualities; which is that it may liberate and empower or it may be responsible for the economic marginalization and exclusion of individuals, communities, and countries especially developing countries.[2] In this regard, it is clear that the exclusion perpetrated by globalisation transcends many layers including individuals, communities and countries. In this thesis therefore even though the spotlight is on Kenya as a country the actual focus is on the poor communities and individuals who have been marginalised and excluded by the current global system.

Globalisation can be said to have historically developed in three main stages. The first stage started with colonialism, which saw the movement of capital moved from one country to another and the establishment of this phenomenon as an important political and economic

[1] L Hughes 'The international Jim Crow: Globalization, poverty and contemporary expression of racial discrimination' in J Oloka-Onyango *Battling over human rights: Twenty essays on law, politics and governance* (2015) 59.
[2] As above.

force in non-Western countries.[3] It therefore emerges from the foregoing that globalisation has its roots in colonialism. The second stage of globalisation led to the development of international human rights and the rise of global civil society to counter hegemonic Western powers.[4] From the second stage it appears that the main concern was hegemony which was being entrenched by Western powers and human rights became the tool of choice utilised by global civil society to oppose the Western hegemony. Lastly, arguably, the second stage and the third stage has run concurrently in terms of the age of late capitalism whereby with the rise of multinational hegemons and the dominance of international financial institutions as supranational centres of authority.[5] The idea here is that the states have taken a backstage over the years and the traditional role played by states in the economy is now substituted by supranational institutions like the WTO and multinational corporations, coming mainly from developed countries. The challenge however is that the third stage has come with revolutionary benefits to humankind there is also the other side of it, which is that a minority groups that is racially, sexually or economically dominant have benefited at the expense of others.[6] Consequently,

> Globalisation has transformed the way in which dominant forces in the global economy have defined their interests in the world outside of their own home base. In earlier economic phases, these forces were focused on ensuring access to cheap raw materials in the periphery as well as whatever access they could get to foreign commodity markets that was compatible with ensuring protected access to their economy at home. They are no longer focused on this. The agenda now of transnational capital is to look for a much broader and far-reaching breakdown of borders as well as removing obstacles to setting up production processes in any part of the world.[7]

The above quote appears to suggest that the process of globalisation is still ongoing and more changes will be seen in terms of how transnational capital is deployed at the global stage, which is increasingly becoming one big integrated market.

Where do developing countries fit in all this? Mutua observes that the form of globalisation which is being promoted by the WTO is disproportionately and negatively affecting third

[3] As above.
[4] As above, 60.
[5] As above.
[6] As above, 61.
[7] T Mentan *The State in Africa: An analysis of the impact of historical trajectories of global capitalist expansion and domination in the Continent* (2010), 36.

world countries even as it seeks to preserve the interests of the US and Europe (especially Britain and France).[8] Another indicator of the place of developing countries can be inferred by looking at the work of the global civil society as subsequently discussed. In the period 1995 to 2000, a lot of activities including workshops, street marches, blockades and occupation of streets were initiated and implemented by hundreds of protestors against the meetings of the WTO in Seattle because the WTO was perceived to be serving the agenda of multinational corporations.[9] The main message of the protestors was that they wanted 'fair trade, not free trade'.[10] The resolve of the protestors was supported by the adverse impacts that free trade had already had in poor countries and for the benefit of multinational corporations, which scoured 'the world for cheap labour, driving down living standards and undermining hard won social victories in rich and poor countries alike.'[11] The effect of globalisation in developing countries is therefore disproportionately perverse. Developed countries have not been spared as well but their situation is comparatively mild. To be fair it is crucial to note that social inequities did not start with globalisation since stratification by class, country, gender, race and other social categories started long before the era of supranational institutions.[12] The impact of globalisation is therefore to contribute and reinforce social inequities in relation to class, country, and urban/rural divides.[13]

Walby distinguishes between opposition to globalisation as a whole and its form and notes that global waves of social and political movements are part to the changes that constitute globalisation.[14] As such, some movements including environmentalism, anti-neoliberalism, feminism, and human rights may appear to be opposed to globalisation, but often they are primarily opposed to the form that globalisation is taking.[15] The form globalisation is taking is not an automatic process. It can be argued therefore that the form globalisation takes may be influenced by two factors, namely: societalisation; and hegemony.[16] Walby defines

[8] M Mutua *Kenya's quest for democracy: Taming leviathan* (2008) 281.
[9] R Burbach *Globalisation and postmodern* politics: From Zapatistas to High-Tech Robber Barons (2001) 101.
[10] As above.
[11] As above.
[12] JA Scholte *Globalization: A critical introduction* (2000) 235.
[13] As above, 236.
[14] S Walby *Globalization & Inequalities: Complexity and contested modernities* (2009) 45.
[15] As above.
[16] As above.

societalisation as 'a process in which a set of principles or an identity, is generalised throughout a social system, so that the whole system becomes self-reinforcing.'[17] In this regard, Walby argues that systems such as globalisation are created (as opposed to pre-given) over a long period of time and in most cases it has to compete with other agenda of societalisation projects in its entirety meaning that it can be replaced or it is never really completed throughout its existence because of the competition.[18] The implication of this is that globalisation as we know it today can be challenged and eventually changed if enough people decide to do so including through embracing human rights ethical principles in order to promote fair trade as opposed to free trade.

The above position is however dependent on the position of hegemons who will always attempt to shape global rules to suit the characteristics of the dominant hegemon and therefore ensure their maximum benefit at the expense of all the other players.[19] Walby contends that the concept of hegemony is important because it at the same time captures other notions of asymmetry, power, and consent which are always reflected at the international level.[20] This concept can therefore be used to understand how the WTO system works.[21] Globally, the current hegemons are mainly the United States (US) and European Union (EU) who will always attempt to influence global rules in their favour at the expense of everyone.[22] Consequently, Kenya should be careful in the context of EU East African Community Economic Partnership Agreement (EU EAC EPA) that it recently ratified.

3.2.2 Globalisation, social movements and human rights

Due to its impact especially on poor people in developing countries, globalisation has been opposed in many quarters. Consequently, the other issue that arises in the context of globalisation is the place of morality or human rights as championed through the fair trade

[17] As above, 45.
[18] As above, 45-46.
[19] As above, 46.
[20] As above.
[21] As above.
[22] AS Taubman 'TRIPs goes east: China's interests and international trade in intellectual property' in DZ Cass, BG Williams & G Barker (eds) *China and the WTO Trading System: Entering the new millennium* (2003), 433. China has a potential to become a hegemon in the near future if it is not yet one in fact.

as opposed to free trade ideology. Falk explores this issue by introducing the concepts of power of rights and right of power in his book.[23] Falk observes that human rights is always in motion because values change and social movements emerge and therefore whilst in the past human rights focused on limiting state power today the focus is transboundary or global.[24] The role of the global media and internet means that the movement of human rights is faster and it can change its character and locus very quickly to cover the entire world especially where an effective form of global governance is missing as it is today.[25] The ineffectiveness of the globalisation as a global governance programme has been described throughout this study. In a nutshell, it is about democratic deficit as explained below:[26]

> Unless the emergence of an effective form of global governance is adequately democratised it will not only reproduce existing acute inequities and exploitative patterns of the present world order, but will almost certainly intensify these malevolent features.[27]

The quote above shows that only democratic forms of governance can deal with the problems facing the world today including inequity and exploitation and that anything else will only make the situation worse.

In the ensuing situation, Falk observes that a tension exists in terms of rights and power under the headings of power of rights and the rights of power.[28] This can be contrasted by the concept of hegemon already discussed separately above in the previous section. Under this concept it is expected that the 'rights of power prevail over the power of rights almost always when strategic interests of major state actors are at stake, and this is true whether the orientation towards world politics reflects a realist or a liberal internationalist persuasion.'[29] The reality of today is however that the power of rights is still relatively weaker when compared to the rights of power in a variety of settings including at the international level.[30]

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[23] R Falk *Achieving human rights* (2009).
[24] As above, 8.
[25] As above, 13.
[26] As above.
[27] As above.
[28] As above, 24-25.
[29] As above, 25.
[30] As above.

It is because of this weakness that globalisation movements in the South are trying to augment the power of rights to counter the rights of power in relation to polices bearing on economic and social justice.[31] It is therefore not uncommon to see social movements rely on the right of power including by way of appropriation of rights and norms to promote current geopolitical objectives even as 'the power of rights confers a normative edge, with a still under-utilised potential for moral and legal mobilization in the struggle to achieve global justice and a humane political order.'[32] The idea is that the use of power of right is usually relevant only where the rights of power fail to deliver justice as has been the case with the work of transnational civil society movements participating in counter-hegemonic creativity.[33] Since the right of power is already well financed and motivated the challenge at hand is therefore to motivate the power of rights in order to produce the right struggle, which is necessary for progress.[34]

Lastly, it can argued that globalisation has reduced the power of state and increased the power of non-state actors including multinational institutions.[35] In this scenario, the state is virtually impotent even as non-state actors including multinational corporations backed by rich countries have become more and more powerful.[36] The emergence of the global civil society is meant to check this growth however their efforts are sometimes undermined by the fact that many of these civil society organisations still have to overcome certain important questions as to whether they are free of the structural prejudices and elements of discrimination that they have blamed on others before and specifically the hierarchy of race, gender, ethnicity and class.[37] Despite these challenges, there are at least two reasons why global justice is important: human rights instruments *per se* cannot be reduced to instruments of *realpolitik,* Euro-American hegemony or globalised capital; and global justice is strategic in that it allows progressive forces to use legal means to rein corporate and state

[31] As above, 26.
[32] As above.
[33] As above, 37.
[34] As above, 38.
[35] Hughes n 1 above, 70.
[36] As above, 71.
[37] As above, 76.

power along democratic and egalitarian lines.[38] In line with the need to motivate human rights actors including trade policy makers, a critical focus should be on implementation of human rights norms in practice. Accordingly,

> human rights only matter to the extent that agents put them into practice via forms of socio-political and ethical action that challenges relations of domination and contribute to systematic change, thereby protecting persons and groups from mass, severe and structural injustices or, more affirmatively, contributing to meeting human needs and making human capacities flourish. Further, considering the ever widening gap between the rhetorical presence of human rights on the one hand, and the reality of severe and pervasive violations of such rights in the world on the other, formalist arguments appear to have reached the threshold of their effectivity.[39]

The above quote is simply calling for a more practical approach as opposed to dogmatic approach to human rights. In essence, therefore, there has been more dogma in the area of human rights and this has inhibited its impact. In this regard, Kurusawa further observes that emancipatory projects should be linked to human rights because there are prospects in shifting 'of analytical focus from formalist arrangements to practices of global justice that through which groups and persons may use human rights discourses and established human rights institutions strategically.'[40] So far there has been more response by global civil society. This challenge is now being put squarely in the path of the state and especially trade policy makers. It is no longer tenable that the state absconds from its duty to fight injustice as its people suffer. The state still retains the primary responsibility to act in the best interest of its citizens and the market theories of morality discussed in the previous chapter has revealed that the state doesn't have to act in a manner that is always inconsistent with its interests even in situation of market failures. Human rights norms are therefore one way a state may respond to a situation of market failures including in relation to globalisation without undermining the market or other critical state interests.

3.2.3 Globalisation and intellectual property rules

In the context of intellectual property rights, what globalisation has done is to influence a paradigm shift since monopoly rights are granted on the basis of ideas rather than specific

[38] F Kurusawa *The work of global justice: Human rights as practices* (2007) 203 Cambridge University Press.
[39] As above, 195-196.
[40] As above, 203.

products as was the case in the past.[41] In the nineteenth century, patents were not issued on ideas but specific products, which situation changed and today patents are mainly issued on ideas and specific areas of knowledge; and, in some cases they have more market value than even the final manufactured product.[42] The result of this is arguably that intellectual property rights are essentially meant to benefit 'corporatized, post-modern economies.'[43] According to Gervais, the net effect of TRIPs Agreement is a valid assumption in terms of the outflow of royalty (rent) payments form mainly developing countries to developed nations including because of the 'patents and trademark rights of the pharmaceutical industry or copyright rights of the software, entertainment, and publishing industries.'[44] In this matrix, WTO members can generally be grouped into four categories as follows:[45]

> 1) Industrialized nations, beneficiaries of additional rent made possible by TRIP[s]-compliant protection; 2) Developing countries where innovation benefits outweighs additional rent extraction by Group 1 made possible by TRIP[s] [arguably China]; 3) Developing countries where additional rent extraction by Group 1 made possible by TRIP[s] outweighs innovation; 4) Least-developed countries, below the threshold at which substantial industrial innovation benefits are likely to develop but now also exempted from most TRIP[s] obligations [especially the waiver on the protection of pharmaceutical patents from 1 January 2016 to 1 January 2033 pursuant to the decisions of the TRIPS Council of 27 June 2002 and 11 June 2015 respectively] (and consequently free from IP-generated additional rent extraction at least in theory).'

Kenya is a developing country, group 3, and as such does not enjoy the 11 June 2015 TRIPs Council's waiver and as such is exposed to rent extraction generated by intellectual property rights protection. Gervais contends that 'the aim of the global development agenda should be to move as many countries as possible from Group 3 to Group 2. This can be achieved in part by measures to limit welfare impacts of TRIPs.[46] The welfare impact of the TRIPs Agreement in Kenya includes lack of access to medicines. However, in the long term it can be sustained only by developing domestic industrial innovation potential.[47] What this means is

[41] Burbach n 9 above, 57.
[42] As above.
[43] RL Gana 'Has creativity died in the third world? Some implications of the internationalization of intellectual property' as quoted in Hughes n 1 above, 66.
[44] DJ Gervais 'TRIPS 3.0: Policy calibration and innovation displacement' in C Thomas & JP Trachtman (eds) *Developing countries in the WTO legal system* (2009) 390.
[45] As above.
[46] As above, 391.
[47] As above.

that a country can turn its fortunes in the context of globalization by developing a domestic industrial potential but the first step is to protect its welfare including access to medicines. In this regard, Kenya's path from Group 3 to Group 2 will require that it minimizes adverse impacts on access to medicines in the short term and develops domestic pharmaceutical companies in the long term.

3.3 International intellectual property rules in developing countries

So far, the study has discussed the issue of globalisation in different contexts. The main argument in the previous section is that globalisation as the current model of governance has failed to eliminate marginalization, inequalities, and exploitation especially in developing countries. This failure is particularly more pronounced in the context of intellectual property rights rules and specifically the TRIPs Agreement. Consequently, developing countries should at least work towards minimising the welfare impact of the TRIPs Agreement in the short term, even as it works towards developing domestic pharmaceutical capacity in the long term in order to address the problem of access to medicines. The use of human rights norms is therefore at the core of the strategies to be undertaken by a developing state at least in the short term to ameliorate the welfare impacts that may arise as a result of globalisation and specifically TRIPs Agreement implementation.

Before delving into the two issue of welfare impact and the development of domestic pharmaceutical capacity, this study reviews some international trade theories and concepts including the Vernon's product cycle theory, Kaldor-Hicks efficiency logic and the group benefit standard to further demonstrate the unsuitability or unjustifiability of the TRIPs Agreement in developing countries under international trade. The TRIPs Agreement according to these theories only makes sense in developed nations and developing countries have a lot more to lose than gain under such a framework.

3.3.1 International trade theories and the illogic nature of TRIPs Agreement implementation in developing countries

The classical theoretical bases for international trade can generally be traced in two main sources: Smith's theory of absolute advantage as documented in his *Wealth of Nations*

(1776); and Ricardo's theory of comparative advantage as documented in *The principles of political economy* (1876).[48] On the one hand, the absolute advantage theory suggests that

> [i]n domestic economic activities, most of us accept that it makes no sense for an individual to try and produce all his or her own food, clothings…but rather to specialize in producing some goods or services for others and perhaps for some limited subset of his or her own needs, while purchasing requirements to meet needs from others who specialize in their production.[49]

From the above, the idea of specialization and trade is introduced. Smith notes that through trade, it is not necessary for individuals to produce all that they need. They can simply specialize in producing some goods or services and the rest can be acquired from others through trade. On the other hand, the comparative advantage theory has been described as follows:[50]

> England could produce a given quantity of cloth with the labour of 100 men. It could also produce a given quantity of wine with the labour of 120 men. Portugal, in turn, could produce the same quantity of cloth with the labor of 100 men. It could also produce a given quantity of wine with the labor of 80 men. Thus Portugal enjoy an absolute advantage over England with respect to the production of both cloth and wine….However, Ricardo argued that trade was still mutually advantageous, assuming full employment in both countries: when England exported to Portugal the cloth produced by the labor of 100 men in exchange for wine produced by 80 Portuguese, she imported wine that would have required the labor of 120 Englishmen to produce. As for Portugal, she gained by her 80 men's labor cloth that it would have taken her laborers to produce. Both countries would be rendered better off through trade.

From the above, it appears both England and Portugal can produce the cloth with 100 labourers but Portugal is more efficient than England in producing wine since it requires 40 labourers less than England. It therefore makes sense for Portugal to trade its wine with England since it enjoys a comparative advantage. In the same manner, England would be better off selling cloth to Portugal than wine since it compared to the two products England has more comparative advantage in cloth than wine since it takes the same number of labourers as in Portugal. It would therefore not make sense for England to sell wine to Portugal but it would make sense for it to sell cloth since it enjoys the same comparative

[48] MJ Trebilcock & R Howse *The regulation of international trade* (1995) 1-4.
[49] As above.
[50] As above.

advantage as Portugal. The two theories form the bedrock of international trade and trade liberalisation in general.

However, in relation to trade in trade-related intellectual property rights, one more theory is relevant, which is Vernon's Product Cycle theory. According to this theory, the US and other highly developed countries consider research and development or innovation as something they enjoy comparative advantage over poor countries because these countries tend to enjoy a superior access to large amounts of financial and highly specialised forms of human capital.[51] From the two factors described above from Vernon's Product Cycle theory, access to finance and highly specialised human capital, it is possible to understand why developed nations are pushing the agenda of intellectual property rights using the trade paradigm.

Based on the theories discussed above, the place of developing countries in relation to the global trade in intellectual property rights is relatively weak. In the context of TRIPs, it appears that there does not seem to be any mutually beneficial exchange between developed and developing countries since the gainers under TRIPs Agreement are currently mostly developed countries.[52] However, it is not possible to know who the final winners and losers of TRIPs Agreement until it is fully implemented and the local industries in all countries have adjusted to the new framework accordingly.[53] The fact that developed countries are currently the ones benefitting more from the TRIPs Agreement is consistent with neoclassical trade theory, which suggests that the decision to have a stronger or weaker intellectual property rights regime is dependent on a country's comparative advantage in relation to innovation or imitation.[54] The US and other developed countries enjoy a comparative advantage over developing countries in terms of innovation and therefore it is

[51] As above, 5-6.
[52] Abbott FM 'The TRIPS-legality of measures taken to address public health crises: Responding to USTR-State-industry positions that undermine the WTO' in Abott FM, Breining-Kaufmann C, & Cottier T (eds) *International trade and human rights: Foundations and conceptual issues* (2006), 346.
[53] E Su 'The winners and the losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and its effects on developing countries' (2004) 23 *Houston Journal of International Law* 211.
[54] Trebilcock & Howse n 48 above, 252.

possible to understand their interest in pushing for stronger intellectual property rights protection.[55]

Why should developing countries be part of the TRIPs Agreement? Some developing countries like China rationalise their membership in the TRIPs Agreement by noting that it is necessary in order to 'safeguard its real trade interests (access to developed-country markets, principally the United States, and the WTO membership).'[56] In this regard, the implementation of the TRIPs Agreement by China as is the case with other developing countries is 'generally characterised as reluctant compliance with externally imposed standards.'[57] China has therefore bowed to pressure from US and other developed nations to use criminal sanctions to deter violators even as it still remains concerned about TRIPs Agreement implementation.[58] The main reason why the US in particular has been tougher on China as opposed to other countries that have traditionally violated intellectual property is because of the large trade deficit between US and China and the fact that a rising China threatens the hegemony of the US.[59] Notwithstanding that the US and other developed countries may be tough on China in terms of protecting intellectual property rights, Peerenboom argues that violations of intellectual property will continue in China perpetrated mainly by domestic companies until its benefits to the political economy outweighs the costs. Consequently, he posits as follows:

> Intellectual property violations will continue regardless of the nature of the regime until the cost to the domestic political economy exceed the benefits, just as they did in the West and in the other successful Asian countries. Already, domestic businesses are the main victims of [intellectual property] violations. However, domestic companies face the same issues as foreign companies, including an unwillingness on the part of local government dependent on economic growth to put a stop to [intellectual property] violations, combined with insufficient resources; and strong economic incentives for [intellectual property] violators to risk punishment, even criminal sanctions, given the lack of alternatives in a developing country such as China where many people are employed or underemployed.[60]

[55] As above.
[56] Taubman n 22 above, 345.
[57] As above.
[58] R Peerenboom *China modernizes: threats to the west or model for the rest?* (2007) 76.
[59] Trebilcock & Howse n 48 above, 259.
[60] As above.

The quote above may simply be interpreted to mean that for as long as the incentives for exploitation of intellectual property rules are superior to compliance with the intellectual property rules it will be very difficult to enforce intellectual property rights at the national level. That said it is also crucial to point out that the Chinese experience is unique and can be distinguished from the realities of many other developing countries including Kenya. China, unlike many developing countries, is an exporter of technology and innovation as can be seen through its diverse products and services all over the world.[61] As early as 1998, China's industrialism and technological progress was proceeding at 'a breakneck pace, especially in the south.'[62]

From the foregoing, the main imperative of intellectual property rights protection by developing countries is market access in developed countries. The desire to access the rich countries' markets especially in terms of textile and agricultural products is partly responsible for the decision by developing countries to be part of the TRIPs Agreement even if it means that they have to pay some price by being members. In this regard, the TRIPs Agreement on its own does not make sense in developing countries. At best, the TRIPs Agreement is a compromise based on hopes by developing countries for future unguaranteed benefits.

3.3.2 Kaldor-Hicks efficiency argument

From the previous section, it is clear that the classical theories that underpin international trade do not directly favour the implementation of the TRIPs Agreement in developing countries. It makes more sense to have an international system of trade in intellectual property rights without developing countries until they can accumulate adequate financial muscle and specialised technical skills, which is key for innovation to take place. In this section, the focus is on whether the TRIPs Agreement can be justified using the Kaldor-Hicks efficiency argument.

[61] RA Sirico 'Free trade and human rights: The moral case for engagement' 17 July 1998, Trade Briefing Paper No 2.
[62] As above.

To start with, proponents of trade liberalisation argue that the removal of trade restrictions or protectionism is important because it amounts to a distribution of resources from inefficient to efficient factors of production and in this regard the positive effects of trade liberalisation always jeopardizes the inefficient factors, which includes loss of tariff revenue, unemployment, social and political disruptions.[63] The argument here is that trade liberalisation is capable of ending unemployment as well as political and social disruptions among other things.

On the flipside, trade liberalisation may affect third parties in the process say for instance when agricultural subsidies are removed, which has a negative effect on third parties who are net food importers and thus dependent on the subsidized food.[64] The argument here is that removing subsidies may impact on third parties who benefit from such subsidies at least in the short term.

In the context of the TRIPs Agreement, the Kaldor-Hicks efficiency logic is questionable. It is questionable 'whether gains to economic welfare to countries who benefit from stricter protection outweighs the losses to those countries who lose by it.'[65] The cost-benefit analysis of this trade-off is therefore a matter of concern. Can one justify higher pharmaceutical profits in developed nations at the expense of saving lives in developing countries using the Kaldor-Hicks efficiency logic? The argument against Kaldor-Hicks efficiency in relation to TRIPs Agreement in developing countries is thus as follows: '[i]f the increased protection is to shift productive resources from an activity in which a country has a comparative advantage, imitation, to that in which it has less comparative advantage, innovation, then global allocative efficiency would be reduced by increased protection.'[66] This quote simply means that developing countries are better off pursuing imitation than innovation because it enjoys a comparative advantage in the former's case than the latter. Consequently, the

[63] L Bartels 'Trade and human rights' in D Bethlehem, D McRae, R Neufeld, & I van Damme *The Oxford handbook of international trade law* (2009) 578-579.
[64] As above, 580.
[65] Trebilcock & Howse n 48 above, 253.
[66] As above.

global trade in intellectual property rights cannot be justified from the Kaldor-Hicks efficiency logic.

Consequently, in a 2003 report, the United Nations Development Program (UNDP) suggested that '[a]n alternative to TRIPs, either within or outside the ambit of the WTO, ought to be debated at the highest level.'[67] In this regard, it called for 'serious thinking' around this issue since 'replacing or fundamentally altering TRIPs will not be easy or sudden, given the differences in national positions on this issue.'[68]

3.3.3 The aggregate group benefit standard argument

From the previous sections, it appears that trade liberalization inherently bears some positive and negative costs. The question therefore is how to mitigate the adverse impacts of trade liberalisation. The first approach to deal with this issue focuses on the fact that trade liberalisation usually tends to be welfare enhancing and any loses can usually be corrected using the enhanced resources generated by the liberalisation of trade.[69] In developed countries, this can be achieved through government-run programmes such as retraining and unemployment assistance.[70] The challenge however is that the same options are not available for poor countries that are usually unable to afford similar programmes due to lack of resources.[71] Because of the above reason, it is plausible that trade liberalisation is likely to produce cost that is both uncompensated and not compensable especially in poor countries.[72] At the heart of the problem is therefore poverty. The existence of widespread poverty in developing countries therefore necessitates a much more careful approach to trade liberalisation. Poverty also eliminates any options that may be employed by developing countries to correct any adverse impacts of trade liberalisation as discussed above. This is the first point.

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[67] United Nations Development Programme *Making global trade work for people* (2003),221, http://ctrc.sice.oas.org/trc/Articles/UNDP_FULL.pdf (accessed 19 April 2016).
[68] As above, 222.
[69] Bartels n 63 above, 580. The argument is that liberalization usually meets the Kaldor-Hicks efficiency.
[70] As above, 580-581.
[71] As above.
[72] As above, 581.

The second approach is to use the human rights framework. In human rights, unlike in trade, the aggregate group benefit is usually seen as being inferior to the individual rights including in the area of economic, social and cultural rights.[73] In this regard, the focus is usually on the individual and not the aggregate group benefit, which means that due to this variation the conflict between trade liberalisation and human rights may in fact be inevitable particularly in the short term.[74] Dommen notes that

> [o]ne key difference between the human rights and trade regimes is that the former will judge whether a chosen policy promotes well-being on the basis of disaggregated, and often non-monetary, measures. It will assess the effects of a particular policy on the most vulnerable people within a country and will rule against choices that involve discrimination.[75]

The above quote simply means that the focus of human rights is on individuals and the focus of trade is on the aggregate group benefit, which means that even where the aggregate group benefit is achieved due to trade there may still be a remedy under human rights where individuals' stakes especially the poor and marginalised are at issue. It is therefore not enough to focus on the group but the individual in order to justify the TRIPs Agreement. So far, in many developing countries and as noted throughout this study, the poor people still lack access to medicines and the TRIPs Agreement has a direct contribution.

3.4 The link between human rights and trade in relation to access to medicines in developing country

Having explored the trade arguments, this section explores the human rights arguments. This section discusses the problem of access to medicines in developing countries, which has been described in the previous chapter as a problem of market failure in relation to intellectual property rights rules, by tracing it to the mandatory pharmaceutical patent provisions under the TRIPs Agreement. The implication of this has been immense and includes making medicines unaffordable in developing countries as well as leading to the problem of neglected diseases in developing countries. In essence this section discusses both

[73] As above.
[74] As above, 581.
[75] C Dommen 'Human rights and trade - Two practical suggestions for promoting coordination and coherence: Commentary on Victor Mosoti' in TS Cottier, J Pauwelyn, & E Burgi (eds) *Human rights and international trade* (2005) 202.

the intellectual property rights protection in relation to its welfare impact and development of local pharmaceutical capacity in short term and long term perspectives.

3.4.1 Is pharmaceutical patents a problem in developing countries?

The discourse on access to medicines in developing countries has developed into a binary debate on patents and non-patent barriers. This discourse gained more popularity when Attaran having conducted a survey in many developing countries found that patents do not frequently block access to generic medicines. He posited as follows:[76]

> [P]atents very infrequently block access to generic versions of essential medicines. For the sixty-five countries we studied, where the majority of people in the developing world live, patents and patent applications exist for essential medicines 1.4 percent of the time (300 instances out of 20,735 combinations of essential medicines and countries). However, this overstates the frequency with which patents totally block access to generics, because it is only a subset of patents that are absolutely fundamental and that generic manufacturers can never circumvent (normally, a patent on the active pharmaceutical ingredient, and for medicines containing two such ingredients, a patent on their co-formulation). By this standard, there are 186 fundamental patents or applications, or 0.9 percent of the total. Thus, there are no patent barriers to accessing generic essential medicines in 98.6 percent of the cases we studied, which we stress is an overall probability and not prognostic in any specific case.[77]

From the quote above, Attaran implies that the main problem of lack of access to medicines in developing countries is not attributable to pharmaceutical patents but health infrastructure. In this manner, the attention in terms of resolving the problem of access to medicines should be on health infrastructure as opposed to pharmaceutical patents.

Similarly, Sihanya has argued that patents are actually important in the realisation of access to medicines alongside other measures such as efficient policy, legal, institutional and administrative reforms of public health and research and development.[78] The assumption here is that patents actually drive the research and development of medicines in developing countries, which assumption has been challenged by the existence of neglected diseases problem in many developing countries. According to Sihanya, access to medicines and

[76] A Attaran 'How do patents and economic policies affect access to essential medicines in developing countries' (2004) 23 *Health Affairs* 3, 155-166.
[77] As above.
[78] B Sihanya'Patents, parallel importation and compulsory licensing of HIV AND AIDS drugs: The experience of Kenya' Managing the challenges of WTO participation cases study 19.

specifically ARV drugs in Kenya can be boosted using the following strategies: therapeutic value pricing; pooled procurement; negotiated procurement; planned donations; government commitment; and differential or dynamic pricing.[79] Patents are not included in this list by Sihanya implying that they are not or should not be viewed as a problem.

However, scholars like Hestermeyer have insisted on viewing pharmaceutical patents as a barrier to access to medicines in developing countries. He contends that the conflict between the TRIPs Agreement and international human rights law is manifested in the manner in which patents interfere with access to medicines due to the price effects.[80] Hestermeyer also contends that the 'question whether patents impede access is not negated by the fact that other factors impede access even more.'[81]

Hestermeyer further contends that the reluctance to patent drugs in all markets cannot be equated to lack of patent barrier on access.[82]In this regard, 'a company needs only obtain patents in all markets with the capacity to produce the drug because it can then use the patents to prevent others from manufacturing the drug without its consent.'[83] The argument being made by Hestermeyer above is that the lack of patents in many developing countries does not tell the true story since many developing countries in fact depend on importation of medicines. It is therefore important to take into account the patent situation in countries that supply developing countries in order to understand the problem at hand. It is therefore not enough to rely only on data from the developing countries to make the conclusion made by Attaran.

Consequently, it appears patent-barriers do still significantly affect access to medicines in developing countries, a position which is reflected throughout this study. The focus on pharmaceutical patents is informed by the effect it has on prices of patented medicines

[79] As above.
[80] H Hestermeyer *Human rights and the WTO: The case of patents and access to medicines* (2007) 137-150.
[81] As above, 151.
[82] As above, 150.
[83] As above.

especially the newly developed medications for communicable and non-communicable diseases, its threat to generic medicines as expounded upon below.

3.4.2 The Trade Related Intellectual Property Rights Agreement and access to medicines

One of the unique features of the TRIPs Agreement is its mandatory patent protection of products and processes inventions in all fields of technology provided that they meet the following criteria: new; involve an inventive step; and capability of industrial application.[84]

The principle of non-discrimination under the TRIPs Agreement means that pursuant to Articles 27, 70(8) and (9), among others, flexibilities previously available under the Paris Convention of 1883 in relation to the exclusion from patents of the following inventions have been removed: pharmaceuticals; agrochemicals; and food substances.[85]

The period for protection of patents has also been set at a minimum of 20 years for all members.[86] According to Trebilcock, the international stage currently existing has been greatly modified by patent provisions since all members of the TRIPs Agreement must now provide mandatory 20years protection in all fields of technology.[87]

The only exemptions allowed under the TRIPs Agreement can be found under Article 27(2), which allows for the exclusion from patentability inventions in the interest of '*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.' Article 27(3)(a) of the TRIPs Agreement also provides for exceptions to patent protection in the areas of 'diagnostic, therapeutic and surgical methods for the treatment of human or animals.'[88] Arguably, the reason for this exemption is that life-

[84] Article 27(1) of the TRIPs Agreement.
[85] B Sodipo *Piracy and counterfeiting: GATT TRIPS and developing countries* (1997) 199.
[86] See Article 27(1) of the TRIPs Agreement.
[87] Trebilcock & Howse n 48 above, 267.
[88] Pursuant to Article 27(3)(b), also qualifying for exemption from patentability are plant and animals other than micro-organisms, and essentially biological processes for the production of plant or animals other than non-biological and microbiological processes. Notwithstanding this leeway, members are expected to 'provide for the protection of plant varieties either by patents of by an effective *sui generis* system or by any combination thereof. Kenya has opted for plant varieties legislation.

saving treatment should not be subjected to private exclusive rights.[89] This argument is a moral one and therefore it can also be used to interrogate other controversial aspects of the TRIPs Agreement. For instance, why has the TRIPs Agreement failed to provide for a qualified exemption to life-saving medicines or essential medicines in developing countries to be more precise? Put differently, should essential medicines in developing countries qualify for exemption to the patentability criteria under the TRIPs Agreement? This move will ensure that many developing countries meet their obligations under the right to health even though it will mean that pharmaceutical companies lose royalties in those markets but they can still make profits just like generic companies. However, the problem with the above argument is that it assumes a bigger challenge, which is the issue of research and development of medicines as discussed in the next section.

Lastly, the pharmaceutical patent has an economic argument as well. The trade movement at the WTO 'successfully promoted the frame that "patents= free trade + investment = economic growth," which became the normative block of the TRIPS Agreement.'[90] From the above, the justification of the patent system from an economic perspective has been that it is a tool for the promotion of free trade and investment, which is essential for economic growth. However, in relation to access to medicines, Sykes observes that it is not possible to ascertain whether the TRIPs Agreement provisions 'governing pharmaceutical patents afford inadequate protection (suboptimal incentives to innovate) or excessive protection (excessive periods of monopoly pricing relative to what is necessary to encourage innovation).'[91] Notwithstanding the various arguments that may be made, Sykes concludes that

> one can neither prove nor refute the possibility that patent rights in pharmaceuticals create excessive rents for pharmaceutical companies, and that some reduction in patent protection might be socially productive. If so, then the relaxation of pharmaceutical patent protection in

[89] B Ley 'Patent rights and access to medicines: Are patent rights really the only barrier for good health care in developing countries?' in M Sinjela *Human rights and intellectual property rights: tensions and convergences* (2007) 107.
[90] SK Sell & A Prakash 'Using ideas strategically: The contest between business and NGO networks in intellectual property rights' (March 2004) 48 *International Studies Quarterly* 1, 145.
[91] AO Sykes 'International trade and human rights: An economic perspective' (2003) 21 John M. Olin Program in Law and economics, Working paper No 188.

> developing countries might seem a particularly attractive option given the humanitarian concerns.[92]

3.4.3 Research and development of new medicines

The main issue is that researching and developing new medicines is a resource-intensive undertaking.[93] Since the current funding model for pharmaceutical research and development also currently includes private funding, the patent system acts as an insurance system or a guarantee for returns on investment as observed below:

> The research and development business model thus ties investment to potential markets, suggesting possible issues in public heath, in that markets for a medicine arguably drive the research and development agenda. In this context, it is the creation of a "market" in developing countries that underpin the argument by largely industrialized nations and their dominant industries for stronger intellectual property rights.[94]

The patent system as such offers protection to creators without subjecting their innovations to secrecy or in exchange of disclosure.[95] In this regard, the patents system works as a monopoly system and in this regard gives greater power and rights to inventors over their products; including the power to set the pricing of medicines without necessarily taking into account the quality or benefit of the product protected.[96]

Patents therefore, in theory, allows for the owner of the patent to decide on prices of medicines unhindered with the ultimate result being that it creates a system essentially driven by profits as opposed to a system hinged on the therapeutic value of a product and the intended consumer.[97] Through its emphasis on monopoly system, patents are arguably immoral and may potentially restrict access to medicines especially if the prices set by inventors become unaffordable for people in developing, and, in some cases, wealthy countries.[98] In a recent case, Daraprim drug prices for Hepatitis C owned by Turing

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[92] As above, 22.
[93] Sell & Prakash n 90 above, 107.
[94] J Gibson *Intellectual property, medicine and health: Current debates* (2009) 81.
[95] A Kapczynski & T Sayed 'The continuum of excludability and the limits of patents' (2013) *122 The Yale Law Journal*, 1909.
[96] Gibson n 94 above, 182.
[97] As above.
[98] 'Drugs goes from $13.50 a tablet to $750, overnight' 20 September 2015 *New York Times, Business Day*, http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0 (accessed 20 October 2016).

Pharmaceuticals abruptly rose without any meaningful justification whatsoever, apart from profit, from $13.50 a tablet to $750 overnight in the US.[99] In this regard, Western intellectual property rights owners as well as the TRIPs Agreement draw their justification from a utilitarian perspective. Accordingly,

> [i]n such a perspective the benefit from the *positive* incentive for creative activity by the grant of temporary monopoly rights through patents and copyrights has to be balanced against the negative aspect of any monopoly, viz. monopolists will charge a higher price for their products compared to competitive producers.[100]

Apart from the patent system, there are other innovative monopoly systems that have been developed to compensate the cost of research and development, namely: the use of supplementary protection certificates; and data and marketing exclusivity.[101]As noted by Kapczynski,

> [t]he relationship between exclusion and appropriation in the context of information goods is that conventional economic actors will only produce a good when they can appropriate sufficient returns to recoup the capitalized costs of providing goods.[102]

The assumption of the monopoly systems is that the markets in developing countries are large or profitable enough to drive research and development but in many cases this is not true, which has led to the problem of medicines for neglected diseases in developing countries.

3.4.4 The problem of neglected diseases in developing countries

Those skeptical about the patent system and the argument that it is necessary for recouping pharmaceutical research and development costs point out that the current system has brought with it a myriad of problems especially in developing countries including the problem of neglected diseases.

On this issue, Kapczynski observes that the fact that the IP system inevitably leads to a situation whereby access to and the types of goods to be produced are influenced by price,

[99] As above.
[100] See comment by TN Srinivasan as quoted in Abbott n 52 above, 344-345.
[101] Gibson n 94 above, 84.
[102] Kapczynski & Sayed n 95 above, 1908.

the poor will always lose especially where their needs compete with the wealthy.[103] In other words, if price is linked to innovation then what will be invented will only reflect the demand in the market in terms of who can pay better and not necessarily who is in actual need. The experience in availability of ARV medication is important in this regard. According to Kapczynki, the reason why access to medicines movement for ARVs developed successfully is because there also exists a significant number of individuals infected with the virus in developed countries thus driving innovation and thus making the medicines available in terms of research and development.[104] The result is that developing countries and the poor are benefitting in default from the availability of these medications. The same cannot be said with regards to diseases such as extensively drug-resistance tuberculosis which affects mainly South Africa since the medicine is not available and therefore the patent system or the flexibilities under the TRIPs Agreement are rendered ineffective.[105] Therefore, what emerges is that providing patent monopolies in poor economies 'is worth very little' in terms of access to both available and unavailable drugs.[106] With regards to the former it makes their prices prohibitive and in the case of the latter it does not stimulate research and development.

Srinivasan is also skeptical about the actual benefits of enforcing monopoly systems in developing countries and observes as follows:

> [A]ny acceleration of innovative activity, which is the only rationale for granting monopoly rights, if it comes at all, will take place mostly in rich countries. Whether some of the benefits from any acceleration of innovation in the rest of the world will accrue to poor countries, is arguable. In any case the benefits, if any, are uncertain and in the future, but the costs to developing countries are concrete and in the present.[107]

What Srinivasan is saying is that the monopoly system will only benefit the rich countries and the poor countries can only benefit in the future but even this is not guaranteed. What is

[103] A Kapczynski 'The cost of price: Why and how to get beyond intellectual property internalism' (2012) 59(1) *UCLA Law Review* 978-979.
[104] As above, 999.
[105] As above.
[106] A Kapczynski, S Chaifetz, Z Katz, & Y Benkler 'Addressing global health inequalities: An open licensing approach for university innovations' (2005) 20(2) *Berkely Technology Law Journal* 1053.
[107] See comment by TN Srinivasan as published in Abbott n 52 above, 347.

certain however is that developing countries will pay dearly in the short-term period including the issue of neglected diseases.

The focus on intellectual property was also a key focus of the former UN Special Rapporteur on the right to the highest attainable standards of physical and mental health particularly Paul Hunt.

In 2003, Paul Hunt wrote a report that amongst other things focused on the problem of neglected diseases in terms of research and development.[108] According to Paul Hunt, there existed three types of diseases as follows: Type I diseases like Hepatitis B, which occur in both poor and rich countries; Type II diseases like HIV and AIDS and tuberculosis disproportionately affects the poor countries even though they affect both rich and the poor and thus termed as neglected diseases; Type III diseases like river blindness and sleeping sickness are termed as very neglected disease because overwhelmingly or exclusively affect poor countries.[109] Some diseases like malaria fall between Type II and Type II diseases as classified above and as such there is no rigid classification of the above categories.[110] According to the Special Rapporteur on the right to health, the imbalance in terms of research and development of medicines to address the Type II and especially Type III neglected and very neglected diseases respectively have been documented including by the Commission on Health Research and Development[111] which noted 'what became known as the 10/90 disequilibrium: only 10 per cent of research and development spending is directed at the health problems of 90 per cent of the world's population.'[112] The Special Rapporteur on the right to health notes that while many initiatives to remedy the above problem are underfunded the 2001 Doha Declaration offers a fresh impetus by reflecting 'human rights

[108] Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health, Paul Hunt, 13 February 2003 [E/CN.4/2003/58].
[109] As above, paras 73-74.
[110] As above, para 75.
[111] The Commission on Health Research for Development was an independent international initiative with the aim of improving health and development in what were then called 'developing countries'. It was active between 1987 and 1990, when it completed its work with the publication of its landmark report: Commission on Health Research for Development *Health Research: Essential Link to Equity in Development. https://en.wikipedia.org/wiki/Commission_on_Health_Research_for_Development* (accessed 10 November 2017).
[112] Report of the Special Rapporteur, n 108 above, para 79.

perspectives, especially the right of health and the right to enjoy the benefits of scientific progress, which is enshrined in article 27 of the [UDHR].'[113] In another report, the Special Rapporteur on health explained the problem of TRIPs Agreement and neglected diseases as follows:[114]

> In essence, intellectual property rights and related agreements-including the TRIPs Agreement-provide an incentive for health research and development where there is a market for a new drug, vaccine or other medical intervention. But, in the context of neglected diseases, there is no effective market and thus no effective incentive and this contributes to the 10/90 gap.

3.4.5 The issue of unaffordable medicine prices and generic competition

The current patent system will not deliver the research and development of medicines for developing countries. The best developing countries can hope for is that their diseases also inflict rich countries so that they can benefit from the medicine that is meant for them as is the experience in the HIV and AIDS. Notwithstanding the above, another issue remains problematic, which is the issue of affordability of medicines which have already been put out there in the market. Relatedly, generic competition has been largely responsible for reducing the prices of medicines in developing countries, which means that its restrictions as a result of patents should also be concerning for developing countries.

To begin with, t'Hoen identifies the factors that affect availability of drugs in developing countries to include 'logistical supply and storage problems, substandard drug quality, inappropriate use, inadequate production and prohibitive prices.'[115] On prohibitive prices, she notes that the challenge is mainly the patent monopoly system.[116] As explained below, generic medicines made it possible to challenge the prohibitive prices of especially life-saving treatment.

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[113] As above, paras 79-87
[114] Interim Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health, Paul Hunt, 10 October 2003 [A/58/427], para 76.
[115] E t'Hoen 'TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha' (2002) 3 *Chinese Journal of International Law* 28.
[116] As above, 27.

Accordingly, concerns about the prices of drugs came apparent for the international media in particular in the context of access to life-prolonging ARV drugs.[117] According to a report by the *Médecins Sans Frontières* (MSF) Access Campaign, the price of first-line regimen of ARV drugs has continued to fall from over USD 10,000 per person per year for first-line treatment in 2000 to around USD 140 per person per year in 2014 as a result of generic medicines.[118]

MSF however notes that the prices of second-line and third-line regimens will remain high because of patents for decades to come unless governments, generic companies and civil society exploit their laws to encourage generic competition.[119] It should be noted pharmaceutical companies oppose such exploitation of laws including through the interpretation of TRIPs Agreement in terms of compulsory licensing and domestic production of drugs whose patent is held elsewhere thus further complicating matters.[120] The patent system as such becomes a barrier to access generic medicines in developing countries and it depends on the goodwill of all actors to ensure that this is not the case.

However, it should also be acknowledged that not everyone agrees with the position that patents are to blame for higher prices of medicines in developing countries. For instance, Switzerland is on record denying any direct link between patents and prices of medicines because, in their view, medicines prices are affected by many factors including import taxes, national medicines supply system, and the role of intermediaries.[121] It is sufficient to note that Switzerland is not a developing country and their position may be supported by the

[117] See comment by TN Srinivasan as published in Abbott n 52 above, 347.
[118] MSF Access Campaign 'Untangling the web of ARV price reductions' (July 2014, 17th Edition) 2, https://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf (accessed on 3 May 2017). The report also notes that second-line medicines are now being produced in India by generic producers after sustained campaigns by Indian civil society especially with regards to opposing patents by way of filing pre-grant oppositions. Some countries are benefitting from lower prices like Thailand, Indonesia and Ecuador who have utilized compulsory licensing to enable generic production. However, many countries still pay higher prices for these drugs. With regards to third-line, or salvage regimens, the prices are still very high for most people and governments in developing countries.
[119] As above.
[120] See comment by TN Srinivasan as published in Abbott n 52 above, 346.
[121] 'Access to medicines resolution adopted by UN Human Rights Council' *IP Watch* 1 July 2016, http://www.ip-watch.org/2016/07/01/access-to-medicines-resolution-adopted-by-un-human-rights-council/ (accessed 14 November 2016).

reality on the ground, which is all people have enough resources to afford medicines at prices which would otherwise be unaffordable for developing countries and they also have a big local pharmaceutical industry.

Consequently, the main concern regarding the TRIPs Agreement is its impact on the prices of medicines in developing countries mostly. According to the *World Medicines Situation,* 2011 report in many low- and middle-income countries, the prices of medicines are high, treatment is unaffordable, and availability of medicines is unreliable.[122] This report serves to confirm further that the problem of unaffordable prices of medicines remains an issue in developing countries alongside other challenges to date.

3.4.6 World Trade Organization reforms and access to medicines

Vawda notes that from its inception, the TRIPs Agreement had the intention of limiting rather than promoting greater accessibility to drugs in developing countries.[123] This is supported by the fact that the language of accessibility is largely missing in TRIPs whose main concern is the protection of intellectual property rights and the promotion of trade.[124] Notwithstanding this, Vawda notes that developing countries can still rely on flexibilities available under TRIPs including compulsory licensing, parallel importation, and Bolar provisions to respond to challenges in public health.[125] Vawda also observes that some useful provisions in the TRIPs Agreement like 'the notion of "extreme urgency"' remains largely untested by developing countries.[126] But as will be seen below, compulsory licensing has been singled out as a key strategy for developing countries' public health interventions.[127] Many countries however are yet to make use of this flexibility.[128]

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[122] World Health Organization 'World medicines situation report' (2011) 12, http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf (accessed 5 April 2016).
[123] Y Vawda 'Tripped-up on TRIPs: The story of shrinking access to drugs in developing countries' (2002) 13 *Stellenbosch Law Review* 352.
[124] As above, 355.
[125] As above, 365.
[126] As above.
[127] In Kenya, parallel importation has worked well though.
[128] In Africa, only Rwanda has attempted to utilize compulsory licence and this however did not last long. Only one attempt was made in collaboration with Canada.

There are reasons for this poor utilization of the compulsory licensing. Under Article 31 of the TRIPs, elaborate procedures have been put in place that effectively makes it difficult for developing countries to exploit the compulsory licensing flexibility. An account of what transpired from Doha to Cancun in respect of this issue is revealing.[129] The issue of the difficulty of utilizing the compulsory licensing provision under TRIPs was highlighted under the Doha Declaration paragraph 6 but no solutions were proposed particularly with regards to the utilization of compulsory license in countries with insufficient or no manufacturing capacity.[130] This issue was carried forward to other forums and the solution was thought to lie somewhere between articles 30 and 31 of TRIPs dealing with limited exceptions and compulsory licensing respectively.[131] After failing to resolve this issue in different forums, the US in particular was severely criticized for negotiating in bad faith leading to a stalemate that was brokered by its 2002 concession allowing for a conditional 'moratorium' on the enforcement of article 31(f).[132] Another key gain was the announcement by the European Community (EC) of its support of the Doha Declaration in 2003.[133] All these developments culminated in the eventual adoption of the 30 August 2003 judgment by the Council for TRIPs meeting in Geneva even though in Vawda's view instead of an 'expeditious' solution the judgment proposed a solution that 'introduce[d] a complicated procedural minefield and complex system of notification.'[134] Notwithstanding the procedural difficulties raised by Vawda, he notes that it is up to states to 'test' it by taking full advantage of all flexibilities under TRIPs, 'imperfect as they are'.[135] Apart from Rwanda, no other African country has utilized this flexibility to improve access.[136]

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[129] Y Vawda 'Current developments: From Doha to Cancun: The quest to increase access to medicines under WTO rules' (2003) 19 *South African Journal on Human Rights.* 679.
[130] As above, 681. The Doha declaration instructed the Council of Ministers to find an expeditious solution on this issue and report back before end of 2002.
[131] Article 30 Agreement solution was also considered relying on the fact that it required the taking into account of the legitimate interests of third parties, which can be interpreted to include public health and humanitarian concerns.
[132] Vawda, n 129 above, 683.
[133] As above, 685.
[134] As above, 687.
[135] As above, 689.
[136] Canada was the first country to notify the WTO about its intention to manufacture generic medicines for Rwanda in line with paragraph 2(c) of the 30 August 2003 judgment. 'Canada is first to notify compulsory license to export generic drug' *WTO* 2 October 2007, https://www.wto.org/english/news_e/news07_e/TRIPs_health_notif_oct07_e.htm (accessed 19 April 2016).

Apart from flexibilities including compulsory licensing, international procurement may also deliver on securing access to affordable medicines in developing countries and perhaps in a more effective manner.[137] However, other authors like Velasquez and Schoen Amgerer have termed this assertion as an unfair attack partly because they state that the methodology used was flawed.[138] The reality on the ground is that even with the reforms that have so far happened at the WTO, the uptake of compulsory licensing flexibility is still minimal or non-existent. The general picture therefore is that the problem in developing countries is extra-legal. The existence of appropriate TRIPs Agreement flexibilities has not been able to solve the problem of access to medicines in developing countries.

3.4.7 TRIPs-plus measures and access to medicines: Beyond the WTO system

Before concluding on this issue, access to medicines is also affected by the issue of the TRIPs-plus agenda that is currently being promoted by developed countries in the context of regional and bilateral FTAs and other strategies.[139] Previously, intellectual property rights protection was dealt with under the World Intellectual Property Organization (WIPO). WIPO's intellectual property rights instruments included the Paris Convention for the Protection of Industrial Property (Paris Convention)[140] and Berne Convention for the Creation of an International Union for the Protection of Literally and Artistic Works, combined with the Additional Act and the interpretative Declaration (Berne Convention).[141]

Subsequently, the WTO forum was deliberately chosen to deal with trade-related aspects of intellectual property rights in what Drahos has argued is 'forum shifting' strategy, which is a common practice that has been employed by the US and its allies to push for and protect

[137] RF Beall, R Kuhn & A Attaran 'Compulsory licensing often did not produce lower prices for ARVs compared to international procurement' (2015) 34(3) *Health Affairs,* 493-501.
[138] G Verlasquez & T von Schoen-Angerer 'Unfair attack to developing countries' efforts to use compulsory licenses' (March 2015) Keionline.org, lists.keionline.org/pipermail/ip-health_lists.keionline.org (accessed 24 November 2016).
[139] SK Sell 'TRIPs-plus free trade agreements and access to medicines' (2007) 28 *Liverpool Law Review* 41.
[140] Paris Convention for the Protection of Industrial Property (March 20, 1883; effective July 7, 1884, and amended June 2, 1934 and July 14, 1967).
[141] Berne Convention of the 9th September 1886 for the creation of An International Union for the Protection of Literary and Artistic Works, combined with the Additional Act and the Interpretative Declaration of the 4 May 1896.

their intellectual property rights agenda in the world. [142]At the heart of the problem is the reality that that there is a strong external influence on the WTO by the constitutional systems of US and the EU acting in their capacity as the major trading powers including in the area of intellectual property rights.[143]According to Drahos, this strategy became even more relevant especially when developing countries began initiating resistance against intellectual property rights in the 1960s and 1970s at WIPO.[144] As a result of the resistance initiated at the WIPO, the forum was shifted to WTO and, according to Drahos, this strategy of forum shifting continues to be employed even today whenever developing countries register progress in any way at any forum.[145]

The proliferation of bilateral trade agreements and free trade agreements around the world may be symbolic of another change in forum away from the embattled WTO forum. Okediji in capturing this phenomenon has observed that the period of 'third multilateralism' is still ongoing owing to 'the proliferation of bilateral and regional trade agreements with requirements that enhance and further raise minimum intellectual property standards.'[146] Along these lines, Sell has opined that '[b]ilateral and regional agreements threaten to undermine any gains that developing countries may bargain for or achieve in multilateral settings.'[147] Some standards in particular those relating to data exclusivity have been observed to be not only TRIPs-plus but also US-plus.[148] Unlike before, Sell argues, it appears that when put against broader public policy goals like public health, 'in the past 20 years intellectual property rights have been elevated from servants to masters – crucial for their own sake.'[149] Sell also has also warned that '[t]o insist that all countries adopt high

[142] P Drahos 'Developing countries and international intellectual property standard-setting' (2002) *The Journal of World Intellectual Property* 769.
[143] EU Petersmann 'Constitutionalism and WTO law: From a state-centered approach towards a human rights approach in international economic law' in DLM Kennedy & JD Southwick (eds) *The political economy of international trade law: Essays in honour of Robert E. Hudec* (2002), 32-33.
[144] Drahos n 142 above, 768.
[145] As above, 780.
[146] RL Okediji 'The international relations of intellectual property: Narratives of developing country participation in the global intellectual property system' (2003) 7 *Singapore Journal of international & Comparative Law* 315, 338.
[147] Sell n 139 above, 58.
[148] As above, 59.
[149] As above, 58.

protectionist standards of protection denies them the opportunity to pursue the public policy strategies that every "developed" country enjoyed.'[150]

The issue of TRIPs plus is also inherent within the anti-counterfeiting agenda at the national level. The key aim of anti-counterfeiting agenda is to define generic medicines as a public safety issue.[151] In legal terms, this means introducing subject-matters which are beyond what is expressly required under the TRIPs Agreement. In this regard, the TRIPs Agreement only envisaged that only 'pirated copyrights' and 'counterfeit trademarks' done wilfully and on a commercial scale be subjected to criminal measures. In Kenya, criminal measures have been extended to patents thereby fitting the TRIPs plus narrative for instance in relation to the Anti-Counterfeit Act, 2008.

3.4.8 Anti-counterfeiting and the use of criminal enforcement measures

As early as the 1970s, the US had a particular proposal that was not well received by developing countries, which was the putting in place of an anti-counterfeiting code, and subsequently the TRIPs Agreement.[152] There are also views that developing countries failed to pay significant attention in relation to intellectual property rights and there was a significant domestic legislation with regards to these laws.[153] Part of the reason for this is that developing countries were outbalanced in terms of policy-making apparatus during the negotiations.[154] The preamble of the TRIPs Agreement is therefore clear about the need for effective enforcement measures of which the war on counterfeiting is very much at the core of it all. This background sets the stage for the paradigm shift in intellectual property rights enforcement measures from being mainly civil to also include criminal measures in the TRIPs Agreement. It is important to note that the US working together with the EC and Japan have been very keen to ensure that the TRIPs Agreement is implemented in full by everyone

[150] As above.
[151] W Hein, S Moon, & NK Poku *Informal norms in global governance: Human rights, intellectual property rules and access to medicines* (2013) 140.
[152] Abbott n 52 above, 313.
[153] As above.
[154] As above, 314.

including developing countries.[155] Apart from forcing developing countries to be part of TRIPs Agreement this group also resisted any proposals from developing countries on matters that affected their own interests.[156]

According to Gervais, one of the major achievements of the TRIPs Agreement is its enforcement section.[157] Criminal measures have been considered under the TRIPs Agreement as an essential ingredient to fight against organized infringements.[158] Indeed, the World Health Organization (WHO), WTO, and World Intellectual Property Organization (WIPO) (WHO-WTO-WIPO) trilateral study observed that the public interest is usually at stake when the infringement of the intellectual property reaches criminal levels.[159] This means that there is a strong justification for criminal measures in the intellectual property arena in order to safeguard public interest. The main issue at hand is therefore about the appropriate scope of especially criminal measures in the context of intellectual property rights enforcement that is necessary to protect the public interest including the right to health.

One way of determining the appropriate scope that intellectual property enforcement measures especially criminal measures is to look at the drafting history. In the context of the TRIPs Agreement, the drafting history suggests that the issue of criminal measures for intellectual property enforcement was one of the contentious issues. The current TRIPs Agreement provision on criminal measure was negotiated back and forth between July and December 1990 and the main issue was that there was no consensus as to whether criminal measures should apply to all infringements or be limited to cases of willful, commercial

[155] As above, 316. Abbott notes that from his own conversation with developing country delegations, he would 'understand that there was no viable alternative to accepting the TRIPs Agreement. The United States Trade Representative (USTR) threatened to continue its Section 301 actions. The US, EC, and Japan made clear that economic cooperation in its myriad forms was dependent on its [TRIPs Agreement] conclusion. There would be no reforms in the textile sector without TRIP[s].'
[156] As above.
[157] Gervais n 44 above, 287.
[158] As above, 327.
[159] WHO-WTO-WIPO *Promoting access to medical technologies and innovation: Intersection between public health, intellectual property and trade* (2012) 70, http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf (accessed 14 November 2016).

infringements directly affecting public order.[160] From the preamble, one of the purposes of the TRIPs Agreement includes 'the need for new rules and discipline concerning the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account the differences in national legal system.' The last phrase 'taking into account the differences in national legal system' is significant since it recognizes the existence of various enforcement mechanisms including criminal measures.

The aim of enforcement procedures however is deterrence which is also in line with the public interest objective stated above. In this regard, Article 41(1) of the TRIPS Agreement provides that:

> Members shall ensure that enforcement procedures as specified in this part are available under their law so as to permit effective action against any act or infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and r*emedies which constitute a deterrentto further infringements.* These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. (My emphasis)

It thus appears that criminal remedies are envisaged under the TRIPS Agreement for the main purposes of deterrence. However, Article 41(5) of the TRIPS Agreement further provides that specialized criminal enforcement mechanism of intellectual property rights is not an obligation under the TRIPS Agreement. In other words, the provision requires the utilization of existing mechanisms for enforcement unless the country decides otherwise.[161] Thus, the TRIPs Agreement provides as follows:

> It is understood that this Part does not create any obligations to put in pace a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

In contrast, the TRIPs Agreement draft of 23 July 1990 did not contain the above provision signaling that this must have been one of the compromise provisions of the TRIPs

[160] Gervais n 44 above, 287.
[161] As will be seen later under chapter 6 subsection 3, Kenya is one of the countries that have put in place an Anti-Counterfeit Agency that is responsible for leading the war on counterfeiting in Kenya.

Agreement.[162] As explained above, ordinary criminal justice system may be used to enforce intellectual property rights where public interest demands so.[163] According to Gervais, because of resource constraints, developing countries had sought to avoid the cost of putting in place a special judicial or other system to enforce intellectual property rights.[164]

After what appears to be protracted negotiations, Article 61, which is the only provision of the TRIPs Agreement dealing with criminal measures, eventually provided as follows:

> Members shall provide for criminal procedures and remedies to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of infringing goods and of any materials and implements the predominant use of which has been made in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in *other cases of infringement of intellectual property rights*, in particular where they are committed willfully and on a commercial scale. (My emphasis)

From the above, the inclusion of the phrase 'other cases of infringement of intellectual property rights' means that patents are not expressly excluded from the ambit of the above provision but it is an optional measure for which the countries have the liberty to decide the applicable standard depending on their needs at the national level. In this regard, criminal measures under the TRIPs Agreement are only guaranteed and therefore mandatory for 'willful trade mark counterfeiting and copyright piracy on a commercial scale'. According to Gervais, the effectiveness of criminal deterrence is debatable but 'the level of such penalties must reflect the seriousness of the crime, in light of the penalties of other cries under national law of the WTO Members concerned, and in keeping with Article 41(1).'[165] In other words, the protection to be accorded should not be any less in terms of gravity to that accorded to serious crimes against property at the national level.[166] In this manner, criminal measures should only apply to the extreme cases of infringements of intellectual property rights and not to all infringements. The test applicable is the standard adopted for serious crimes

[162] Gervais n 44 above, 287.
[163] As above.
[164] As above.
[165] As above, 327.
[166] As above.

against property. The operative word being: 'serious crimes'. This leads us to the question as to whether it is desirable for developing countries to extend criminal measures beyond what is mandatory in the TRIPs Agreement especially in developing countries.

As noted above, under TRIPS Agreement, the scope of criminal measures is unlimited and may include patents if a country so desires or wishes. However, the TRIPs Agreement has also provided sufficient guidance in terms of the minimum obligation of the government with regards to utilization of criminal measures in the context of intellectual property rights infringements. As noted by Sodipo,

> Prior to TRIPS, there was no definitive guide on which acts should be criminalized. TRIPS goes a little further. Article 61 requires national laws to criminalize at least two sets of infringements: copyright piracy done willfully on a commercial scale; and counterfeit of trade marks done willfully on a commercial scale. National authorities, however, have the *discretion to extend criminal sanctions to other infringements of intellectual property rights which are done willfully and on a commercial scale.*[167] (My emphasis)

As noted above, TRIPs Agreement does not preclude criminal sanctions in the context of patents under its Article 61 however unlike counterfeit trade mark and pirated copyrights done willfully and in a commercial scale, patents present a special challenge as explained by Sodipo below:[168]

> Unlike the case with copyright and trademarks, most national laws do not apply criminal law to patents infringement; neither does any international treaty require such application. Three reasons are suggested for this. Civil proceedings are seen as adequate to address the patent problem, hence industry has rarely lobbied for the introduction of criminal sanctions. Secondly, unlike criminal prosecution of trade mark and copyright, which can be done without much involvement from the injured party, the expense and technical nature of Patents, especially where they defendant challenges the validity thereof, are major disincentives for the inclusion of patents infringement offences. It is possible, however, that patents which have been held valid in civil proceedings may in future be used in criminal proceedings.

From the above, the cost of criminal prosecution of patents thus appears to be a main consideration especially in developing countries where resource-constraints is a big problem for delivery of services. It is absurd for developing countries therefore to rush into

[167] Sodipo n 85 above, 230.
[168] As above.

patent protection using criminal measures whilst no obligation exists under international law. The drafting history of TRIPs reveals previous attempts to make all intellectual property rights subject to criminal measures but clearly this was rejected and the current restrictions thus apply for a purpose which should not be ignored especially by developing countries. The purpose is not to unnecessarily overburden developing countries with intellectual property protection and enforcement beyond what is necessary.

Another argument to discredit the extension of anti-counterfeit war to patents can be found in the context of the WHO-WTO-WIPO trilateral study, which clarified the difference between the meaning of 'counterfeit' in public health and intellectual property contexts.[169] In this regard, the study observed that under the public health paradigm, 'counterfeit' is defined in the broadest sense taking into account the regulatory aspects but in the context of intellectual property and access to medicines, this definition is usually much narrower and relates mainly to commercial use of trademarks without the authority of the owner.[170] Since much anti-counterfeit legislation, including the Kenyan one, are mainly intellectual property rights enforcement instruments as opposed to public health regulation tools, the narrow definition should therefore apply without implicating or restricting generic medicines or patent exploitation for that matter. It should be noted also that the WHO itself has warned that there is no universally agreed definition of 'Counterfeit Medicines' and that it will continue to use the term Substandard, Spurious, Falsely-labelled, Falsified and Counterfeit (SSFFC) medical product until an agreement is reached on a new definition.[171]

From the foregoing, it appears that the issue of criminalizing patent infringement is retrogressive and should be avoided if access to medicines is to be safeguarded especially in developing countries. Put simply, it is a TRIPs plus measure, which is undesirable because it

[169] WHO-WTO-WIPO study n 159 above, 70.
[170] As above.
[171] 'Definitions of SSFFC medical products' *WHO,* http://www.who.int/medicines/regulation/ssffc/definitions/en/ (accessed 14 November 2016). The WHO previously defined counterfeiting as follows: A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging.

further limits beyond TRIPs what the government can do in terms of the policy space to intervene including in the realization of access to medicines. There should be a way to detail the exact impact the stronger intellectual property rights protection including by way of a TRIPs plus anti-counterfeit law at the local level can do. The discussion of anti-counterfeiting and access to medicines in relation to Kenya is discussed separately under chapter 6 subsection 3.

3.5 Options for resolving the problem of access to medicines in developing countries

As part of the third wave of globalization, the TRIPs Agreement and specifically its mandatory pharmaceutical patent provision is responsible for market failures in developing countries especially in the pharmaceutical sector by making the prices of medicines unaffordable for both the state and the individuals, what options are available for developing countries to resolve this? There are at least two main approaches that have been proposed to solve this issue. The first one relates to the flexibilities available under the WTO framework. The second strategy is the utilization of human rights framework, which is also a moral framework. Both strategies as argued in chapter two may be justified in the context of market failures. In fact, these strategies serve the same purpose – to correct this failure - but as will be discussed below one option is particularly attractive to developing countries than the other.

3.5.1 Correcting market failures using the WTO framework

The WTO system allows for countries to deal with the cost of liberalisation in different ways including through: providing for a large number of flexibilities; import restriction for developing countries and subsidies for low income and poor countries; as well as the right of WTO members to impose trade restrictions that are necessary for the protection of human life or health in the absence of other alternatives.[172] Petersmann notes that 'all WTO guarantees of freedom and non-discrimination are subject to safeguard clauses (e.g., in Article XX GATT and Article XIV General Agreement on Trade in Services (GATS)) which allow restrictions under conditions of *non-discrimination* and *necessity* that complement the

[172] Bartels n 63 above, 582.

non-discrimination and necessity principles in human rights treaties.'[173] In many ways, therefore, the WTO solutions can be compared to those under the human rights framework.

In general, however, many poor countries have, in practice, been unable to fully take advantage of the inherent solutions available within the WTO in order to correct the market failures at the national level because of mainly what can be termed as structural barriers including: unaffordability of the cost of investigations in the context of trade restriction; lack of adequate capacity in terms of human and financial resources to negotiate; and the high cost of subsidising products.[174]

As observed above, in practice, even the flexibilities under the TRIPs Agreement are not suitable for developing countries. Joseph notes that it is possible that the TRIPs Agreement flexibilities may permit states to comply with their human rights including right to health obligations, however, for poor countries 'it makes that task more difficult.'[175] These sentiments were captured by Udagama and Oloka-Onyango who characterised the implementation of WTO rules and specifically the TRIPs Agreement obligations as a 'veritable nightmare' for developing countries.[176] The main challenge therefore appears to be the practical barriers within the WTO system. This leads to the second option discussed below, namely: the human rights framework.

Most importantly, the flexibilities under TRIPs remain just that and in many cases governments cannot as a matter of obligations exploit them. This is the weakness the human rights framework discussed below addresses.

[173] Petersmannn 143 above, 46.
[174] Bartels n 63 above, 582-583
[175] S Joseph *'Blame it on the WTO?: A human rights critique* (2011), http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8 (accessed 19 August 2016).
[176] J Oloka-Onyango & D Udagama 'The realization of economic, social and cultural rights: Globalization and its impact on the full enjoyment of human rights' ESCOR, Sub-Commission on the Promotion and Protection of Human Rights, (2000) para 51 [E/CN.4/Sub.2/2000/13], http://hrlibrary.umn.edu/demo/Globalization_Oloka-Onyango,Udagama.pdf (accessed 23 August 2017).

3.5.2 Correcting market failure using the human rights framework

In a nutshell, the value addition of human rights in the context of TRIPs Agreement flexibilities is that it turns the flexibilities into government obligations. The nature of obligations is that they are binding and should therefore attract sanctions if violated. In other words, they should be enforceable using the legal framework in place either at the national or international plane.

According to Sellin, developing countries have two options to deal with the problem of lack of access to medicines. The first one is to 'assist individuals in buying the medicines they need, for example by granting financial aid, financing the health care system or providing certain medicines free of charge'.[177] Secondly, they can work towards ensuring that the prices of medicines are low or affordable.[178] However, Sellin observes that because of the challenge of resource constraints in many developing countries, the second option is more feasible for many countries and the key mechanism to regulate medicine prices in developing countries is curtailing patent barriers.[179] With regards to the first option, since the challenge of unaffordable medicines is today not just limited to developing countries, recent reports indicate that patients in rich countries are resorting to forming 'buyers' clubs for cheaper drugs' in order to buy medicines for their own private use and specifically for Hepatitis C and HIV treatment.[180] The system works by taking advantage of the flexibility under the TRIPs Agreement that allows for limited importation for private use.[181] This system however cannot work in the context of poverty in many developing countries and thus the need to take the second option very seriously, namely: working towards ensuring that prices of medicines remain low or affordable. The only option available for trade actors, especially in the context of the TRIPs Agreement, is to embrace human rights norms and integrate it in the process of trade policy-making at the national level if the same has become elusive at the

[177] J Selin *Access to medicines: Interface between patents and human rights. Does one size fits all?* (2014), 143.
[178] As above.
[179] As above.
[180] 'Buyers clubs for cheaper drugs help fight hepatitis and HIV' *Reuters* 6 November 2016, http://www.reuters.com/article/us-pharmaceuticals-buyers-clubs-idUSKBN1310FA (accessed 28 November 2016).
[181] As above.

international or WTO level. This is the only way the free trade system that has promoted inequalities in developing countries can be transformed into a fair trading system. The best part is that in the context of market failures the use of morality including human rights norms can be described to be a rational response, which is also consistent with traditional market theories.

The focus on human rights in relation to intellectual property rights is therefore important, including in Kenya, because of the adverse impacts international intellectual property trade rules portend to developing countries and their people. Apart from being a legal obligation, using such norms are also market friendly in such contexts of market failure including high prices of medicines as may be occasioned by the implementation of international trade rules in developing countries.

3.6 Conclusion

The main conclusion of this chapter is that globalization has led to market failures in many developing countries. In the context of international intellectual property rights agreement, the main issue is that intellectual property rights rules do not benefit developing countries in terms of trade. The other problem is that these rules often negatively impact on access to medicines in developing countries in two ways. Specifically, the problem is that the mandatory patent system under the TRIPs Agreement has led to medicines prices being unaffordable in developing countries, challenges in research and development of new drugs as well as the neglected diseases. Using various strategies it is possible to correct the problem at hand. There are two ways to do this. The first option is to exploit the flexibilities under the TRIPs Agreement but this option is not practical for many poor countries due to challenges of interest or capacity. The second option is to exploit human rights norms, which means that the flexibility under the TRIPs Agreement is not just a set of available options for the state to decide whether or not to exploit but a duty to be implemented by the state and failure to which violations may be imposed. Whilst it is advisable to take advantage of all the opportunities available in both options, using human rights norms may be more feasible in poor countries. The next chapter therefore analyses the relevant human rights norms and specifically the right to health framework for access to medicines in developing countries.

CHAPTER FOUR: THE RIGHT TO HEALTH NORMATIVE FRAMEWORK AND ACCESS TO MEDICINES

4.1 Introduction

The previous chapter focused on the adverse effects of the implementation of Trade Related Intellectual Property Rights (TRIPs) Agreement in developing countries, which is necessary to justify the utilization of human rights impact assessment (HRIA). From the chapter, it appears that the implementation of the TRIPs Agreement has limited dividends for developing countries and it is not in their best interest to implement it. However, since the obligations are mandatory, developing countries should balance the implementation of the TRIPs Agreements obligations with its other competing interests including human rights and the realization of access to medicines locally. Achieving the full utilization of the TRIPs Agreement flexibilities in order to safeguard other non-trade interest including access to medicines is therefore key. This can be done through using non-binding trade framework or the binding human rights framework. The value addition for human rights is therefore that it turns the implementation of the TRIPs Agreement flexibilities from being optional to being obligatory.

The norms under the right to health in relation to the TRIPs Agreement implementation as discussed in this chapter is particularly preferred because it is elaborate enough to sufficiently guide a trade policy maker. This section covers the following main areas: the link between human rights and intellectual property; right to health protection and access to medicines; right to health interpretation and access to medicines; right to health obligation of the state; violation of the right to health; and the status of access norms.

4.2 The link between health, human rights and intellectual property

The relationship between health and human rights is not always obvious. However, the link between these two areas have usually emphasised two things, namely: access to health care

services; and the effects of human rights violations on health.[1] Why is the link between human rights and health important? It has been suggested that one of the main reasons for linking human rights and health is that it is intended to advance human wellbeing beyond what can be achieved by health or human rights separately.[2] In other words, hinging health outcomes on human rights is more beneficial to developing countries due to their high diseases burden and lack of adequate resources to guarantee full access for everyone.

As noted above, one way to view the right to health is in terms of *access* to healthcare services.[3] Accordingly, in order to achieve 'a state of complete physical, mental, spiritual and social wellbeing', an individual needs access to health care services.[4] Therefore, basing the right to health on among other things *access* to health services provides the appropriate foundation for making the right intelligible as a matter of international and national law.[5] Therefore, the right to health is important and fundamental because of the fact that without *access* to health care, life can be a 'mere minimum of brutish existence'.[6] The right to health care access, which forms part of the right to health *inter alia* 'requires that all medically unnecessary physical [and mental] suffering be prevented.'[7] The goal of the right to health is therefore stated as 'the realization of the right to health for everyone – with two targets being universal health coverage (UHC) anchored in the right to health and a healthy social and natural environment for all.'[8]

[1] DP Fidler *International law and public health: Materials on and analysis of global health jurisprudence* (2000), 277.
[2] As above, 281.
[3] As above, 302
[4] As above.
[5] As above.
[6] J Donnelly & HE Rhoda 'Assessing national human rights performance: A theoretical framework' (1987-1988) 10 *Human Rights Quarterly* 214, 222.
[7] As above. The authors explain that the term 'unnecessary is used to mean physical suffering that readily available national and international health care system could prevent.
[8] 'Realizing the right to health for everyone: the health goal for humanity' (undated), Go4 Health, http://www.go4health.eu/wp-content/uploads/Go4Health-interim-report-September-20131.pdf 9 (accessed 26 July 2017).

At the national level, more than one hundred national constitutions explicitly or implicitly recognise the right to health.[9] The right to health is perhaps one of the most prominent right that has been enshrined in Kenya's Constitution.

In Kenya, the right to health is contained under Article 43(1)(a) of the Constitution, which provides that: 'Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care[.]' In relation to access to medicines, the right to reproductive healthcare is however not directly relevant. Article 2(5) and 2(6) of the Constitution similarly allows for the application of international law and principles to be directly applicable in Kenya with regards to the right to health. In this regard, international instruments ratified by Kenya is also a valid source of the right to health obligations. Therefore, the government of Kenya has extensive obligations to respect, protect and fulfil the right to health emanating both from national as well as international sources. In order to undertake these obligations, the content of the right to health has been clarified in many international and national documents.[10]

Private interest including intellectual property rights may intersect with the right to health.[11] This could be either because a private company is providing a health-related facility or services or when private entities undertake activities that do affect the underlying determinants of health.[12] The link between the right to health and intellectual property is therefore based on the involvement of the private sector in the area of health. This development in terms of the widespread move by the private sector in the provision of public services including health has necessitated the need for more attention on the question of accountability.[13]

[9] S Marks & A Clapham *International human rights lexicon* (2005) 199.
[10] The most authoritative text to date is the General Comment 14: The right to the highest attainable standard of health (Art. 12), Adopted at the Twenty-second session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4).
[11] Marks & Clapham n 9 above, 204.
[12] As above.
[13] As above.

4.3 International human rights protection of the right to health and access to medicines

There are at least five human rights provisions that apply in the context of TRIPs Agreement and access to medicines. The main provisions include right to health, right to life, and right to human dignity. In addition to these, the right to information and the right to public participation have become increasingly important in fostering transparency and accountability in relation to trade negotiations.[14] This section however only focuses on the right to health as elaborated upon below.

The right to health is heavily protected under international law. It should be noted that the 1946 WHO Constitution was the first international instrument that recognised the right to the highest attainable standard of health in its preamble.[15] The preamble of the WHO Constitution therefore states that '[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political beliefs, economic or social condition.' The right to health has been reaffirmed in many other declarations sponsored by the WHO including the Alma Ata Declaration of 1978 and the World Health Declaration of 1998.[16]

Apart from the WHO documents, the right to health is also prominently recognised in many human rights instruments. Below is an account of the right to health protection at the international and continental levels.

4.3.1 Global human rights instruments

At the global level, the right to health has been protected in many key human rights instruments. At the global level, the starting point is Article 25 of the Universal Declaration of Human Rights (UDHR),[17] which provides that '[e]veryone has the right to a standard of

[14] D Ovett 'Making trade policies more accountable and human rights-consistent: A NGO perspective of using human rights instruments in the case of access to medicines' in W Benedek, K de Feter& F Marrella (eds) *Economic globalization and human rights* (2007) 183.
[15] As above, 199.
[16] As above
[17] United Nations General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III), http://www.refworld.org/docid/3ae6b3712c.html (accessed 7 March 2016). Article 25(1) of the UDHR

living adequate for the health and well-being of himself and his family including food, clothing, housing and medical care and necessary social services'. Marks and Clapham observe that this provision does not specifically proclaim a right to health but it might be viewed as being important because it encouraged the development of a right to health in subsequent instruments.[18]

The most influential instrument in addition to the UDHR at the international level is the International Covenant on Economic, Social and Cultural Rights (ICESCR).[19] The right to health is protected under Article 12(1) as follows: 'The state Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.' The provision also highlights some key aspects of the right to health pursuant to Article 12(2) as follows:

> 2. The steps to be taken by the State parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (a) The provision for the reduction of still-birth rate and of infant mortality and for the healthy development of the child;
> (b) The Improvement of all aspects of environmental and industrial hygiene;
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
> (d) The creation of conditions which would assure to all medical services and medical attention in the event of sickness.

Article 12(2) is a direct testament that the right to health extends to the underlying determinants of health including 'food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.'[20]

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provides: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.'

[18] Marks & Clapham n 9 above, 199-200.

[19] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, available at: http://www.refworld.org/docid/3ae6b36c0.html (accessed 3 March 2016). Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966. Entry into force 3 January 1976, in accordance with article 27.

[20] General Comment 14 n 10 above, para 4.

Article 12(2) provisions have also been interpreted from an access to medicines perspective as follows. One, Article 12(2)(a) dealing with maternal, child and reproductive health services requires the right to access ARVs in order to prevent mother-to-child transmission of HIV.[21] Two, Article 12(2)(c) on the right to prevention, treatment and control of diseases can be interpreted to mean 'the right of access to certain medicines, namely medicines necessary for immunization and medicines specifically required to combat particular epidemics (such as ARVs which, although they do not combat the epidemic, are essential in the management and control thereof).'[22] Three, Article 12(2)(d) relating to the right to health facilities, goods and services also include the provision of essential drugs.[23] However, Article 12(2)(b) has no direct relationship with access to medicines in so far as it does not relate to the need to discourage abuse of drugs.[24] Article 12(2)(d) is perhaps the clearest link between right to health and access to essential medicines.[25] Article 12(2)(c) is equally important since 'access to medicines is especially relevant in the event of preventing, treating and controlling epidemic, endemic, occupational and other diseases.'[26]

The ICESCR is supplemented by many other thematic global human rights instruments including: Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW);[27] Article 24 of the Convention on the Rights of the Child (CRC);[28] Article 5(e)(iv) of the Convention on the Elimination of All Forms of Racial Discrimination

[21] Z Strauss & D Horsten 'A human rights-based approach to poverty reduction: The role of the right of access to medicines as an element of the right of access to health care' (2013) 16 *Potchefstroom Elec. Law Journal* 304.
[22] As above, 305.
[23] General Comment 14 n 10 above, para 17.
[24] As above, para 15.
[25] Strauss & Horsten n 21 above, 305.
[26] J Selin *Access to medicines: Interface between patents and human rights. Does one size fits all?* (2014) 80.
[27] UN General Assembly, *Convention on the Elimination of All Forms of Discrimination Against Women*, 18 December 1979, United Nations, Treaty Series, vol. 1249, p. 13, http://www.refworld.org/docid/3ae6b3970.html (accessed 7 March 2016). Article 12(1) provides as follows: 'States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.'
[28] UN General Assembly, *Convention on the Rights of the Child*, 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3, http://www.refworld.org/docid/3ae6b38f0.html (accessed 7 March 2016). Article 24(1) provides as follows: 'States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.'

(CEDAW);[29] and Article 25 of Convention on the Right of Persons with Disabilities (CRPD).[30] The purpose of these thematic instruments is to reinforce the importance of the right to health globally.

4.3.2 Continental human rights instruments

At the continental level, the African Charter on Human and Peoples' Rights (the African Charter)[31] is the starting point. The African Charter enshrines the right to health under its Article 16(1) as follows: 'Every individual shall have the right to enjoy the best attainable state of physical and mental health.' Unlike the ICESCR, Article 61(2) of the African Charter is brief and only requires State Parties to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.' Accordingly, this provision is the basis in which the State is under an obligation to provide health and medical services for their populations despite the implementation challenges.[32] From the text, the link between access to medicines and the right to health under the African Charter may be found in the context of providing medical attention when people are sick.

The African Charter is also supplemented by other regional human rights instruments including: Article 14 of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Maputo Protocol);[33] and Article 14 of the African Charter on

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[29] UN General Assembly, *International Convention on the Elimination of All Forms of Racial Discrimination*, 21 December 1965, United Nations, Treaty Series, vol. 660, p. 195, http://www.refworld.org/docid/3ae6b3940.html (accessed 7 March 2016).

[30] UN General Assembly, *Convention on the Rights of Persons with Disabilities: resolution / adopted by the General Assembly*, 24 January 2007, A/RES/61/106, http://www.refworld.org/docid/45f973632.html (accessed 7 March 2016). Article 25 of CRPD provides: 'States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation….'

[31] Organization of African Unity (OAU), *African Charter on Human and Peoples' Rights ("Banjul Charter")*, 27 June 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), available at: http://www.refworld.org/docid/3ae6b3630.html (accessed 3 March 2016). Adopted by the OAU (now AU) in Nairobi, Kenya, on 27 June 1981 and entered into force on 21 October 1986.

[32] J Rehman *International human rights law* (2nd edition, 2010) 320.

[33] African Union, Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa, 11 July 2003, http://www.refworld.org/docid/3f4b139d4.html (accessed 7 March 2016). Article 14(1) provides: 'States Parties shall ensure that the right to health of women, including sexual and reproductive health is respected and promoted.'

the Rights and Welfare of the Child (ACRWC).[34] The link between the right to health and access to medicines under Article 14 of the Maputo Protocol is remote since the provision heavily focuses on sexual and reproductive rights as well as protection from HIV and AIDS. Similarly, Article 14 of the ACRWC is also very brief only focusing on the right to access to healthcare services and the underlying determinants.

Since Kenya is a signatory to both the Maputo Protocol and the ACRWC, it has additional obligations to provide access to medicines for these categories of people accordingly.

4.3.3 Sub-regional documents on the right to health

At the sub-regional level, there are some documents that also recognize the right to health. In relation to Kenya, Article 33 of the East African Community Human and Peoples' Rights Bill[35] provides for the recognition of the right to health. However, it should be noted that this document is still pending before the East African Community Legislative Assembly (EALA). There is also a thematic legislation enacted by the sub-regional body that provides for the right to health, which is the East African Community HIV and AIDS Prevention and Management Act, 2012.[36]

4.4 Interpretation of the right to health in relation to access to medicines under international law

At the international level, in order to determine the nature and scope of the right to health in relation to access to medicines, reliance is often paid on 'soft' laws. A 'soft' law is a non-binding but persuasive instrument, which is usually relied upon to clarify the normative standards applicable in relation to the rights defined under an instrument such as the right

[34] Organization of African Unity (OAU), *African Charter on the Rights and Welfare of the Child*, 11 July 1990, CAB/LEG/24.9/49 (1990), http://www.refworld.org/docid/3ae6b38c18.html (accessed 7 March 2016). Article 14(1) provides: 'Every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health.'

[35] East African Community on Human and Peoples' Rights Bill, 2011, http://www.kenyalaw.org/kl/fileadmin/pdfdownloads/EALA_Legislation/BILLSUPPLEMENT12thAugust20121.pdf (Accessed 7 March 2016). This Bill is yet to be enacted into law. At the moment, the EAC Court of Justice has a limited jurisdiction with regards to human rights cases as will be explained in the next chapter.

[36] East African Community HIV and AIDS Prevention and Management Act, 2012, Adopted during the Fifth Session of the East Africa Legislative Assembly, held in Nairobi, Kenya on 23 April 2012 and entered into force on 14 December 2014.

to health discussed above. Moreover, unlike the 'hard' laws discussed above, the link between the right to health and access to medicines including in the context of intellectual property rights is clearly explained in detail in many 'soft' laws as discussed below. There are three main positions that are discernible in the soft laws. The first approach is that only access to essential medicines is part of right to health. The second approach is that the right to health encompasses only life-saving medicines. The last approach is that access to all medicines is part of right to health. These three approaches have been expounded upon in turns below.

4.4.1 Access to essential medicines

As stated above, the first interpretation views access to medicines as being a right exclusive to essential medicines alone. For instance, a glance at the General Comment 14 reveals an implicit recognition of the right to access to essential medicines as opposed to access to medicines more generally.

General Comment 14 is important because it adopts a broad definition of the right to health beyond what is provided for under the preamble of the WHO Constitution to not only include access to health care but also the 'underlying determinants of health, such as food and nutrition, housing, access to safe and portable water and adequate sanitation, safe and healthy working condition, and a healthy environment.'[37] General Comment 14 also notes that the right to health is not synonymous with the right to be healthy and that the former has both freedoms and entitlements.[38] It further notes that Article 12(1) notion of 'the highest attainable standard of health' takes into account both the individual's biological and socio-economic preconditions and a '[s]tate's available resources'.[39] General Comment 14 identifies the four essential elements of the right to health as follows: availability; accessibility (including non-discrimination, physical accessibility, economic accessibility

[37] General Comment 14 n 10 above, para. 4.
[38] As above, para 8. According to this paragraph, '[t]he 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, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest level of health.'
[39] As above, para 9.

[affordability] and information accessibility), acceptability and quality.[40] The concept of 'access' in relation to access to medicines has been interpreted to include the four elements of the right to health as follows:

> When examining access to medicines and access to knowledge, this necessarily introduces a broader and fuller concept of access. The definition of 'access' in this sense is enhanced by four principles of the right to health: availability; accessibility; acceptability; and quality. These four elements constitute the broader possessory concept of 'use' of which access is a component.[41]

From the above, 'access' can encompass all the four elements under the right to health. Therefore, the present study is restricted to the narrow interpretation of the concept of 'accessibility', which under the General Comment 14 paragraph 12 means '[h]ealth facilities, goods and services must be accessible to everyone without discrimination….'

Using the restricted definition of 'access' it is possible to discuss whether the same applies to only access to essential medicines or access to medicines in particular. What is clear from the General Comment 14 however is that the right to essential medicines is a core obligation of the government, which means that the government cannot derogate from this responsibility.[42] It is not clear however from the text of General Comment 14 about the extent of the right to health in relation to access to medicines more generally. This confusion has been the subject of documents of the UN for a long time as will be discussed below.

At the regional front, the Principles and guidelines on the implementation of economic, social and cultural rights in the African Charter on Human and Peoples' Rights (AU ESRs principles and guidelines)[43] applies. The minimum core obligations under this document emphasizes

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[40] As above, para 12. In brief, availability connotes a '[fu]nctioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity….' Accessibility connotes '[h]ealth facilities, goods and services must be accessible to everyone without discrimination…' Acceptability connotes that '[a]ll health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.' Lastly, quality connotes 'health facilities must also be scientifically and medically appropriate and of good quality.'

[41] J Gibson *Intellectual property, medicine and health: Current debates* (2009) 173.

[42] General Comment 14 n 10 above, para 43(d).

[43] Principles and guidelines on the implementation of economic, social and cultural rights in the African Charter on Human and Peoples' Rights, adopted during the 48th Ordinary Session of the ACHPR on Human and Peoples' Rights held from 10 to 24 November 2010 at Banjul, The Gambia.

on the provision of ARV drugs by the State.[44] This is important because HIV and AIDS is a scourge and ARVs for its treatment must be guaranteed by the State because of the high poverty level in the Continent.

The AU ESCRs principles and guidelines also require that states set a target of at least 15% of their annual budget to the improvement of the health sector following the Abuja declaration commitment with particular focus on funding the fight against malaria, HIV and AIDS, tuberculosis and other related diseases.[45] Also, the AU ESCRs principles and guidelines require that states should 'ensure that the privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.'[46]

4.4.2 Access to life-saving medicines for HIV and AIDS, malaria, and tuberculosis

General Comment 14 was adopted in the year 2000. This period saw an increase in political commitment to deal with the scourge of HIV and AIDS particularly in the developing world. Through this work, many documents recognizing the right to access to life-saving medicines were generated. The then UN Sub-Commission on Human Rights was very instrumental in developing the work relating to access to life-saving medicines. This body adopted a series of resolutions focusing on access to life-saving medication in the context of pandemics such as HIV and AIDS thus helping in making access to medicines a priority internationally. This trend was followed keenly by the United Nations General Assembly (UNGA). As will be noted below, a key focus of the Sub-Commission on Human Rights and UNGA was on the utilization of TRIPS Agreement flexibilities as being consistent with the realization of the right to health.

To begin with, resolution 2001/33 was adopted in April 2001 recognizing among others 'that access to medication in the context of pandemics such as HIV and AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the

[44] As above, para 67(b).
[45] As above, para 67(g).
[46] As above, para 67 (p).

enjoyment of the highest attainable standard of physical and mental health[.]'[47] In this regard, the resolution called on states to

> ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies.[48]

From the above, the resolution expressly identified access to life-saving medication in the context of pandemics such as HIV and AIDS as not just an element but one of the fundamental elements of the right to health. Moreover, it effectively required states to consider right to health in their international dealings in order not to undermine access to medicines. In June 2001, the UNGA Declaration of Commitment on HIV and AIDS[49] (the UNGA Declaration) was also adopted to, amongst other things, 'set common targets for reducing the spread of HIV and AIDS and alleviating its impact.'[50] Setting the stage for this political commitment, the resolution noted that about 90 per cent of the 36.1 million people living with AIDS worldwide were in developing countries, of which 75% came from sub-Saharan Africa.[51] The UN Declaration further recognized that

> the cost, availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects and that there is need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies.[52]

The UN Declaration also acknowledged that

> lack of affordable pharmaceuticals and of feasible supply structures and health systems continues to hinder an effective response to HIV and AIDS in many countries, especially for the poorest people, and recalling efforts to make drugs available at low prices for those in need.[53]

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[47] Sub-Commission on Human Rights Resolution 2001/33 on access to medication in the context of pandemics such as HIV AND AIDS, para 1.
[48] As above, para 4b.
[49] United Nations General Assembly, Special Session on HIV and AIDS 25-27 June 2001, http://www.unaids.org/sites/default/files/sub_landing/files/aidsdeclaration_en_0.pdf (accessed 11 March 2016).
[50] As above, foreword by UN Secretary General, Kofi A. Annan.
[51] As above, para 3.
[52] As above, para 21.
[53] As above, para 22.

One of the key proposals made in this declaration was to address the issue of affordability of drugs by 2003.[54] Sokalsa has observed that the special session, which was convened as a matter of urgency, was just the first step towards the implementation of the millennium development goals (MDGs) especially those that relate to HIV and AIDS.[55] It emerges from this resolution that the cost of ARV treatment was a key challenge in the fight against HIV and AIDS worldwide since ARVs were viewed as being important to save lives. It is possible to argue that to the extent that the right to health is applicable, access to medicines was restricted to access to life-saving treatment or drugs.

At the regional front, in 2001, the AU also adopted the Abuja Declaration on HIV and AIDS, Tuberculosis and other Related Infectious Diseases declaring AIDS as a State of Emergency in Africa and called for the lifting of 'all tariff and economic barriers to access to funding of AIDS-related activities.'[56] In the same document, the fight against HIV and AIDS was put at the 'forefront and as the highest priority issue' in Africa's national development plans.[57] In this document states also pledged to allocate at least 15% of their annual budget to the improvement of the health sector.[58] African states also resolved to 'enact and utilize appropriate legislation and international trade regulations to ensure the availability of drugs at affordable prices.'[59]

At the level of the ACHPR, the resolution on the HIV and AIDS pandemic – threat against human rights and humanity[60] was important for declaring the HIV and AIDS pandemic a 'human rights issue which is a threat against humanity.' [61] The leadership of the AU Heads of State and Government should be acknowledged here since the present resolution was adopted in May 2001, about one month after the AU had considered AIDS as a state of emergency in the continent under the April 2001 Abuja Declaration discussed above. In

[54] As above, para 55.
[55] ME Sokalska 'HIV AND AIDS epidemic – A global response: The twenty-sixth special session of the General Assembly of the United Nations on HIV AND AIDS' (2002) 8 *European Journal of Health Law* 353.
[56] Abuja Declaration on HIV AND AIDS, Tuberculosis and other Related Infectious Diseases, African Summit on HIV AND AIDS, tuberculosis and other infectious diseases, 2001, [OAU/SPS/Abuja/3], para 22.
[57] As above, para 23.
[58] As above, 26.
[59] As above, para 31.
[60] ACHPR Resolution on the HIV and AIDS pandemic – Threat against human rights and humanity, [ACHPR Res.53/(XXIX)01].
[61] As above, para 1.

2005, the AU also adopted a Decision on the Interim Report on HIV and AIDS, Tuberculosis, Malaria and Polio[62] and in it urged Member states to 'take lead in TRIPs Agreement negotiations and in implementing measures identified for promoting access to affordable generic drugs.'

The UN Sub-Commission on Human Rights Promotion and Protection continued to develop the area of access to life-saving medicines in relation to the right to health. In this process, two main resolutions were subsequently adopted. The first one is resolution 2002/32, which is also important because it endorsed the Doha Declaration on the Agreement on Trade-related Aspects of Intellectual Property Rights and Public Health (Doha Declaration) and also stressed the importance of having the TRIPs Agreement as 'part of the wider national and international action to address the problems of access to medicines.'[63] This resolution is important because it made it possible to view the implementation of the Doha Declaration as being in conformity with the right to health. In its subsequent resolution 2004/26, the UN Sub-Commission on Human Rights Promotion and Protection further urged states 'to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the TRIPs Agreement[.]' This resolution builds upon the previous one by requiring specific measures to be undertaken which includes domestic law reforms in the area of patents in order to provide for TRIPs Agreement flexibilities whenever necessary.

In 2006, another UN Political Declaration on HIV and AIDS was adopted with a much clearer focus on specifically the issue of access to life-saving treatment and intellectual property rights protection. It is therefore amongst the first UN documents to have established a clear link between access to life-saving medicines and intellectual property. In this regard, the Member states of the UN had resolved 'to assist developing countries to enable them to employ the flexibilities outlined in the TRIPs Agreement, and to strengthen their capacities for this purpose.'[64] It is clear from this resolution that intellectual property rights protection affected access to affordable life-saving medicines and it was therefore necessary to propose

[62] Decision on the Interim Report on HIV and AIDS, Tuberculosis, Malaria and Polio, 2005, [Assembly/AU/Dec 55 (IV)], para 7.
[63] Resolution 2002/32, para 7.
[64] Political Declaration on HIV and AIDS, 2006, [A/Res/60/262], para 44.

more action taken including providing an assistance programme based on the TRIPs Agreement flexibilities framework for developing countries. In 2006, the AU noted at its Special Summit on HIV and AIDS, tuberculosis and malaria that one of the key obstacles and challenges is still inadequate access to essential medicines across Africa.[65] In calling for accelerated action towards universal access to HIV and AIDS, tuberculosis and malaria services by 2010, the AU still considered these three diseases as a state of emergency in Africa.[66] With regards to access to affordable medicines and technologies, it provided as follows:[67]

- To enact and utilize appropriate legislation and international trade regulations and flexibilities, to ensure the availability of medicine and commodities at affordable prices as well as technologies for the treatment, care and prevention of HIV and AIDS, tuberculosis and malaria including vaccines, medicines and [ARVs].
- To promote regional bulk purchase and local production of generic medicines and other commodities.
- Support work on regional production of generic [ARVs].

The ACHPR in 2008 also enacted a resolution on access to health and needed medicines in Africa,[68] which specifically clarified the obligations of the government with respect to access to health and needed medicines in Africa. Thus it called on states to fulfill their duties with respect to intellectual property and access to medicines as subsequently explained. With regards to promotion,

> refraining from measures that negatively affect access, such as…implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO Agreement on Trade Related Aspects of Intellectual Property that promote access to affordable medicines, including entering 'TRIPs Plus' free trade agreements.

With regards to protect, states should 'protect access to needed medicines from actions by third parties through regulatory systems that…stimulate and promote competition, intellectual property, consumer protection and other laws to promote access to medicines.' Lastly, with regards to fulfill, states are required to adopt

> all necessary and appropriate positive measures to the maximum of its available resources to promote, provide and facilitate access to needed medicines, including: immediately

[65] Abuja Call for Accelerated Action Towards Universal Access to HIV and AIDSHIV and AIDS, Tuberculosis and Malaria Services, 2006, [Sp/Assembly/ATM/2(1) Rev.3, para 7.
[66]As above, para 10.
[67]As above.
[68] Resolution on access to health and needed medicines in Africa, [ACHPR/Res141(XXXXIIII)08.

> meeting the minimum core obligations of ensuring availability and affordability to all of essential medicines as defined by the country's essential medicines list and the WHO Action Programme on Essential Drugs; immediately creating a national medicine strategy monitoring systems to ensure compliance with human rights obligations; promoting meaningful participation by affected individuals and groups in decisions that affect access to medicines, including regulatory, pricing and patent decisions; creating systems in which patent information and registration status for medicines is readily and publicly accessible; expediting the regulatory review and registration of needed medicines and creating incentives for companies to register needed medicines expeditiously; [and] individually and together with other States and non-governmental entities, developing and implementing need-based research and development programmes to address currently neglected diseases and conditions[.]

In June 2011, the UN Political Declaration on HIV and AIDS set to intensify efforts to eliminate HIV and AIDS.[69] In this declaration, the link between intellectual property and access to medicines was also made in a much stronger language than the one stated in the 2006 Political Declaration on HIV and AIDS. Thus its paragraph 71(a) provided that by 2015 states should take certain measures including amending national laws and regulations so as to optimize:

> The use, to the full, of existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights Agreement specifically geared to promoting access to and trade of medicines, and, while recognizing the importance of the intellectual property rights regime in contributing towards a more effective AIDS response, ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities, as confirmed by the Doha Declaration on the TRIPs Agreement and Public Health, and call for early acceptance of the A/65/L.77 12 11-36784 amendment to article 31 of the TRIPs Agreement adopted by the General Council of the World Trade Organization in its decision of 6 December 2005[.]

From the foregoing, the commitment to provide access to life-saving treatment gave rise to state obligations which was a development away from the provision of assistance by the UN. Using the TRIPs Agreement flexibilities, the UN had made it clear that access to life-saving medicines in developing countries gave rise to obligations on the part of the government to take certain measure including the amendment of laws and regulations.

4.4.3 Access to all medicines

The Human Rights Council (HRC) was established in 2006. The HRC is responsible for the global strengthening of human rights promotion and protection. The HRC also engaged with

[69] Political Declaration on HIV and AIDS: Intensifying our efforts to eliminate HIV and AIDS, UN Doc. A/65/L.77.

the issue of access to medicines and adopted several resolutions. A key focus for the HRC has been among others the enforcement of intellectual property rights as opposed to protection of intellectual property rights and access to medicines in a general sense. The Commission on Human Rights that preceded the HRC focused mainly on medications for HIV and AIDS.

In 2009, the second Special Rapporteur on the right to health, Anand Grover, published a report on access to medicines and the right to health especially from the intellectual property point of view. According to him, as a result of product patents, intellectual property law has an impact on the right to health by allowing a patentee to set higher prices.[70] Thus in order to promote competition by lowering the number of patents granted, countries should adopt higher as opposed to lower patentability criteria argues the Special Rapporteur.[71] Noting the importance of generic medicines in lowering prices of HIV medications from as high as US$ 10,000 per patient per year to US$ 350 per patient per year, the Special Rapporteur noted that the post-2005 TRIPs Agreement period will pose challenges in terms of the manufacture and the importation of generic medicines owing to the new obligations of states under TRIPs.[72] In the interest of public health, the Special Rapporteur argued that countries should be allowed to use the following TRIPs flexibilities:

> (a) make full utilization of the transition periods; (b) define the criteria of patentability; (c) issue compulsory licenses and provide for government use; (d) adopt the international exhaustion principle to facilitate parallel importation; (e) create limited exceptions to patent rights; and (f) allow for opposition and revocation procedures.[73]

The Special Rapporteur also noted the pressure imposed on developing countries by developed countries and multinational corporations in the context of utilizing TRIPs Agreement flexibilities.[74]

Apart from the utilization of TRIPs flexibilities, the Special Rapporteur on right to health also addresses the issue of Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs), which he observed are bad because they lack 'transparency or

[70] 'Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health' A Grover, 31 March 2009, [A/HRC/11/12], para 17-18.
[71] As above, para 18.
[72] As above, para 20-21.
[73] As above, para 27.
[74] As above, para 56.

participation from the public, and often establish TRIPs plus provisions, which undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPs.'[75] He urged countries to analyze such multilateral or bilateral agreements for potential health violations and insist on transparency and openness at all stages of negotiations.[76] In his view, the TRIPs plus provisions in FTAs can serve one or more of the following purpose: 'extend the patent term; introduce data exclusivity; introduce patent linkage with drug registration and approval; and create new enforcement mechanisms for intellectual property rights.'[77]

In October 2009, HRC resolution 12/24 incorporated some of the proposals made by the UN Special Rapporteur on Health and encouraged 'all states to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures.'[78] The focus here was that the enforcement of intellectual property rights should not be a barrier to trade in medicines and that safeguards should be put in place to guarantee that such measures and procedures for enforcing intellectual property rights will not be abused. Illustratively, as will be discussed in a separate chapter, a key safeguard for access to medicines in the context of anti-counterfeiting is to delink patents from anti-counterfeiting legislation.

In March 2011, HRC resolution 16/28 was adopted focusing on enforcement. The resolution 'encourages all states to apply measures and procedures to enforce intellectual property rights in a manner that avoids the creation of barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures, taking into account, inter alia, the [Doha Declaration].'[79] The key addition here is the fact that the Doha Declaration should at all times be taken into account while enforcing intellectual property rights domestically. Around the same time, the Special Rapporteur on the right to health had identified as one of the emerging challenges in the area of access to medicines,

[75] As above, para 69.
[76] As above, para 70.
[77] As above, para 75.
[78] HRC resolution 12/24, 2009, UN Doc A/HRC/RES/12/24, para 6.
[79] HRC resolution 16/28, March 2011, UN DOC A/HRC/Res/16/28, para 19.

the issue of 'ensuring access to medicines for non-communicable or chronic diseases.'[80] It would be important in the future that the Doha Declaration is expanded to include also non-communicable diseases in addition to HIV and AIDs, tuberculosis and malaria.

In July 2011 the HRC adopted resolution 17/14, which called on states '[t]o promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which provide flexibility for that purpose, recognizing that the protection of intellectual property is important for the development of new medicines as well as the concerns about its effects on prices'.[81] It should be noted that this resolution focused on the development of medicines and not just access to medications and thus the moderate language, which calls for intellectual property protection as well as utilization of TRIPs flexibilities.

In 2013, the Special Rapporteur on the right to health undertook another extensive study focusing on the existing challenges and good practice with regards to access to medicines in the context of the right to health as mandated by the UN HRC resolution 17/14.[82] According to the Special Rapporteur, the right to health framework is composed of the following key elements that ensure access to medicines as derived from paragraph 12 of CESCRs General Comment 14):: availability, accessibility, acceptability and quality as key elements of the right to health.[83] This report is especially relevant in this study and will be referred to throughout the subsequent chapters of this study, where it is deemed appropriate. Thus, the substantive contents of this report will not be set out here in order to avoid unnecessary duplications.

Perhaps the clearest indication that the HRC intended to broaden the scope of the right to health beyond access to ARVs to all medications is the June 2013 resolution 23/14 of the HRC. This resolution focused on access to medicines for everyone as opposed to ARVs only that had been hitherto stressed upon. Most importantly, it 'recognizes that access to

[80] Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health: Expert consultation on access to medicines as a fundamental component of the right to health, Anand Grover, 16 March 2011, [A/HRC/17/43], para 48.
[81] HRC resolution 17/14, July 2011, UN Doc A/HRC/Res/17/14, para 7(g).
[82] 'Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health', Anand Grover, 1 May 2013, [A/HRC/23/42], para 1.
[83] As above, para 8.

medicines is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'[84] In this regard therefore unlike sub-Commission on Human Rights resolution 2001/33, access to medicines as a right to health is not limited to pandemics such as HIV and AIDS.

Among other things, the HRC resolution 23/14 urged states to 'use, to the full of the provisions of the [TRIPs] Agreement which provide flexibility for that purpose, recognizing that the protection of intellectual property is important for the development of new medicines, as well as the concerns about its effects on prices.'[85] This paragraph is conflicted because on one hand it notes that pharmaceutical patents are important for development of new medicines but on the other hand it also recognizes that pharmaceutical patents have an impact on medicine prices. In this regard, it adopts a middle ground with regards to pharmaceutical patents.

The HRC resolution 23/14 also urged states to 'apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of affordable, safe, efficacious and quality medicines, and to provide for safeguards against the abuse of such measures and procedures.'[86] This paragraph focuses on the intellectual property enforcement by noting that they should be implemented in manner that does not create a barrier to legitimate trade and also through providing safeguards against potential abuse of such measures and procedures. Consequently, if pharmaceutical patents are to stay then its enforcement should not undermine legitimate trade for instance in generics.

The resolution further urged states '[t]o ensure that investment, industrial or other policies promote development and access to medicines, in particular their affordability.'[87] This paragraph notes the critical role played by investment and industrial policies in the

[84] HRC resolution 23/14, June 2013, A/HRC/Res/23/14, para 2.
[85] As above, paragraph (h).
[86] As above, paragraph (j).
[87] As above, para (m).

development and affordability of medicines. It is therefore incumbent upon authorities not to sacrifice affordability of medicines in particular.

At the regional front, in 2013, the AU in a progress report also recognized that, amongst other things, 'a critical enabler to a sustainable AIDS and tuberculosis response remains an intellectual property framework that is sensitive to public health objectives.'[88] In that report, the following was recommended: '[S]trengthen review of laws and measures to fully incorporate and utilize all public health related [TRIPs Agreement] flexibilities and to avoid limits on the use of public health related TRIPs flexibilities.'[89]

From the above, it appears that the scope of the application of the right to health has moved from the focus on access to essential medicines as advocated by the General Comment 14, to a focus on life-saving medicines in the context of HIV and AIDS medications as was advocated for by the UN Sub-Commission on Human and Peoples' Rights, and lastly, to access to medicines in the broadest sense as advocated for by the HRC. The UN has focused more on HIV and AIDS medications while the AU has expanded the list to include malaria and tuberculosis. The norms relating to right to health and access to medicines are relatively clear and comprehensive at the international level including at the African continental level. In summary, states are required to utilize to the maximum the flexibilities under TRIPs Agreement and also avoid taking measures that may limit the use of TRIPs Agreement flexibilities in order to provide affordable medicines including generics in the health care system for all. In particular, enforcement measures adopted should not hinder legitimate trade in medicines and in this regard safeguards should be put in place.

4.5 The obligations of the State

4.5.1 Obligations to respect, protect and fulfil

The right to health, like many other human rights, imposes three main obligations on the State, namely: obligation to *respect;* obligation to *protect;* and obligation to *fulfil*.[90] The

[88] Implementation of the Abuja Call for Accelerated Action Towards Universal Access to HIV and AIDSHIV and AIDS, Tuberculosis and Malaria Services, 2013, Progress Report 2010-2012, [Sp/Assembly/ATM/II(IV), para 44.
[89] As above.
[90] General Comment 14 n 10 above, para 33. It provides that '[t]he right to health, like all human rights, imposes three types of obligations on State parties: the obligations to *respect, protect* and *fulfil.* In turn, the obligation to

obligation to fulfil also connotes the obligations 'to facilitate, provide and promote.'[91] In the African context, the obligation to *promote* has been recognised independently of the obligation to *fulfil.*[92] To begin with, the obligation to *respect* requires that the State should 'refrain from interfering either directly or indirectly with the enjoyment of the right to health.'[93] Consequently, the State would be in violation of the obligation to *respect* under the right to health if, among other things, its actions, policies or laws contravened the standards set out under the right to health.[94] In particular, the State would be in violation of the right to health if it adopted 'laws or policies that interfere with the enjoyment of the right to health.'[95] Similarly, adopting incompatible legislation or policies with pre-existing right to health domestic or international legal obligations would amount to the violation of the obligation to *respect* under the right to health.[96] Secondly, the obligation to *protect* requires states 'to take measures to prevent third parties from interfering with Article 12 guarantees.' Lastly, the obligation to *fulfil* requires states 'to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.'[97] In the context of pharmaceutical trade policies, the obligation to *respect* is often at stake as explained above.

In addition, with regards to the obligation to respect, the need to safeguard public health may result into ambiguous results. For instance, it remains a matter of dispute as to what extent the practice of 'alternative' medicines is restricted or prohibited.[98] Under obligation to protect, the substantive aspect of the right to health is the right to enjoy 'a social order in

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fulfil contains obligations to facilitate, provide and promote. The obligation to *respect* requires states to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires states to take measures that prevent third parties from interfering with article 12 guarantees. Finally, the obligation to *fulfil* requires states to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.

[91] As above.

[92] 'ACHPR 'Principles and guidelines on the implementation of economic, social and cultural rights in the African Charter on Human and Peoples' Rights', paras 8 & 9. The obligation to promote includes the creation of awareness and information sharing. It also includes promoting values and objectives of economic, social and cultural rights in judicial decision-making.

[93] General Comment 14, para 33.

[94] As above, para 50.

[95] As above.

[96] As above, para 48.

[97] As above, para 33.

[98] A Eide 'Economic and social rights' in J Symonides (ed) *Human rights concepts and standards* (2000) 154.

which protective measures have been taken by or through the encouragement of the state to remove as far as possible the causes of ill-health, and to prevent as far as possible epidemic, endemic, and other diseases.'[99] This obligation also includes the obligation to regulate corporations and private sector in the health sector. The obligation to facilitate: International instruments also require states to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health.[100] As regards obligation to fulfil, Article 12(2)(d) of ICESCR, states are required to create 'condition which would assure all medical service and medical attention in the event of sickness.' The specific obligation of states with regards to providing access to healthcare for their populations, however, still remains vague. Special attention has been paid to mother and child care, as enshrined in several international instruments.[101]

For most developed, industrialised countries it would be possible to organise 'an all-embracing system, which is funded partly by obligatory contributions by all who can pay them, but extended to all on a basis of near-equality, even to those who have been unable to contribute.' Developing countries however have fewer possibilities for direct assistance, 'though this varies greatly with their level of GNP/per capita and with several factors such as urbanization ratio.' A low-cost primary health care should be the focus instead of having in place expensive health care facilities in the urban centres.[102]

4.5.2 Progressive realization and minimum core

The obligations of the government under the right to health include the obligation to: take steps, as well as to utilize maximum available resources. These concepts have been elaborated upon below.

a. "Take steps"

The concept of taking steps is closely associated with the concept of progressive realization. General Comment 3 of the CESCR dealing with the nature of States parties' obligations

[99] As above.
[100] As above.
[101] As above.
[102] As above.

(General Comment 3) is therefore directly relevant.[103] The General Comment 3 observes that Article 2 of the Covenant has 'a dynamic relationship with all the other provisions of the Covenant.'[104] The document contends that in order to understand the nature of state party's obligations one must appreciate in the context of the need to realize economic and social rights progressively and the limits of state resources the existence of immediate obligations on the part of the state including non-discrimination.[105] In terms of the undertaking 'to take steps' under Article 2(1), the steps should 'be deliberate, concrete and targeted as clearly as possible towards meeting the obligations recognized in the Covenant.'[106] The document also observes that apart from legislation other measures that may be appropriate is the provision of judicial remedies for economic and social rights.[107] The document realizes that the principal obligation of progressive realization recognizes 'the fact that full realization of all economic, social and cultural rights will generally not be able to be achieved in a short period of time.'[108] This however does not deprive the obligation of all meaningful content and that:[109]

> It is on the one hand a necessary flexibility device, reflecting the realities of the real world and the difficulties involved for any country in ensuring full realization of economic, social and cultural rights. On the other hand, the phrase must be read in light of the overall objective, indeed the raison deter, of the Covenant which is to establish clear obligations for State parties in respect of the full realization of the rights in question. It thus imposes an obligation to move as *expeditiously* and *effectively* as possible towards that goal. Moreover, any deliberately retrogressive measure in that regard would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources. (My emphasis)

With respect to minimum core obligations, the document provides that State parties should ensure that they are satisfied since they are the 'minimum essential levels of each rights'.[110]

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[103] General Comment 3 of the Committee on Economic, Social and Cultural Rights: The nature of states parties' obligations (Article 2, Para 1), Adopted at the Fifth Session of the Committee on Economic, Social and Cultural Rights, on 14 December 1990 [contained in Document E/1991/23].
[104] As above, para 1.
[105] As above.
[106] As above, para 2.
[107] As above, para 5.
[108] As above, para 9.
[109] As above.
[110] As above, para 10.

All efforts must be expended to ensure the implementation of minimum core obligations and they must be a prioritized.[111]

b. "Maximum available resources"

The phrase 'to the maximum of its available resources' 'refers to both the resources existing within a State and those available from international community through international cooperation and assistance.'[112] In this regard, the State cannot rely on the fact that it lacks resources internally in order to meet its obligations under the right to health. It must show that it has looked for resources from the international community in form of development assistance before it can be allowed to rely on this element to explain any challenges in realization of the right to health.[113]

4.5.3 Non-discrimination principle

The General Comment 20 on non-discrimination in economic, social and cultural rights under section 2(2) establishes that non-discrimination is an immediate and cross-cutting obligation in the Covenant.[114] Discrimination therefore

> constitutes any distinction, exclusion, restriction or preference or other differential treatment that is directly or indirectly based on the prohibited grounds of discrimination and which has the intention or effect of nullifying or impairing the recognition of, enjoyment or exercise, on equal footing, of Covenant's rights. Discrimination also includes incitement to discriminate and harassment.

Under General Comment 20, both direct and indirect discrimination is covered. The former referring to a less favorable treatment of an individual based on the prohibited grounds.[115] The latter refers 'to laws, policies or practices which appear neutral at face value, but have disproportionate impact on the exercise of Covenant rights as distinguished by prohibited

[111] As above.
[112] As above, para 13.
[113] As above.
[114] General Comment 20 on non-discrimination in economic, social and cultural rights (art. 2, para 2), para 7.
[115] As above, para 10(a).

grounds of discrimination.'[116] However, there is also a permissible scope of differential treatment provided that it is 'reasonable and objective.'[117]

4.6 Violations of the right to health

The main instruments include General Comment 14, the Limburg principles and the Maastricht guidelines.

4.6.1 Inability and unwillingness to comply

It is important in the context of violations to distinguish between inability and unwillingness to comply. Accordingly, General Comment 14 deals with violations of Article 12 and notes that a distinction must always be made between inability and unwillingness to comply.[118] This is because Article 12(1) only requires the highest attainable standard of health and Article 2(1) also recognizes resource limitations.[119] Under the Maastricht guidelines,[120] the distinction of inability from the unwillingness of a State to comply with its treaty obligations is explained as follows:

> A state claiming that it is unable to carry out its obligation for reasons beyond its control has the burden of proving that this is the case. A temporary closure of an educational institution due to an earthquake, for instance, would be a circumstance beyond the control of the State, while the elimination of a social security scheme without an adequate replacement programme could be an example of unwillingness by the State to fulfil its obligations.[121]

Notwithstanding this, 'a state party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are non-derogable.'[122]

With special reference to access to medicines, the violation of the obligation to respect may be as a result of taking into account the right to health obligations in the context of entering

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[116] As above, para 10(b).
[117] As above, para 13. According to the General Comment 20 this will include 'an assessment as to whether the aim and effects of the measures or omissions are legitimate, compatible with the nature of the Covenant's rights and solely for the purpose of promoting the general welfare in a democratic society.'
[118] As above, para 47.
[119] As above.
[120] International Commission of Jurists (ICJ), *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, 26 January 1997, http://www.refworld.org/docid/48abd5730.html (accessed 11 July 2018).
[121] As above.
[122] General Comment No 14 n 10 above, para 47.

into 'bilateral or multilateral agreements with other states, international organizations and other entities, such as multinational corporations.'[123] The obligation to protect may be violated through failing 'to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others[.]'[124] Lastly, the obligation to fulfill may be violated by the failure to 'adopt or implement a national health policy designed to ensure the right to health for everyone.'[125]

4.6.2 Effective use of resources

The issue of resources is usually at the core of the implementation of economic, social and cultural rights. The Limburg principles deal with the issue of effective use of resources. In this document, it was clarified that the '[t]he obligation of progressive achievement exists independently of the increase in resources; it requires effective use of resources available.'[126] As such, states' cannot point to a lack of increase in resources to justify a lack of progress. What is more, respect for minimum core elements is guaranteed regardless of the level of economic development.[127] The violations of ESCRs means '[a] failure by a State party to comply with an obligation contained in the Covenant is, under international law, a violation of the Covenant.'[128]

4.6.3 Obligations of conduct and of results

Under the Maastricht guidelines[129] the meaning of violations of economic, social and cultural rights is further elaborated by the introduction of the concepts of obligations of conduct and of result. Under paragraph 7, it is observed that

> the obligations to respect, protect and fulfil each contain elements of obligation of conduct and obligation of result. The obligation of conduct requires action reasonably calculated to

[123] As above, 50.
[124] As above, 51.
[125] As above, 52.
[126] UN Commission on Human Rights, *Note Verbale dated 5 December 1986 from the Permanent Mission of the Netherlands to the United Nations Office at Geneva addressed to the Centre for Human Rights ("Limburg Principles")*, 8 January 1987, para 23 [E/CN.4/1987/17], http://www.refworld.org/docid/48abd5790.html (accessed 11 July 2016).
[127] As above, para 25
[128] As above, para 70.
[129] Maastricht Guidelines n 120 above, 70.

> realize the enjoyment of a particular right. In the case of the right to health, for example, the obligation of conduct could involve the adoption and implementation of a plan of action to reduce maternal mortality. The obligation of result requires states to achieve specific targets to satisfy a detailed substantive standard. With respect to the right to health, for example, the obligation of result requires the reduction of maternal mortality to levels agreed at the 1994 Cairo International Conference on Population and Development and the 1995 Beijing Fourth World Conference on Women.

4.6.4 Margin of discretion

With regards to margin of discretion, the Maastricht guidelines clarify that the state has the burden to demonstrate that it is taking appropriate steps that can be measured to realise a human right.[130] Similarly, under Limburg Principles, states are afforded a margin of discretion to carry out its objectives and this includes taking into account factors beyond its control that may affect its capacity to undertake its obligations.[131]

4.7 The status of the 'access' norm: Is it formal or informal?

Having elaborated the international right to health framework, a critical question that remains to be answered is whether access to medicines is a formal or informal norm. The distinction between a formal and an informal norm is important because a formal norm is easier to implement and an informal norm requires more consensus building before it can be implemented. So for instance, the right to life-saving medicines may be a formal norm but the right to access to medicines in a more general manner may be an informal norm and therefore hard to implement even at the local level.

To begin with, Sellin contends that the right of access to medicines under international law is recognized formally under the ICESCR.[132] Sellin also contends that the ICESCR and the TRIPs Agreement do not necessarily contain mutually exclusive obligations.[133] In this regard, patents and the right of access to medicines are not directly at conflict with each other even though some tensions between the two fields could exist.[134] Sellin further contends that this tension can be resolved through interpreting the TRIPs Agreement in a manner that

[130] As above.
[131] As above, para 71.
[132] Sellin n 26 above, 438-439.
[133] As above.
[134] As above, 28.

promotes and protects human rights.[135] Consequently, Sellin observes that the 'pro-development interpretation of and implementation of the TRIPs Agreement should allow developing members to strike a balance between complying with their obligations under TRIPs [Agreement] and international human rights law.'[136] She also notes that the role of human rights norms including the right to health and social movements is crucial in ensuring that the patent system does not undermine the priority health needs of the global poor.[137] In this regard, to the extent that Article 2 of the Constitution of Kenya recognizes the ICESCR as being part of the laws in Kenya then access to medicines is a formal norm in Kenya.

However, Hein, Moon and Poku categorize access to medicines norms as an informal norm.[138] The main reason appears to be that the access norm is still highly contested in many spaces and in this regard it cannot be regarded as a formal norm. These authors contend that the access to medicines norms are informal because they are still under steady attack from trans-national pharmaceutical companies and the industrialised countries in terms of their push for stringent intellectual property rights norms in the developing world.[139]Below is an example of this contestation.

In South Africa, a country considerably more economically and politically developed than Kenya and many other developing countries, a decision to amend the Medicines and Related Substances Control Act of 1965 in 1997 led to international sanctions and court cases against South Africa largely by developed countries led by the United States and dozens of pharmaceutical companies.[140] In retaliation, a group of pro-access to medicines civil society actors led by the *Médecins Sans Frontières* (MSF) launched an international campaign that eventually saw the pharmaceutical companies and the United States back off from attacking

[135] As above.
[136] As above, 457.
[137] As above, 458.
[138] W Hein, S Moon, & NK Poku *Informal norms in global governance: Human rights, intellectual property rules and access to medicines* (2013) 140.
[139] As above, 142.
[140] See generally H Mwakyembe, GM Kaya & M Munkhondla 'Implications of the TRIPS Agreement on access to cheaper pharmaceutical drugs by developing countries: Case study of South Africa vs The Pharmaceutical companies, Research paper in partial fulfillment of the award of Post-Graduate certificate in intellectual property at WIPO Worldwide Academy and the faculty of Law University of Turin, November 2001, http://www.turin-ip.com/course-documents/documents-2007/archive/2007-edition/papers/papers-2001/KanjaMunkhondiaMwakyembe.pdf-1 (accessed 25 April 2015).

South Africa from taking actions to protect its public health, which was indeed a major victory for access to affordable medicines in South Africa.[141] The case was therefore not concluded in court and it is not clear how this would have ended. However, the point to be made here is that if access to medicines was regarded as a formal norm it would not have faced such challenges from pharmaceutical companies in the first place. It seems like there was no consensus amongst all actors on this front at least in South Africa then and thus the stand-off. However, the import of this case is that it demonstrated the power held by civil society in terms of advocating for access to medicines and their ability to deliver change even in the face of a formidable adversary like big pharmaceutical companies around the world. As noted by Mbali, 'this successful campaign against the court case had meaningful impacts for poor patients in developing countries. This favourable outcome permanently altered the politics of HIV drug pricing and, in a broader sense, global health in developing countries.'[142]

In light of the above experience in South Africa, Hein, Moon and Poku also contend that there is need to strengthen the access to medicines norms since it has only been stable in the HIV and AIDS world but remains highly contested elsewhere.[143] These authors further contend that strengthening the access norm can happen through one of the following ways: the formalization of the access norm either through national or international law; and/or the reframing of the norm to incorporate innovation.[144]

In Kenya, notwithstanding the contestation above regarding the exact nature of the access norms activists have been to court and successfully challenged the anti-counterfeit legislation in Kenya for being against the right to health in the case of *PAO & 2 Others v AG*.[145] To the extent that the High Court sided with the activists it seems that access to medicines

[141] 'Drop the case! Support the struggle for medicines in South Africa' (8 March 2001) MSF Access Campaign, http://www.msfaccess.org/about-us/media-room/press-releases/drop-case-support-struggle-medicines-south-africa (accessed 25 April 2016).
[142] Mbali, M 'Pharma v Mandela: South African moral capital in a global movement, 1998-2001' in Mbali M *South African AIDS Activism and global health politics* (2013) 136.
[143] Hein, Moon & Poku n 139 above, 142.
[144] As above.
[145] *PAO & 2 Others v AG & 2Others* [2012] eKLR.

norms in Kenya can no longer be regarded as informal but formal norms. This is point number two.

Also, the Special Rapporteur on the right to health has decried the use of pressure by developed countries to intimidate developing countries in the context of TRIPs Agreement implementation.[146] It therefore follows that intimidation of developing countries does not translate into making informal the access norms.

From the above, it appears that internationally and perhaps in many countries the access to medicines norm is still informal. However, in Kenya, the norm may be formal as a result of the ICESCR, which is part of the Kenyan law pursuant to Article 2 of the Constitution, and the *PAO* case.

4.8 Conclusion

Within the general human rights approach to development are debates on the exact role human rights can play in development. One such role is the introduction of legal obligations in the context of development. The right to health being the most comprehensive set of norms in relation to international trade rules has been adopted in this study. The right is also recognized and enshrined in the Kenyan Constitution thereby imposing on the state the obligations to respect, protect and fulfil access to medicines for all. The international legal framework on right to health encompasses both the right to health care and the underlying determinants of health. Access to medicines is principally located in the right to health care. According to Sellin, '[t]he right of access to medicines requires, firstly that access is guaranteed on a non-discriminatory basis and, secondly, entails the following elements: availability, physical accessibility, affordability, cultural acceptability, and good quality of essential medicines.'[147] This is the broader meaning of access. This study only focuses on the narrow meaning of access, which is affordability of medicines and especially essential medicines. Under General Comment 14, essential medicines are expressly recognized as forming part of the non-derogable minimum core elements under Article 12 of the ICESCR.

[146] Report of the Special Rapporteur on the right to health n 70 above, 56.
[147] Sellin n 26 above, 121.

Through the 'soft' laws, it also emerges that access to medicines particularly for HIV and AIDS treatment has preoccupied both the UN and the AU and by extension the member states of these institutions. Under the HRC resolution 23/14, however, the broader access to medicines as opposed to the narrower access to essential medicines has been interpreted to constitute also a fundamental component of the right to health. This development is important because while its desirable to focus on essential medicines because of the priority needs of a country, new challenges especially in the area of non-communicable diseases are also emerging and some of the medicines required to treat these diseases are not yet contained in the EML. The right to health framework should be able to allow countries sufficient latitude to deal with emerging situations pending the listing of medicines in the EML by WHO and subsequently at the national level. In terms of violations, the Limburg principles and Maastricht guidelines provide clear guidance with regards to the obligations of the state under the ICESR including the right to health. A key factor is the issue of resources which according to the above guidelines require that resources should be used effectively. Approached this way, the state cannot abdicate its duty of ensuring access to medicines by pointing at resource constraints. The onus is on the state to prove that available resources are used effectively. Lastly, the 'access' norm is still being defined and recent scholarships have also emphasized the innovation component. A more universal concept of 'access' including under the right to health therefore will have to incorporate some aspects of innovation in addition to focusing on access.

CHAPTER FIVE: ECONOMIC SOCIAL AND CULTURAL RIGHTS MEASUREMENT METHODOLOGIES INCLUDING THE MECHANISM OF HUMAN RIGHTS IMPACT ASSESSMENT

5.1 Introduction

The previous chapter discussed right to health norms that may be used in relation to the implementation of the TRIPs Agreement. It emerges that there is a sufficient legal basis for developing countries that have ratified the International Covenant on Economic, Social and Cultural Rights (ICESCR) and other instruments enshrining the right to health to implement their obligations on access to medicines as a fundamental component of the right to health. In this regard, depending on the specific context, different methodologies may be used at the national level. In this chapter, the focus shifts to the methodologies available for the implementation of especially economic, social and cultural rights (ESCRs) in order to determine the appropriate methodology that should be employed in relation to resolving the adverse impacts of pharmaceutical trade policies. The ESCRs methodologies may be discussed under three main categories as follows: indicators and benchmarks; indexes; and impact assessment including human rights impact assessment (HRIA). The main argument advanced in this chapter is that the HRIA is best suited to resolve *beforehand* the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya using the right to health framework. The other methodologies may be useful in different contexts but they may not deliver the same results as HRIA. All these methodologies are discussed separately below.

5.2 Indicators and benchmarks

According to Green, benchmarks and indicators are distinct terms when one considers human rights literature.[1] On the one hand, benchmarks may be defined as 'goals or targets that are specific to the individual circumstances of each country.'[2] Benchmarks is therefore usually about measuring performance relative to standards that have been defined

[1] M Green 'What we talk about when we talk about indicators: Current approaches to human rights measurement' (2001) 23 *Human Rights Quarterly* 1073.
[2] As above.

independently and in the context of ESCRs they are sometimes known as minimum thresholds.[3] On the other hand, indicators measures 'human observation or enjoyment in absolute terms.'[4] The use of indicators and benchmarks is popular in different contexts as discussed below.

5.2.1 OHCHR's structural, processes and outcome indicators

The use of indicators is actively being promoted by the OHCHR. The movement towards the use of indicators began in earnest at the request of the inter-committee of the treaty bodies.[5] This request came from the fact that the treaty bodies were experiencing difficulties in terms of analyzing and making use of the statistical information being presented by State Parties' including Kenya in line with their treaty obligations.[6] The OHCHR was therefore requested for assistance in this regard.[7] The development of indicators at OHCHR is aimed at ensuring that the monitoring bodies at the UN and especially the treaty bodies can be able to make effective use of statistical information in measuring human rights compliance of State Parties appearing before them.

OHCHR defines human right indicator as

> specific information on the state or condition of an object, event, activity or outcome that can be related to human rights norms and standards; that addresses and reflects human rights principles and concerns; and that can be used to assess and monitor the promotion and implementation of human rights.[8]

Accordingly, the OHCHR regards the use of indicators as a more concrete and practical tool for enforcing human rights and measuring implementation.[9] The focus on indicators comes from the realization that general statistics in themselves are less effective and therefore

[3] As above.
[4] As above.
[5] As above, 5.
[6] As above, 5.
[7] As above, 5.
[8] OHCHR, Human rights indicators: A guide to measurement and implementation, (2012) 16, http://www.ohchr.org/Documents/Publications/Human_rights_indicators_en.pdf (accessed 23 July 2017).
[9] As above, 2.

there is need to progress towards identifying specific indicators that could also be used in monitoring human rights.[10]

Therefore, indicators can be both qualitative or quantitative with the former taking the character of any information articulated as a narrative or in a categorical form and the latter referring to statistics.[11] The OHCHR observes that the use of both qualitative and quantitative data is potentially useful because assessing human rights compliance is usually a complicated exercise.[12] Consequently, quantitative indicators usually facilitate the evaluation of qualitative data by for instance being able to measure the magnitude of certain events.[13] Similarly, qualitative information can also complement quantitative indicators in terms of interpretation.[14] In the context of human rights indicators, the OHCHR notes that human rights measurement should address the following issues:[15]

> What to measure? How to go about selecting potential indicators of what we want to measure? How many indicators are required to assess the implementation of a human right? Will the identified indicators used to rank countries according to their human rights performance?

To aide in the utilization of human rights indicators, the OHCHR has developed guidelines for use by stakeholders, which have so far been integrated in the work of both the Committee for Economic, Social and Cultural Rights (CESCR), which is responsible for monitoring the implementation ICESCR, as well as the Human Rights Committee, which is responsible for the implementation of the International Covenant on Civil and Political Rights (ICCPR). Currently the reporting guidelines of CESCR and HRC have been revised to provide for the reporting by government on disaggregated statistics and indicators for the rights under both the ICESCR and ICCPR; taking into account the framework and list of illustrative indicators developed by the OHCHR.[16]

[10]As above.
[11]As above, 16.
[12] As above, 17.
[13] As above.
[14] As above.
[15] As above, 28.
[16] As above, 6.

To enable the effective uptake of the use of indicators by other stakeholders, the OHCHR has also published a manual to assist in monitoring ESCRs using among others indicators.[17] The manuals could be expanded to cover thematic areas in order to encourage direct reporting including in the area of access to medicines in developing countries and elsewhere, if necessary. In relation to Kenya, the issue of access to medicines has not been a key focus in terms of state reporting. This may be illustrative of the problem at hand. There is low uptake on the use of indicators amongst the stakeholders in the access to medicines sector. This can be remedied if the proposal to publish the OHCHR manual using thematic areas is considered in terms of focusing on more thematic trainings including in the area of access to medicines. The OHCHR can partner with other stakeholders to implement this. Accordingly, the OHCHR considers three major steps in the use of indicators as follows:[18] structural indicators;[19] process indicators;[20] and outcome indicators.[21] In the process indicator, one could for instance identify the measures states could have taken specifically to extend access to essential medication.[22]

Suffice to note the use of indicators in OHCHR or elsewhere has not been without criticism especially from a trust perspective. This criticism boils down to the fact that indicators are usually qualitative in nature and therefore less influential in some cycles than quantitative

[17] OHCHR, Manual on human rights monitoring, http://www.ohchr.org/Documents/Publications/Chapter20-48pp.pdf (accessed 23 July 2017).
[18] See OHCHR n 8 above, 87.
[19] Under this category one can do the following: identify gaps in domestic law vis-à-vis international human rights law and obligations of State party to human rights treaties; identify gaps in public policy documentation on the issue under consideration with respect to international best practices; identify customary practices and domestic institutions seen as being relevant to the implementation of human rights obligations.
[20] According to OHCHR, the following points should be noted: process indicators should be contextually relevant and locally driven; multiple feasible process indicators may be desirable, if feasible; focus on administrative data for process indicators; and devise additional process indicators and interventions for implementing human rights based on global best practices. This should lead one to: identify target groups e.g. minority, indigenous people, women e.t.c; refine illustrative indicators for ongoing local programmes contributing to human rights implementation; and focus on national and local budgetary processes for mainstreaming human rights.
[21] In this segment, the OHCHR notes that the standard formulation of indicators are universally relevant but may need to be customized to specific target population groups.
[22] See OHCHR n 8 above, 80.

data.[23] As noted by Bui, since indicators are usually used to develop benchmarks, the function of benchmarks also suffers from the same weaknesses as indicators.[24]

5.2.2 Violation's approach

Apart from the OHCHR methodology discussed above, the use of indicators and benchmarks has also been suggested by academics in the context of state reporting but from a violation's approach. In the mid-1990s, Chapman proposed a 'violations approach' to be utilized for monitoring ESCRs if they are to be taken seriously.[25] Chapman argues that the current reliance on 'progressive realisation' standard to assess compliance by states is inexact and renders ESCRs difficult to monitor.[26] Chapman therefore proposes another approach focusing on the following three areas, monitoring violations: (1) resulting from government's actions and policies; (2) relating to discrimination patterns; and (3) relating to the failure by the state to fulfil its minimum core obligations in all rights.[27] Chapman notes that the violation approach is needed because of the failures in the utilisation of the progressive realisation approach to evaluate compliance with human rights obligations at the international level.[28] In this regard, at the crux of Chapman's 'violations approach' are the following observations:[29]

> What is being advocated here is the open and explicit adoption of a review process for evaluating compliance with the [ICESCR] which is consistent with the review processes used for other international instruments. While not labelling it as such, the Committee's current format for its concluding observations on state parties' reports approximates a 'violations approach', detailing the Committee's concerns and suggestions/recommendations. The Committee does not and cannot assess progressive realisation; if effective and systematic monitoring of [ESCRs] is to take place, then non-governmental organizations, governments, and human rights-monitoring bodies need to reorient their work to identifying and rectifying violations. This is not to diminish the importance of continuing with efforts to conceptualise

[23] AJ Rosga & ML Satterthwaite 'The trust in indicators: Measuring human rights' 27 (2009) *Berkeley Journal of International Law* 253-315.
[24] H Bui 'Human rights budgeting: Making governments accountable for economic, social and cultural rights' (2015) 2 *QMHRR* 1, 124, http://www.law.qmul.ac.uk/humanrights/Docs/hrlr/2015/176997.pdf (accessed 23 July 2017).
[25] AR Chapman 'A "violation approach" for monitoring the International Covenant on Economic, Social and Cultural Rights' (1996) 18 *Human Rights Quarterly* 23.
[26] As above.
[27] As above, 24.
[28] As above, 36.
[29] As above, 36-37.

> the content of the constituent rights in the Covenant and to develop indicators, but rather to separate these initiatives from the monitoring process.

Indeed, as noted above, the gaps that led Chapman to propose the violations approach may have already been addressed in the current human rights framework. Already, the normative contents of ESCRs have been elaborated and continue to be elaborated. It is therefore possible to use the violations approach to discuss government compliance with its obligations in relation to access to medicines.

In particular, the failure by the government to protect access to affordable generic medicines or regulate the work of pharmaceutical companies in developing countries can constitute a right to health violation. The government can also violate its right to health obligations by passing laws and policies that restricts the utilization of TRIPs Agreement flexibilities.

5.2.3 Minimum threshold or minimum core approach

Another effective use of indicators has been suggested in relation to the minimum threshold approach. In the 1980s, 'the minimum threshold approach' was popular with the Inter-American human rights system in relation to the implementation of ESCRs.[30] Minimum threshold approach requires the establishment of 'country-specific thresholds measured by indicators to determine for example what amounts to "the best attainable state of physical and mental health" or "necessary measures to protect the health of their people."'[31] The idea behind the 'minimum threshold approach is as follows:

> [I]t is possible to operationalize a minimal threshold for human rights realization by means of country-specific thresholds measured by indicators measuring nutrition, infant mortality, disease frequency, life expectancy, income, unemployment, etc. and indicators relating to food consumption (proneness to disease, premature death.[32]

Consequently, the minimum threshold approach could be utilized at the national or regional level to 'require state accountability for those policies, decisions, and practices' that would

[30] SC Agbakwa 'Reclaiming humanity: Economic, social and cultural rights as the cornerstone of African human rights' (2002) 5 *Yale Hum. Rts. & Dev. L.J.* 177, 213.
[31] As above 213.
[32] A Eide 'Realization of social and economic rights: The minimum threshold approach' (1989) 43 *I.C.J. Rev.* 40, 47.

violate ESCRs.[33] However, 'the minimum threshold approach' was thought to be too intrusive into the domains of executive and legislature in terms of their responsibilities for the allocation of resources as policy organs.[34] Arguably, due to this reason, it was not popular in Africa as it was in the Americas. Suffice to note, the term 'minimum threshold' is sometimes used synonymously as 'minimum core' as is with one of the CESCR documents on poverty and the implementation ICESCR, where it was noted that core obligations when grouped together 'establish an international minimum threshold that all developmental policies should be designed to respect.'[35]

In the 1990s, the progressive realization and minimum core obligations was introduced via the CESCR General Comment 3 on the nature of state parties' obligations.[36] According to General Comment 3, '[t]he concept of progressive realization constitutes a recognition of the fact that full realization of all economic, social and cultural rights will generally not be able to be achieved in a short period of time.' On the other hand, while the concept of minimum core is also dependent on resources, the CESCR General Comment 3 observes that 'a State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, failing to discharge its obligations under the Covenant.'[37] CESCR continues that '[i]f the Covenant [ICESCR] were to be read in such a way as not to establish such a minimum core obligation, it would be largely deprived of its raison d'etre.'[38] In other words, the ESCRs would have no essence at all if minimum core obligations are not satisfied

[33] Agbakwa n 30 above, 213.
[34] As above, 214.
[35] 'Substantive issues arising in the implementation of the international Covenant on Economic, Social and Cultural Rights: Poverty and the International Covenant on Economic, Social and Cultural Rights' CESCR, [UN Doc. E/C/2001/10], para 17. The actual paragraph provides that '[t]hus, the core obligations of economic, social and cultural rights have a crucial role to play in national and international developmental policies, including anti-poverty strategies. When grouped together, the core obligations establish an international minimum threshold that all developmental policies should be designed to respect. In accordance with General Comment 14, it is particularly incumbent on all those who can assist, to help developing countries respect this international minimum threshold. If a national or international anti-poverty strategy does not reflect this minimum threshold, it is inconsistent with the legally binding obligations of the State party.'
[36] General Comment 3 of the Committee on Economic, Social and Cultural Rights: The nature of states parties' obligations (Article 2, Para 1), Adopted at the Fifth Session of the Committee on Economic, Social and Cultural Rights, on 14 December 1990 [contained in Document E/1991/23], para 9.
[37] As above, para 10.
[38] As above.

in a country. In 2010, the ACHPR through its Principles and Guidelines on ESCRs[39] also expressly adopted the twin-notions of 'progressive realization' and 'minimum core'.[40]

On the flipside, the minimum threshold approach has been criticised for being too restrictive on states obligations. Olowu for instance has noted that this approach 'lends itself to escapist interpretations as it suggests that nothing more may be required of a state once it has demonstrated its compliance with the minimum standards.'[41] Olowu further argues that economic conditions in a country are not static and that since the minimum threshold approach relies on long term collection of statistics, the methodology is incapable of responding to short-term dynamic changes in a country.[42]

As noted above, the minimum threshold approach relies mainly on the minimum core approach as opposed to the progressive realization approach. The difference between minimum threshold approach and minimum core approach is that the former relies on long term collection of statistical data while the latter is based on the normative framework set by the treaty bodies. It can be argued that at the international level the minimum threshold approach has currently developed into the concept of minimum core approach under ICESCR's General Comment 14. Consequently, Forman and others have called for the concept of minimum core obligations to be strengthened under the right to health in order to 'produce a more feasible and grounded conception of legally prioritized health needs that could assist in advancing health equity.'[43] The relevance of the minimum threshold approach especially in Africa is therefore not far-fetched even though it may be couched as a minimum core approach. In the context of access to medicines, the government has the duty to provide

[39] Principles and guidelines on the implementation of economic, social and cultural rights in the African Charter on Human and Peoples' Rights.
[40] Pretoria Declaration on Economic, Social and Cultural Rights in Africa (2004) also contained the notions of minimum core and of progressive realization. Also, in ACHPR Communication 241/01: Purohit and Moore v The Gambia, the notions of minimum core and of progressive realization were tacitly accepted. However, the State Reporting Guideline of 1989 were silent on these notions.
[41] D Olowu *An integrative rights-based approach to human development in Africa'* (2009) 196.
[42] As above.
[43] L Forman, G Ooms, A Chapman, E Friedman, A Waris, E Lamprea, & M Mulumba 'What could a strengthened right to health bring to the post-2015 health development agenda?: interrogating the role of the minimum core concept in advancing essential global health needs' (2013) 13 *BMC International Health and Human Rights* 48.

essential medicines as part of their minimum core obligations.[44] This obligation cannot be violated even in the context of low resources. The WTO has continued to develop the concept of essential medicines in order to guide countries about the medicines that are essential and improve their availability at the national level.

From the foregoing, it appears that the use of indicators and benchmarks is widespread. It has been mainstreamed in the UN system especially for considering state reports in line with its obligations of the State under the applicable treaties. The UN applies mainly a 'progressive realization' approach while doing so in line with Article 2 of the ICESCR. However, as argued by Chapman, indicators and benchmarks are also useful in identifying violations. Lastly, the use of indicators and benchmarks is also useful in terms of the minimum core obligations of the government. In relation to access to medicines this means that the government must set an indicator or benchmark to assess whether it has met its obligation, which is to provide essential medicines. The use of indicators and benchmarks are important especially in terms of holding government accountable during the process of reporting. This process is usually evaluative and is usually conducted periodically so as to assess government progress in implementing ESCRs. To this extent, it is not the best tool to rely upon if one is looking at anticipating and correcting potential adverse impacts in the context of pharmaceutical trade policies. This is more so because draft legislation or agreements are usually not considered as a concrete measure for evaluation using indicators and benchmarks unless concluded or finalized.

5.2.4 OPERA Framework

The use of indicators and benchmarks also include the outcomes, policy, efforts, resources and assessment (OPERA) framework.[45] The OPERA framework was developed by the Centre

[44] General Comment 14: The right to the highest attainable standard of health (Art. 12), Adopted at the Twenty-second session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 [Contained in Document E/C.12/2000/4], para 43(d).
[45] Outcome is described in three parts as follows: measure aggregate levels of rights enjoyment (minimum core obligations); measure disparities in rights enjoyment (non-discrimination); and measure progress over time (progressive realization). Similarly policy efforts has the following three parts: identify legal and policy commitments (take steps); examine policy content and implementation (AAAQ criteria); and analyse policy processes (panther principles, right to remedy). Also, resources have the following three parts: evaluate resource allocation (maximum resources); evaluate resource generation (availability of resources); analyse

for Economic and Social Rights (CESR) in order to overcome certain institutional failures in terms of understanding the 'complex causal link between poor human rights outcomes and shortcomings in states' policy efforts.'[46] According to CESR, early ESCRs monitors have focused on identifying violations in relation to a negative or immediate obligation.[47] CESR notes that the 'violations' approach is 'less equipped to identify the multidimensional factors and multitude of actors that often determine whether social and economic policies fulfill ESC rights or lead to ESC rights deprivation.'[48] The OPERA Framework was developed by taking into account various quantitative and qualitative tools and techniques borrowing from multidisciplinary sources of law, social sciences, statistics, public policy and economics.[49] As noted by CESR,

> [b]y making explicit this crucial link between the various human rights standards and principles that underpin the obligation to fulfill and the different assessment methods available to monitor them, the framework enables a systematic approach to building evidence of the failures to fulfill [ESCRs].[50]

In this regard, CESR observes that the 'OPERA framework examines both obligations of conduct and result-and importantly, makes the link between the two [obligations].'[51] The framework however as noted by CESR is not a 'rigid one-size-fits-all formula.'[52] In 2014,

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policy processes (PANTHER principles). Lastly, the assessment part has the following three parts: identify other determinants (indivisibility and interdependence); understand state constraints (respect and protect, duty to cooperate); and determine state compliance (obligation to fulfil). CESR 'The OPERA framework: Assessing compliance with the obligation to fulfil economic, social and cultural rights', (2014) 13, http://archive.cesr.org/downloads/the.opera.framework.pdf (accessed 23 July 2017).

[46] As above, v.

[47] As above, 6.

[48] As above.

[49] As above, 13.

[50] As above.

[51] As above. CESR further notes that the OPERA framework 'looks at different dimensions of the obligation to fulfil, grouped around Outcomes, Policy Efforts and Resources. It then triangulates the findings from each step to make an Assessment of a state's compliance with its obligation to fulfil human rights. To assess the obligation of result, the "outcomes" step gives a snapshot of enjoyment of the right(s) under review in a country. However, outcome alone cannot give a full understanding of a state's compliance. The 'policy efforts' step analyzes obligations of conduct by exploring whether the laws and policies that give effect to the right(s) under review have been designed and implemented in line with human rights standards and principles. The 'resources' step looks at the generation, allocation and expenditure of resources, as well as the larger macro-economic policy context that determines the availability of resources for the right(s) under review. The 'assessment' step looks at the broader constraints facing the government, before making a judgment about the level of compliance or non-compliance of a state with its human rights obligations based on a cumulative assessment of the findings from the prior three steps.

[52] As above, 14.

CESR began the process of training national human rights institutions and others in the Asia Pacific region in order to monitor ESCRs effectively in their respective countries.[53] The main point to note is that the OPERA framework relies on both the quantitative and qualitative methods. It is also based on multidisciplinary approach. Lastly, it focuses on collecting evidence in terms of the fulfilment of ESCRs by governments. To this extent, the mechanism is not apt for identifying and redressing the adverse impacts of pharmaceutical trade policies on access to medicines.

In Kenya, the OPERA framework has been used by the Kenya National Commission on Human Rights (KNCHR) to monitor the state of mental health services in 2011 following a CNN documentary concerning Kenya's mental health infrastructure that is decaying.[54] In the absence of a similar analysis in relation to access to medicines, the KNCHR analysis will be elaborated upon in brief details. Therefore, in terms of outcomes, the KNCHR team measured the elements of minimum core obligations and non-discrimination in order to get a clear picture of the state of mental health in Kenya:[55] In order to evaluate the outcomes of mental health, indicators were analysed by KNCHR to reflect the overall levels mental health rights realisation in Kenya and to determine whether significant disparities existed if at all.[56] On assessing policy efforts, the KNCHR focused on national and international level framework and how it has been translated on the ground in terms of goods and services.[57] The

[53] 'CESR develops training resource on OPERA framework to support national human rights institutions' *ESCR-NET* 3 June 2014, https://www.escr-net.org/news/2014/cesr-develops-training-resource-opera-framework-support-national-human-rights-institutions (accessed 23 July 2017).
[54] 'OPERA in practice: Silenced minds – The systemic neglect of mental health in Kenya' (2011) 1, http://www.cesr.org/sites/default/files/opera_case_study_kenya_FINAL.pdf (accessed 27 July 2017).
[55] As above. Minimum core obligations: Are people in Kenya able to enjoy a basic level of mental health? The entire population has the right to enjoy minimum essential levels of the right to mental health regardless of the country's level of economic development. Non-discrimination: Are there disparities in the level of realization of the right to mental health among different groups in society? All people must be able to enjoy the right to mental health without legal discrimination (*de jure*) or discrimination in practice (*de facto*).
[56] As above.
[57] As above, 2. The following norms informed this step: Obligation to take steps: Has the government taken sufficient steps to realize the right to mental health? Satisfying this obligation means that Kenya must take concrete and deliberate measures intended to realize the right to mental health. AAAQ criteria: Have the steps taken created the necessary goods and services that meet the standards of availability, accessibility, acceptability, and of adequate quality? In order for individuals to realize the right to mental health, Kenya is obligated to provide necessary goods and services that are available within reasonable distances, accessible to all people regardless of economic or social status, are culturally acceptable and meet adequate standards of quality. Participation, transparency, accountability and right to a remedy: Have people been able to actively participate in the creation and implementation of relevant policies? Rights holders must be able to participate

measurement of this part was done by examining the international human rights treaties that Kenya has ratified and the domestic laws, mental health obligations contained in relevant policies and programs and assessing compliance with international obligations. On assessing resources, the KNCHR analyzed the allocation and spending of resources as well as the procedure for deciding the budget to establish if the amount allocated is equitable and effective in relation to the resources available.[58] In order to evaluate the obligation of the government to use to maximum its available resources, the KNCHR evaluated the budget allocated in the mental health sector and the extent of participation of civil society as well as the public in the process.[59] In terms of assessment, the KNCHR measured Kenya's compliance with its human rights obligations by focusing in both the constraints facing individuals as well as the constraints placed on the government.[60] To achieve this the team relied on consultations of stakeholders and staff and administrators interviews as the source of primary information on the local political and social-cultural context.[61] Having utilized the OPERA framework, the KNCHR concluded the whole exercise by proposing to government some recommendations in order to assist it fulfill the respect, protect and fulfill obligations under the right to mental health.[62]

From the above, it appears that the OPERA framework is an elaborate framework that can be used to monitor the implementation of ESCRs in the country. But as can be discerned, it requires elaborate human and financial resources to execute and to this extent it is recommended for established governmental and non-governmental institutions. In relation to the present issue, the OPERA framework also suffers from the fact that it focuses on past

in the creation and implementation of laws and policy. If policies have adverse effects on individuals, there must be a mechanism(s) that allow for complaints to be heard and remedies sought.

[58] As above, 3. The following were considered: Planned and actual resource expenditure: How reasonable was funding for programs concerning the right to mental health? Relevant policy processes: Was the public allowed to voice their concerns and desires regarding revenue expenditure and generation? Public voices should be taken into account when budgetary decisions are made, and the process should be transparent.

[59] As above.

[60] As above, 4. Constraints facing individuals: What social, political, economic cultural factors limit people's rights enjoyment? Reflecting the indivisibility and interdependence of rights, it is important to identify the factors beyond the health sector that might impede an individual's mental health. Constraints placed on the government: What other actors or structural factors influence the delivery of mental health care services? Structural factors-such as broader institutional dysfunctions or the conduct of other actors, including other states and international institutions-may limit the government's ability to deliver mental health care services.

[61] As above.

[62] As above.

actions or omissions of the state in order to determine compliance levels. It is not also fashioned to be able to predict future outcomes of a law or policy as contemplated in this study. To this extent, it is not a desirable tool of choice if one is looking to resolve potential or existing adverse impacts of a particular pharmaceutical law or policy especially before it is enacted even though the World Health Organization (WHO) has used it in the context of universal health care and the right to health.[63]

5.2.5 RIA Framework

Another framework that uses the benchmarks and indicators system is the Recognition, Institutionalization and Accountability (RIA) framework. Alston has argued that there has been strong resistance by many states in terms of their proper recognition of ESCRs.[64] In Alston's view, the apparent avoidance of human rights terminology do in fact show that it matters and can make a big difference as follows:[65]

> human rights framework ensures that in programmes designed to promote collective wellbeing, the rights of the individual are taken into account; in contrast to generic social justice language, human rights discourse directs policymakers and others back to the internationally agreed formulations of economic and social rights and the jurisprudence that has painstakingly evolved; treating economic and social rights as human rights rather than long-term goals introduces an element of immediate salience that might otherwise not be present; and perhaps most importantly, the language of rights recognizes and insists on the dignity and agency of all individuals and it is intentionally empowering because the legal conception of human rights presupposes and demands accountability.

Alston argues that a number of great initiatives have been witnessed in the areas of the rights to housing, food, health and water. However, there has been marginal acceptance of ESCRs in both law and practice as to whether these rights are human rights at all including its legal consequences.[66] Accordingly, in order to remedy the above problem, three things are

[63] See WHO 'Anchoring universal health coverage in the right to health: What difference would it make?' Policy brief, http://www.who.int/gender-equity-rights/knowledge/anchoring-uhc.pdf (accessed 31 October 2018).
[64] P Alston 'Phantom rights: the systemic marginalization of economic and social rights' 4 August 2016, https://www.opendemocracy.net/openglobalrights/philip-alston/phantom-rights-systemic-marginalization-of-economic-and-social-rights (accessed 22 May 2017).
[65] As above.
[66] As above.

required in order to guarantee the economic and social rights recognition and implementation:[67]

> (a) the need to accord legal recognition to the rights; (b) the need for appropriate institutional arrangements to promote and facilitate realization of the rights; and (c) the need for measures that promote governmental accountability. This is known as the RIA framework.

In terms of recognition, Alston argues that the lack of targeted legislative or similar measures is a challenge in relation to the realization of the 'the obligations to "recognize" the rights, and to "guarantee" non-discrimination'.[68] The recognition of the norms therefore becomes the key element and not just the adoption of measures that are pertinent to the subject-matter of the norm. Also, institutions are needed in order to take lead in terms of implementing the human rights however the 'likelihood is that little will be done to treat it as a human right per se.'[69] Lastly, Alston argues that it is not an accident that the significance of the RIA framework has been overlooked by and therefore the lack of a RIA framework at the national level is symptomatic of the ongoing resistance against ESCRs.[70]

Alston's RIA framework can be distinguished from the frameworks already discussed because it focuses on dealing with the immediate resistance that exists in terms of implementation of ESCRs at the national level. The RIA framework is therefore being proposed as a solution that can overcome this resistance. In this regard, it focuses on broad issues like recognition of norms, and the putting in place of institutions and accountability process in order to overcome the initial resistance as noted above. Arguably, the RIA framework can be utilized in the context of structural indicators to determine government political will in implementing ESCRs. It is therefore a deficient tool to use if one is looking at addressing the adverse impact of pharmaceutical policies.

It is possible to improve the access to medicine situation by for instance advocating for the constitutionalisation of the right to health. The absence of the right to health in the legal system of a country is one major challenge for many health advocates because the tools

[67] As above.
[68] As above.
[69] As above.
[70] As above.

available at their disposal to demand for access to medicines may be limited without the right to health framework. Also, the establishment of a national human rights institution to monitor the implementation of the right to health including access to medicines is crucial. This institution assisted by other stakeholders could for instance be responsible for monitoring, reporting, and advising on access to medicines issues at the national level in order to ensure their smooth implementation. Lastly, there is need to establish local accountability mechanisms including the establishment of a complaint procedures or specifically increasing the capacity of the judiciary to be able to effectively handle access to medicines issues under Article 43(1)(a) of the Constitution on the right to health. The capacity of the judiciary could be improved through appropriate training and education. In Kenya, the role of the judiciary in promoting access to medicines has become enhanced after the decision of the *PAO & 2 Others v AG & 2 Others*.[71] Other mechanisms available for addressing complaints include the Kenya National Commission on Human Rights.

5.2.6 Budget analysis tool

Lastly, benchmark and indicators are also used in the context of budget analysis. Since the implementation of ESCRs requires resources, it makes sense to analyze how government allocates its resources in achieving ESCRs obligations. Bui has suggested that human rights budgeting (HRB) tool is one of the tools that can be used to make governments accountable because there is a tight connection between national budget and governments' obligations for ESCR.[72] According to Bui, budget analysis can be interpreted as a legal requirement through Article 2(1) of the ICESCR.[73] Bui argues that the use of the term 'economic resources' under Article 2(1) means that economic information is needed in order to prove that states are realizing ESCRs. To this extent therefore it is possible to link national budgets under Article 2(1).[74] Apart from Article 2(1), the use of budget analysis also emanates from the

[71] *PAO & 2 Others v AG & 2Others* [2012].
[72] Bui n 24 above, 109.
[73] As above, 114-117. Article 2(1) provides that '[e]ach State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.'
[74] As above.

government's obligation to 'fulfil'.[75] Under ICESCR, the obligation to fulfil requires states to take appropriate legislative, administrative, budgetary, judicial and other measures towards the full realization of ESCRs.[76] Bui also notes that it is possible to use HRB to define 'minimum core' obligations because it is a more concrete measure and can also aide in making it meaningful and justiciable.[77] The Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Maputo Protocol) is perhaps the most direct instrument with regards to this issue. Its Article 26(2) requires the state to 'undertake to adopt all necessary measures and in particular shall provide budgetary and other resources for the full and effective implementation of this Protocol.' Under ICCPR the legal basis for HRB can be found in the provisions relating to freedom of information and transparency.[78] According to CESR, HRB is supposed to measure whether the government is employing to the maximum its available resources akin to what is being done by the International Budget Project (IBP), Fundar (Centro de Analisis e Investigacion), and the International Human Rights Internship Program (IHRIP).[79]

The use of HRB is not alien in Kenya as discussed below but there has not been any analysis done in relation to access to medicines in particular. The use of HRB as a tool is particularly critical at this time when the right to health has been devolved and the counties are expected to allocate enough resources to ensure that medicines are available in all public health facilities. *HakiJamii* and *HERAF* - local non-governmental organizations (NGOs) in Kenya – are some of the NGOs that have integrated the use of HRB in their work in relation to ESCRs.[80] All together, these strategies have focused on government expenditure and has enabled the gaining of insight into how 'effective, fair and efficient state expenditure' in areas that have optimal impact for ESCRs by:[81]

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[75] As above 117.
[76] International Commission of Jurists (ICJ), *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, 26 January 1997, http://www.refworld.org/docid/48abd5730.html (accessed 11 July 2018), para 6.
[77] Bui n 24 above, 120.
[78] As above, 121-123.
[79] CESCR n 45 above.
[80] www.hakijamii.com; www.heraf.or.ke.
[81] As above, 9-10.

> calculating allocation or expenditure ratios on [ESCRs] and comparing them to national or international benchmarks; conducting 'benefit incidence' analysis to identify which groups are benefiting from public expenditure; or using Public Expenditure Tracking Survey (PETS) to ensure accountability for actual expenditures.

Waris and Latif have also recommended the use of taxation principles in the context of sustainable health financing to deliver on UHC.[82]

From the foregoing, the use of budget analysis can play a critical role in implementing ESCRs especially because resources are usually at the core of the problem. However, the focus on resources means that it is not possible to use this tool to anticipate and remedy any adverse impacts of a pharmaceutical trade policy and to this extent it is not suitable for this purpose.

5.3 Indexes

The use of indexes is arguably another way to measure ESCRs implementation. Indexes are 'made up of single numbers, or composite scores, that are calculated by combining multiple indicators.'[83] The following indexes have so far been developed in the area of ESCRs implementation: Basic Capabilities Index by Social Watch; Global Age Watch Index; Global Hunger Index; ITUC Global Rights Index; Open Budget Index; and Social and Economic Rights Fulfilment (SERF) Index.[84] Since indexes are not the focus of this study, the SERF Index and income inequality index have been selected to illustrate how this methodology works and then appropriate linkages have been made in relation to access to medicines.

5.3.1 SERF index

The SERF index can promote access to medicines. Sakiko Fukuda-Parr and others have argued that ESCRs and ending poverty have gained traction in the global south but this is

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[82] A Waris & LA Latif 'Towards establishing fiscal legitimacy through settled fiscal principles in global health financing (2015) 23(4) *Health Care Analysis* 376-390.

[83] 'Monitoring progress: The 'pros' and 'cons' of indexes' *ESCR-Net* (August 2014), https://www.escr-net.org/news/2015/august-2014-monitoring-progress-pros-and-cons-indexes (accessed 23 July 2017). The pros of indexes according to ESCR-Net are: quick and easy comparisons; easy to track improvement or decline; and support advocacy work. The cons are as follows: politically controversial; hides inequality; opaque methodologies; and simplify a complex situation.

[84] As above. The pros of indexes according to ESCR-Net are: quick and easy comparisons; easy to track improvement or decline; and support advocacy work. The cons are as follows: politically controversial; hides inequality; opaque methodologies; and simplify a complex situation.

being ignored by analysts.[85] In their view, there have been notable progress in relation to poverty, child survival, and other indicators in the past decade.[86] The SERF Index is therefore capable of providing empirical evidence to show how governments have improved in terms of fulfilment of ESCRs especially in Africa, Asia and Latin America.[87] According to the SERF Index, the above trend according to statistical analyses is driven by gender equality and not 'the ratification of human rights treaties, nor government social spending, nor a regime of democracy.'[88] Accordingly, the finding above is in line with other empirical research that has established the positive impact of gender equality in education, health, food security and economic growth.'[89] The other importance of this finding is that 'the advance of human rights is not a process of implementing laws that spring up in conference rooms of the UN but a process of sustained social change driven by the agency of people claiming their rights.'[90] The 2017 international SERF index is available online at the University of Connecticut website.[91] An access to affordable medicines index can for example try to understand how different countries have performed in providing access to medicines in their countries. Then the tool can be used to identify the main drivers in terms of access to medicines just like it was done under the SERF index as explained above.

The use of indexes is not unique to ESCRs. Indeed, its greatest use has been in the area of corruption and governance with the most famous one being the Transparency International Corruption perception Index that has been responsible for raising in the international policy

[85] S Fukuda-Parr 'Human rights are not losing traction in the global south; 22 November 2016, https://www.opendemocracy.net/openglobalrights/sakiko-fukuda-parr/human-rights-are-not-losing-traction-in-global-south (accessed 23 May 2017). See also S Fukuda-Parr, T Lawson-Remer, & S Randolph 'An index of economic and social rights fulfilment: Concept and methodology' (2009) 8(3) *Journal of Human Rights*, 195-221. This paper explores a methodology for measuring economic and social rights fulfillment that is reliable and authoritative. It proposes a composite index that: uses available survey-based objective, rather than subjective, data; focuses on state obligations rather than solely on individual enjoyment of rights; and captures progressive realization of human rights subject to maximum available resources. Two calculation methods are proposed: the ratio approach and the achievement possibilities frontier approach.
[86] As above.
[87] As above. According to Fukuda-Parr, freedom from hunger and malnutrition, premature death, exploitative work, homelessness and illiteracy are not as visible as the release of a prominent political prisoner. But they are as essential to a life of freedom and dignity as the freedom of speech.
[88] As above.
[89] As above.
[90] As above.
[91] '2017 international SERF Index downloads', http://serfindex.uconn.edu/2017-international-serf-index-downloads/ (accessed 23 July 2017).

agenda the issue of corruption since 1995.[92] Another common index is the Ibrahim Index of African Governance (IIAG), which provides an annual assessment of the quality of governance in every African country.[93] The IIAG presently consists of more than 90 indicators built up into 14 sub-categories and one overall measurement of governance performance.[94] In similar vein, the SERF index can play a major role in putting ESCRs implementation in the international policy agenda as well as provide information that would assist governments to deliver on their responsibilities with regards to the implementation of ESCRs. By doing so, the SERF index will be indirectly promoting the realization of access to medicines globally. However, it is not the best methodology to use in relation to identifying and mitigating the adverse impacts of pharmaceutical trade policies.

5.3.2 Income inequality index

Apart from SERF index, there is also another index called income inequality index. Charles-Coll notes that one cannot study the subject of inequality from an economic perspective

[92] Corruption Perception Index, https://www.transparency.org/research/cpi/overview (accessed 11 August 2017). According to this website, each year they score countries on how corrupt their public sectors are seen to be. Our Corruption Perceptions Index sends a powerful message and governments have been forced to take notice and act. Behind these numbers is the daily reality for people living in these countries. The index cannot capture the individual frustration of this reality, but it does capture the informed views of analysts, businesspeople and experts in countries around the world. The IIAG provides a framework for citizens, governments, institutions and the private sector to assess accurately the delivery of public goods and services, and policy outcomes, across the continent and for each of the 54 African countries. The IIAG is both a tool to help determine and debate government performance and a decision-making instrument with which to govern. The IIAG allows users to benchmark governance performance across various dimensions at national, regional and continental level. For every year and every country, annual results are available from 2000, enabling the analysis of trends over time and space.

[93] See Ibrahim Index of African Governance, http://mo.ibrahim.foundation/iiag/ (accessed 11 August 2017).

[94] As above. These indicators include official data, expert assessments and citizen surveys, provided by more than 30 independent global data institutions. This represents the most comprehensive collection of data on African governance.

alone.[95] He further notes that the causes of inequality can be endogenous[96] or exogenous.[97] In terms of measurement, Charles-Coll notes that income inequality relies mainly on mathematical procedures and statistical tools as the most common procedure.[98] According to Blackorby and others, it is rare to find income inequalities indices that are purely descriptive.[99] This means that they must be integrated with a particular purpose for instance in policy formation and other purposes such that when there is reduction in their use it is an indicator of social progress.[100] As such, 'the theory of ethical inequality measurement attempts to find indexes that are based on reasonable, ethically attractive social value judgments.'[101] It is on the basis of these types of indices that one can use it to 'monitor social and economic progress and to aid in policy formulation.'[102] Illustratively, the Dalton measure and the Atkinson are some of the normative measures that utilises value judgments and social welfare function.[103] On the other hand, income inequality can be measured positively using statistical concepts by use of among others: 'Gini Coefficient; Lorenz Curve; Theil

[95] JA Charles-Coll 'Understanding income inequality: Concept, causes and measurement' (2011) 1 *International Journal of Economic and Management Sciences* 17, https://pdfs.semanticscholar.org/efd2/7cc515f6ff94cbf00c73909bf3b2cd72b801.pdf (accessed 27 July 2017). According to Charles-Coll, '[i]n order to be a subject of analysis, the absence referred by the etymological definition of inequality must necessarily be associated to another measurable element, which is normally the unit we will measure and try to objectively evaluate in relation to other distributions of the same elements, the most common examples being income, wealth, consumption, as well as other normative elements such as welfare and utility. This way, the objective of any study on inequality must invariably be focused precisely on the chosen element of reference, as inequality (as a topic) represents only the value judgment of the absence of a homogeneous distribution of such element. In this context, for example, the study of gender, race, opportunities or income inequality, are the chosen elements (the ones to measure and compare), and their distribution is the condition we will evaluate in relation to our judgment on its goodness or badness.'

[96] As above, 18. Endogenous refers to 'a set of circumstances or characteristics intrinsic to individuals and which can potentially determine their future income as the result of influencing their comparative advantages either in the form of higher productivity or by the possession of scarce attributes which make them comparatively more market-valuable or even, in a broader sense, more socially competitive.'

[97] As above, 19-21. These includes external factors like land, education and globalization.

[98] As above, 21.

[99] C Blackorby, W Bossert, & D Donaldson 'Income inequality measurement: The normative approach' in J Silber (ed) *Handbook of income inequality measurement* (1999) 133.

[100] As above.

[101] As above.

[102] As above.

[103] J Meng 'What is the distinction between positive and normative measures of income inequality? Refer to the properties of one positive and one normative measure. Can the Gini coefficient be interpreted as a normative measure of inequality? If so, is its underlying social welfare function justifiable? Is there always an implicit welfare function underlying positive welfare measures of inequality?' (23 November 2008), http://www.joycemeng.com/writings/inequality.pdf (accessed 27 July 2017).

Measure; relative mean deviation, and the coefficient variation.'[104] Notwithstanding the above assertion, Kaplow appears to suggest that the normative approach to income inequality is not necessary and thus favors the descriptive approach.[105] It thus appears from the above that income inequality indices cannot be purely descriptive and that what is needed is the theory of ethical inequality measurement to assist in monitoring progress in the area of economic and social or to aid in policy formulations. Suffice to note, this tool can best be used with the help of economists who are skilled in the art of numbers and economic development.

Cole for instance has focused on analyzing whether the ICESCR has any impact on the extent of domestic income inequality in a country after accounting for government taxes and transfers.[106] The focus on inequality by Cole was informed by the following three insights:[107]

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[104] As above.

[105] L Kaplow 'Why measure inequality?' (2002) Discussion paper no 386 10/2002, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.200.9385&rep=rep1&type=pdf (accessed 27 July 2017). According to Kaplow, a substantial and growing literature develops various measures of indexes of economic inequality. Some use the Gini coefficient or other measures or relationships drawn from Lorenz curves; some prefer different indicators of dispersion, such as an entropy index; some offer axiomatic derivations of inequality indexes; and still others advocate the use of normative measures derived from social welfare functions. She notes that despite the available literature little has been said about why it is necessary to measure income inequality. In this context, she then examines this question and makes two claims. The first claim she makes is that normative measures of inequality which are designed to have a direct policy relevance, as aspects of overall social welfare are not necessary because there is little need to measure inequality per se even though it is an aspect of social welfare it makes more sense to measure welfare directly; measuring welfare requires additional efforts and yields no return. Second, regarding descriptive measures of inequality such as the ones used in regressions relating inequality and growth, measurement is often necessary. However, she claims that what constitutes a good measure depends on the economic theory and empirical facts in particular contexts, not necessarily on the properties and axioms that have generally been proposed for measures of inequality.

[106] WM Cole 'The international treaty on economic and social rights has positive impacts' 14 May 2015, https://www.opendemocracy.net/openglobalrights/wade-m-cole/international-treaty-on-economic-and-social-rights-has-positive-impacts (accessed 21 July 2017). For a more detailed discussion, see also WM Cole 'International human rights and domestic income inequality: A difficult case of compliance in World society (2015) *American Sociological Review.* In summary, Cole notes that few analysts have studied the ICESCR because its terms are difficult to implement and suitable measures for judging compliance are hard to find. I analyze its association with income inequality, using data for more than 100 countries (1981 to 2005) and methods that account for the possibility of reverse causality. ICESCR membership reduces inequality in both developed and developing countries, although the relationship is stronger for developed countries—precisely those with the greatest capacity to implement their obligations. Other key determinants of income inequality and treaty compliance—left partisanship, union density, workers' rights, and democracy—do not systematically condition the effects of ICESCR membership.

[107] Cole n 106 above.

> regardless of a country's overall wealth, resources can be distributed more or less equitably and that the government attempts to reduce inequality demonstrate an effort to comply with the ICESCR; when governments use taxes and transfers to reduce inequality, they go some way towards satisfying the ICESCR's implied objective of equalizing resources; and lower inequality is also linked to other human rights benefits, including fewer violations of physical integrity rights.

According to Cole, the statistics show clearly that ICESCR has been responsible for tackling the problem of income inequality in both developed and developing countries and that consequently a country is expected to reduce inequality problems by belonging to the ICESCR for a longer period.[108] An interesting find for Cole however was that no evidence existed to support the conclusion that 'domestic political support for or against economic and social rights either promoted or derailed ICESCR compliance.'[109] This finding is important because politics has played a major role in terms of the access to medicines landscape. In this regard, the ICESCR can be used to ensure that politics does not become the key determinant of access to medicines policy-making.

The common thread with the ESCRs methodologies discussed above is that they are usually employed after the effects of a particular program have been realized. They are therefore suitable for utilization after the fact. This makes them unsuitable for use in the context of formulating trade rules. In the next chapter, the mechanism of HRIA is discussed in order to find out whether it is capable of identifying and mitigating the adverse impacts of trade rules beforehand.

5.4 Human rights impact assessment mechanism

Another important ESCRs measurement method is the HRIA mechanism. According to the International Association of Impact Assessment (IAIA), impact assessment is 'the process of identifying the future consequences of a current or proposed action.'[110] A review of the IAIA official website reveals appropriate information about the different subfields of impact

[108] As above.
[109] As above.
[110] International Association of Impact Assessment, www.iaia.org (accessed 8 March 2017). The IAIA is the leading global network on best practice in the use of impact assessment for informed decision making regarding policies, programs, plans and projects. Members of IAIA believe that impact assessment is a practical tool for helping meet today's needs without compromising the opportunities of future generations.

assessment including: biodiversity; corporate social responsibility; cultural heritage; cumulative effects; displacement and resettlement; environmental management systems; gender and gender impact assessment; health; impacts of tourism; indigenous peoples; public participation; social impact assessment; strategic environmental assessment; sustainability assessment; and sustainability assessment.[111] Perhaps the human rights-related impact assessments from the above list are public participation impact assessment and gender equality impact assessments. The IAIA is therefore yet to develop a HRIA based on human rights norms or right to health norms specifically. It can thus be concluded that the field of impact assessments is still a developing field and it is equally diverse since it covers many diverse sectors. The impact assessment for the human rights sector in particular needs to be developed further to be applied in different contexts.

5.4.1 Some advantages and disadvantages

The HRIA mechanism has some advantages and disadvantages. The advantages of HRIA mechanism according to Scottish Human Rights Commission (SHRC) include:[112] enhancement of the protection of human rights;[113] and guarantees legal accountability, specificity as well as participation and transparency.[114]

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[111] http://www.iaia.org/key-citations.php (accessed 8 March 2017).

[112] Scottish Human Rights Commission 'Human rights impact assessment: review of practice and guidance for future assessments' (1 June 2010) 16-19.

[113] These include: A holistic approach to human rights protection: HRIAs address human rights issues during the process of policy development and reflection on existing practice. Therefore they have the potential to impact upon the ways that policy is developed and altered with regard to all individuals rather than only those who have the resources to bring cases to courts. Prevention rather than redress: HRIAs have the potential to prevent human rights violations before they happen if they are undertaken at a point in the policy cycle before decisions are made and before people are affected
Impact on Institutional culture: HRIAs enable human rights to be 'mainstreamed' within policymaking.[113] This has the potential to affect both institutional cultures and individual decision-making more widely in organisations. Particularly where HRIAs are conducted by those who are directly responsible for making policy, there is the potential for real change to be implemented and for the attitudes of policymakers themselves to be changed so that they start to take into account human rights issues regularly in their decision-making processes. Raising awareness – HRIAs have the potential to raise awareness about human rights issues in affected communities and more widely in society.

[114] This means the following: Legal accountability – Human rights represent legal obligations of states. HRIAs should compel 'duty-bearers' to act to protect the rights of 'rights-holders' and provide justifications for their policies in human rights terms. Specificity - HRIA ensures engagement with specific rights, such as freedom of expression that might be ignored in less legally grounded forms of assessment like social impact assessment. The human rights model may also require impacts to be disaggregated to specifically focus on the most

There are also a number of disadvantages including bureaucratisation, cutting off debate, measurement, legalisation, and bad decision-making.[115] For instance the SHRC in realizing the importance of HRIA mechanisms for improving policy-making processes also noted that a poor HRIA could be nothing more than a tick-box exercise with no or very limited meaningful human rights impacts on the vulnerable or disadvantaged communities in terms of their human rights.[116] In this regard, the SHRC compiled an overview of existing practice in the UK and internationally. The report had two conclusions that the methodologies in the UK have tended to be fairly simple and mainly focused on the compliance with the Human Rights Act, 1998. Consequently, the UK's version of a HRIA mechanism is the Equality and HRIA Mechanism, which has been implemented on a periodic basis. Secondly, the experience at the international level has been more varied and in some cases there exists some extremely detailed HRIAs which cover many areas including ESCRs as well as civil and political rights.[117] Arguably, therefore, HRIA mechanisms at the international level may be more detailed and complex than those undertaken at the national level. Secondly, the

vulnerable, poor and otherwise disadvantaged whose rights are most frequently overlooked. Participation and transparency – the human rights model encourages participation in policy making by the people affected, enhancing empowerment, legitimacy and ownership of policy choices. It should also encourage transparency in the process of undertaking impact assessment.[114] However, we need to make sure that the rhetoric is reflected in the reality.

[115] Bureaucratisation – HRIA can become simply a bureaucratic process that must be overcome before a decision is made. It may come to value technique over substance and become a tick box exercise rather than a process that transforms policies, practices and institutional cultures. In worst case scenarios, HRIAs can be utilised in order to justify decisions that have already been made. The danger of bureaucratisation is particularly prevalent where HRIAs are being undertaken by people who are not necessarily themselves experts in human rights (e.g. government officials, business people)[115] or where there is a lack of institutional appreciation of, or commitment to, the value of the role that human rights standards may play with regard to that institution's functions. Cutting off debate. HRIAs can become a mechanism for stopping further debate on an issue ('we have already considered the human rights implications of this when carrying out the impact assessment, there is no need to do it again').[115] Measurement – There is a danger that impact assessment will concentrate on short term impacts that are easily quantifiable rather than long term effects or impacts that are not easily anticipated.[115] HRIAs could thereby be associated with a 'dumbing down' process on human rights fulfilment and on policy-making generally. Legalisation – There is a danger that a minimum level of compliance with legal obligations on human rights can be seen incorrectly as maximum goals ('as long as we can't be sued, we have done our job'). This would have the unfortunate effect of transforming the floor of human rights into the ceiling and may mean that consideration of the broader social impacts of policies may be marginalized or overlooked entirely. Bad Decision Making - Proper HRIA is a complex process. There is a danger that ill-equipped officials may (in good faith) make poor decisions which may undermine the whole human rights framework. Since the passage of the Human Rights Act in 1998 we have seen a trend in the UK for unpopular decisions by public bodies to be blamed on 'human rights'. This could be exacerbated where decision-making is based on poor HRIA analysis which does not reflect true human rights values or standards.

[116] SHRC n 112 above, Foreword.

[117] As above, 5.

national implementation of HRIA mechanisms is mainly driven by legislation such as the Human Rights Act in the UK, which is the basis of the equality and HRIAs mechanism. In Scotland, the SCHRC report however recommends in relation to the equality and HRIA that there should be a movement to move beyond a simple compliance with the Human Rights Act approach as is the case in UK to the fulfilment approach including in the areas of ESCRs, disability rights, women's rights and so forth.[118]

5.4.2 Benefits and risks of human rights impact assessments

The mechanism of HRIA has in addition to the advantages and disadvantages as well as some benefits and risks. Walker in particular has discussed the benefits and risks of HRIA of trade agreements.[119] Accordingly, the benefits include the following: it is a comprehensive framework; it is a more objective standard than other impact assessments such as social impact assessment; it is a relatively well developed analytical framework; it is a limitation to trade-offs; it promotes legal accountability; and it is supportive of network of actors.[120] In terms of the risks, they include the following: politicization; annexation; externalization; imbalance; and feasibility.

5.4.3 The overarching principles of human rights impact assessment

There are several overarching principles that underpin the utilization of HRIA mechanisms. First, the process of elaborating human rights impact assessment principles in relation to trade and investment began in 2011 when the former UN Special Rapporteur on the right to food, Olivier De Schutter, published the guiding principles on human rights and impact assessments of trade and investment agreements.[121] According to the Special Rapporteur, the guiding principles aim at providing states with the necessary guidance they require 'to ensure that the trade and investment agreements they conclude are consistent with their

[118] As above, 5-6.
[119] Walker n 99 above, 187-201.
[120] As above.
[121] O de Schutter 'Report of the Special Rapporteur on the right to food' 19 December 2011 [A/HRC/19/59/Add.5, http://www.srfood.org/images/stories/pdf/officialreports/20120306_hria_en.pdf (accessed 2 August 2017).

obligations under international human rights instruments.'[122] There are six key guiding principles that were enumerated by the UN Special Rapporteur as discussed below.

The first guiding principle relates to the duty to prepare HRIA of trade and investment agreements. According to the guiding principles this means that all states should prepare HRIA before concluding trade and investment agreements in line with their right to health obligations.[123] The suggestion that all states should conduct an impact assessment is particularly crucial because the obligations of the government and the actual impact of a particular measure may differ from one country to another.

The second guiding principle is that states must ensure that the conclusion of any trade or investment agreement 'does not impose obligations inconsistent with their pre-existing international treaty obligations, including those to respect, protect and fulfil human rights.'[124]

The third guiding principle observes that HRIA of trade and investment agreements is best prepared before the agreement is concluded and in good time so that it can be used to influence negotiations and the outcomes. The following responses are available where incompatibility is found in HRIA: 'termination of the agreement; amendment of the agreement; insertion of safeguards in the agreement; provision of compensation by third-State parties; and adoption of mitigation measures.'[125]

The fourth guiding principle is about the methodology of HRIA of trade and investment agreements. In this part, the guiding principle provides that each State should define how to prepare HRIA of trade and investment agreements at any time before its conclusion or before joining one. The HRIA procedure should be guided by human rights-based approach, and 'its credibility and effectiveness depend on the fulfilment of the following minimum core

[122] As above.
[123] As above, 5.
[124] As above, 6.
[125] As above, 8.

conditions:[126] independence;[127] transparency;[128] inclusive participation;[129] expertise and funding;[130] and status.'[131] In addition, this section also notes that states are at liberty to decide on the methodology that they want but the following elements should be considered while choosing a methodology for a HRIA:[132]

> making explicit reference to the normative content of human rights obligations; incorporating human rights indicators into the assessment; and ensuring that decisions on trade-offs are subject to adequate consultation (through a participatory, inclusive and transparent process), comport with the principles of equality and non-discrimination, and do not result in retrogression.

On human rights indicators, the indicators should be able to measure the following:

(a) Whether trade or investment agreement will make it more difficult for the State concerned to ratify a particular human rights instruments, to adapt its regulatory framework to the requirements of human rights, or to set up the institutional mechanisms, that ensure compliance with its human rights obligations (structural indicators);
(b) Whether it creates obstacles to the implementation of the State's policy measures and programmes, or to the functioning of institutional mechanisms, that ensure effective fulfilment of State's human rights obligations, particularly insofar as such obligations require budgetary commitments (process indicators); and

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[126] As above, 9-10.
[127] Whether it is prepared by a national institution for the promotion and protection of human rights, 17 by experts specifically designated for this task, by a parliamentary committee in which opposition political voices are included, or by others, the HRIA should be initially prepared by a body or group of experts that is independent from the Executive which is negotiating, or has negotiated, the trade or investment agreement. That initial assessment should not necessarily be determinative, however: since it is to allow for the meaningful participation of citizens in public affairs and for an improved accountability of the Executive to the other branches of Government (see commentary following principle 1), the initial assessment should, ideally, be debated in Parliament.
[128] The HRIA should be based on sources of information that are made public. It should work on the basis of a clear methodology, defined in advance of the process and made public. And it should be open to receiving submissions, in order to ensure that its information basis will be as broad as possible.
[129] The HRIA should consider the views of the communities directly affected by the trade or investment agreement by ensuring participation in the conduct of the assessment. For this participation to be meaningful, those consulted should be provided with all the available information on the potential impacts, and the assessment should refer explicitly to their concerns and how these concerns could be addressed.
[130] The body or group tasked with preparing the HRIA should be composed of relevant experts and sufficiently well-funded in order to prepare a high-quality assessment. This body or group requires the combination of different methodologies in which different disciplines are represented (including but not limited to human rights and investment/trade), and may also require the commissioning of outside expertise.
[131] HRIAs are a tool for states negotiating trade or investment agreements to ensure that the conclusion of such agreements will not lead these states to violate their human rights obligations or to be unable to fulfil such obligations. Therefore, provided the results of the assessments are taken into account, states may be said to have acted with all due diligence to minimize the risk of such inconsistencies.
[132] de Schutter n 121 above, 11.

(c) Whether the trade or investment t agreement may make it more difficult for a State to make progress in the realization of the human rights it has undertaken to comply with, measured from the perspective of full enjoyment of all human rights by all (outcome indicators).

The last guiding principle relates to the balancing priorities and HRIAs of trade or investment agreements. This is about states using HRIA to ensure that the protection of human rights is achieved through identification of both positive and negative impacts that trade agreements portend.[133]

The above guiding principles are quite comprehensive and can apply across board. In the context of intellectual property rights, Forman and MacNaughton have proposed the following overarching and crosscutting principles that should guide HRIA mechanisms mainly borrowing from the above discussion and other sources:[134]

> (1) it should be flexible, robust and user-friendly, draw on an independent multi-disciplinary team, use a transparent and non-discriminatory methodology, draw on appropriate expertise and funding, and result in parliamentary debate over its recommendations; (2) it should integrate explicit human rights frameworks, citing international human rights law instruments and norms, identifying the rights-holders affected by the policy and state and non-state duty bearers, identifying human rights indicators to measure impact, and articulating conclusions in terms of impact on human rights; (3) It should integrate broad participation as a key human rights principle, as a critical method of gathering evidence of impacts, as a means to assure transparency and accountability, and as a measure to enhance ownership of the decision that is adopted; (4) It should be used with other human rights strategies such as mobilization, campaigning, advocacy, research, and policy analysis, and should involve domestic human rights mechanisms and actors such as national human rights institutions, NGOs and academics, and international mechanisms such as UN and regional treaty bodies; and (5) It should be institutionalized within domestic laws and within the international system.

In terms of criticism, arguably, a HRIA should not necessarily result into a parliamentary debate as proposed by the first principle. While parliamentary debate can be used to improve on its legitimacy as a result of democratic dividend, the reality is that parliamentary debates may actually undermine the integrity of HRIA especially if political considerations are given more weight than human rights. Furthermore, in Kenya, past practice shows that environmental impact assessments are rarely discussed by Parliament and as such there is

[133] As above, 12.
[134] As above.

no imperative that human rights impact assessment should be subjected to parliamentary debate. However, what could be subjected to Parliamentary debate is the final trade agreement or policy document together with the HRIA report on its own since it is a technical rather than a policy document. The final trade agreement or policy should be accompanied by some sort of certificate indicating that it is human rights compliant on the basis of the impact assessment conducted.

Secondly, the third principle envisages that the people should be consulted in the process of HRIA mechanism. Arguably, this may not be required all the time as is the case of social impact assessment, which is about reference to the *status quo* and the people are directly consulted. This however does not mean that human rights experts should not be consulted. Indeed, a proper HRIA should be based on the human rights norms as well as the participation of human rights experts. The views of ordinary people may not necessarily improve the methodology and quality of a particular HRIA even if participation is an integral part of the human rights principles. In exceptional circumstances, however, it may be necessary to collect evidence of the impact in relation to public participation of a particular law or policy especially with regards to impact assessments conducted after a policy or project is already being implemented or has been implemented.

Lastly, principle number five requires the institutionalization of HRIA both at the domestic as well as at the international level. This suggestion is actually important especially if the results of the HRIAs are to be taken seriously without a challenge. A better institutionalization proposal would be to include the requirement to conduct HRIA as part of the mandate of the national human rights institutions so that the national expert body on human rights can be integrated in trade policy-formulations. In Kenya, the National Environmental Management Authority (NEMA) undertakes environmental impact assessments on behalf of the business community and certifies projects as compliant or not.[135] This same approach can be adopted in relation to HRIA, which means that the KNCHR could undertake the impact assessment and award appropriate approvals or certifications as may be required. Institutionalization as such also means the identification of the best

[135] See generally part VI of the Environmental Management and Coordination Act No 8 of 1999.

government department that can undertake a proper HRIA if the requisite technical capacity exists. This department should be preferably the national institution responsible for human rights issues in the country. These institutions therefore must be fully funded and capacitated to formally intervene without necessarily having to be invited and advise on the human rights impacts of trade agreements and legislations before they are enacted and periodically thereafter.

From the foregoing, it emerges that the HRIA mechanism is best suited to resolve the adverse impacts of pharmaceutical trade policies mainly because it is designed to be able to identify and mitigate adverse impacts of policy and programmes. The other methodologies were not designed to achieve the same purpose and as such they are inadequate.

5.4.4 Methodology of human rights impact assessment

The fact that HRIA has evolved in different ways in practice as discussed above means that it has a wide range of methodologies.[136]In the context of intellectual property rights, the methodology proposed by Forman and MacNaughton is very influential and can therefore be adapted for use in the Kenyan context.[137]

There have been numerous efforts to promote the uptake of HRIA at the national level where it still remains largely unexploited by many governments so far. The 'framework methodology' means an outline and guidance in which users can use and develop further in order to respond to specific contexts in terms of HRIA mechanisms.[138] In particular, the framework methodology proposed by Forman and MacNaughton is integral to this study for two main reasons. The first reason is that Forman and MacNaughton, in coming up with their own methodology, integrated existing methodologies and in this regard it can be said that

[136] R Mungoven 'Walking the talk: Exploring methodologies and applications for human rights impact assessment by the United Nations' (OHCHR sabbatical report, February 2016) 9.
[137] L Forman & G MacNaughton 'Lessons learned: a framework methodology for HRIA of intellectual property protection in trade agreements' (2016) *Impact assessment and Project Appraisal*, http://www.dlsph.utoronto.ca/wp-content/uploads/2012/02/Forman-MacNaughton-IAPA-final-.pdf (accessed 30 July 2017).
[138] Forman & MacNaughton n 137 above, 2.

their methodology is the updated one.[139] Secondly, the methodology proposed by Forman and MacNaughton is specific since it was developed to especially respond to the adverse impacts of trade-related intellectual property rights. By and large, what is currently missing is its adaptation and utilization at the domestic level especially by governments in developing countries including Kenya to promote the situation of access to medicines. The purpose of this study is therefore to demonstrate how this tool can actually be employed by governments in practice to promote realization of access to medicines at the domestic level.

The focus on trade-related intellectual property rights methodology of HRIA mechanism developed by Forman and MacNaughton is also justifiable because of the fact that there is a rapid increase in intellectual property protection provisions in many bilateral and multilateral trade agreements over the past decade, which means that government are increasingly being required to provide more stringent patent protection to pharmaceuticals.[140] Apart from bilateral and multilateral trade agreements, the implementation of TRIPs Agreement at the domestic level requires fundamentally reforming existing domestic laws especially those relating to intellectual property rights protection and enforcement in order to respond to the international requirement. In this context, it was necessary for Forman and MacNaughton to develop what they call a 'framework methodology' for HRIA mechanisms in order to assist States to meet their obligations both in the area of intellectual property rights protection as well as the realization of access to medicines in particular.[141]

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[139] The methodologies used by Forman & MacNaughton to develop a right to health impact assessment methodology include: P Hunt, & G MacNaughton 'Impact assessments, poverty and human rights: a case study using the right the highest attainable standard of health' (2006) Geneva: World Health Organization, http://www.who.int/hhr/Series_6_Impact%20Assessments_Hunt_MacNaughton1.pdf (accessed 31 July 2017); United Nations 'Guiding principles on human rights impact assessments of trade and investment agreements' (2011) Report of the Special Rapporteur on the Right to Food [UN Doc. A/HRC/19/59/Add.5], Geneva: United Nations; and S Walker 'The United States-Dominican Republic-Central American free trade agreement and access to medicines in Costa Rica: a HRIA' (2011) 3 *J Hum Rights Prac.*188–213; D Kemp & F Vanclay 'Human rights and impact assessment: clarifying the connections in practice' (2013) 31 *Human Rights and Impact Assessment* 2, http://www.tandfonline.com/doi/full/10.1080/14615517.2013.782978 (accessed 30 July 2017).

[140] Forman & MacNaughton n 137 above, 1.

[141] As above, 2.

Forman and MacNaughton explains that their framework methodology has three unique features from 'the three primary models' they have relied upon.[142] The first unique feature is that it is user-friendly and has a narrow focus on the human rights impact of intellectual property rights on access to medicines alone which has two main advantages.[143] The first advantage is that it can be used independently to generate an evidence-based advocacy tool by non-governmental organizations (NGOs) in terms of assessing the prospective or existent trade or intellectual property laws and agreements.[144] Poor countries and NGOs working in these countries may be unable to conduct complex HRIAs and to this extent the proposed methodology is pragmatic. The second advantage is that 'the proposed methodology may be used as an add-on methodology to be integrated into existing ex ante tools used by policy-makers to assess trade and social impacts, including trade sustainability assessments, economic modeling and causal chain analysis.'[145] Lastly, the two authors stress that their distinctive contribution is the framework methodology's 'focus on 'usability' – privileging ease, brevity, and affordability in order to assure that this tool can be used relatively quickly and cheaply according to context and need.'[146] It should be noted that the framework methodology proposed by Forman and MacNaughton is primarily meant to be used by social actors as part of advocacy campaigns and at the same time the governments can insert it in a larger HRIA study that is aimed at informing policy formation should it elect to proceed in that direction and it has the requisite resources to do so.[147]

According to Forman and MacNaughton, their HRIA mechanism adopts a common step-wise methodology which is as follows:[148]

> (1) screening (a preliminary check on potential impact), (2) scoping (development of an assessment plan including team selection, development of the methodology, selection of an explicit human rights framework based upon applicable human rights obligations and identification of data sources and indicators), (3) evidence collection, (4) rights analysis

[142] As above.
[143] As above.
[144] As above.
[145] As above.
[146] As above.
[147] As above, 11.
[148] As above, 11.

> requiring a comparison of the evidence gathered to the human rights obligations, (5) finalization of the report and methods of implementation, and (6) evaluation and monitoring.

The same key steps were also adopted by the UN Special Rapporteur in the guiding principles document.[149] Below is an elaboration of the steps by the two authors including my criticisms of each step. Other key sources specifically from Walker[150] and SHRC[151] will also be used in this analysis as well. In particular, the best practices as documented by SHRC will be highlighted in the relevant sections following on the structure of their methodology.

5.4.4.1 Preparation

The inclusion of the preparation stage can be useful in terms of providing the context of the process. This step is not included by MacNaughton and Forman. It is however included by Walker who notes that the preparation stage is about clarifying the context of the HRIA by among other things

> identifying the relevant legal, economic, environmental, social, and regulatory context of the country in the form of a baseline study, identifying people affected by and responsible for the policy or project, considering whether an assessment is necessary, setting out the objectives, scale and focus of the assessment, and identifying the skills, resources and time available to carry out the assessment.[152]

The preparation stage is therefore about defining the context of the assessment and ensuring all details that may affect the assessment is reviewed and documented.[153]

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[149] Report of the Special Rapporteur on the Right to Food 'Guiding principles on human rights impact assessments of trade and investment agreements' (2011) [UN Doc. A/HRC/19/59/Add.5], Geneva: United Nations, paras 14-15. Since Forman and MacNaughton have better expounded on these steps, the same will not be replicated here with regards to the special rapporteur framework.
[150] SM Walker *The future of human rights impact assessments of trade agreements* (1996).
[151] Scottish Human Rights Commission 'HRIA: review of practice and guidance for future assessments' (1 June 2010). The report of the SHRC was analysed based on the following sources: UK HRIA and Equality Impact Assessment Materials – including guidelines and toolkits for conducting EIAs and combined EIAs and HRIAs and the assessments produced using these toolkits; International HRIA Materials including HRIAs (both published and unpublished) and guidelines and toolkits on the conduct of HRIAs; Commentaries and Critical Analysis - Academic articles, Policy Papers and other commentary on the conduct of HRIAs and EIAs; Other Relevant Materials - Papers and other guidance concerning the development of human rights indicators (e.g. by relevant UN, EU bodies); relevant guidance on standards of consultation beyond that contained in the HRIAs set out above; Discussions with Practitioners and Commentators – We have held discussions with a number of practitioners and commentators who have been involved in the practice of HRIAs, have designed methodologies, or who have critically examined how they have functioned in the UK and internationally.
[152] Walker n 150 above, 87-89.
[153] As above, 89.

Suffice to note, the SHRC does not include this stage as part of its methodology. In this study, the preparation stage is handled in the next Chapter in so far as it clarifies the contextual environment of pharmaceutical trade policies in relation to the issue of access to medicines in Kenya.

5.4.4.2 Screening

The next step is the screening stage, which is mainly about conducting a preliminary check using human rights norms to establish whether a particular agreement potentially adversely impacts on access to medicines.[154] The preliminary check proceeds as follows according to Forman and MacNaughton:[155]

> First, applicable human rights laws are scanned, including international and regional treaties ratified by the state in question, national laws and national case law to provide a framework of applicable and binding entitlements and duties related to medicines. This scan explicitly adopts a right to health approach focused on minimum core obligations to assure accessible, available, acceptable, quality essential medicines, as well as on state obligations to respect, protect, and fulfill the right to health. Second, existing intellectual property rights are identified, looking at international agreements such as TRIPs, other multilateral or bilateral agreements, and national laws and policies. Third, prospective changes within an anticipated intellectual property law are identified, focusing in particular on those provisions most likely to affect the affordability and availability of medicines. Fourth, the proposed intellectual property rights are provisionally assessed according to the analytical framework of the right to health, asking how these rights may impact the state's ability to realize its right to health duties, with relevant duties specified at the outset, supplemented with additional specified duties drawn from national law and cases. These prospective comparisons are intended to identify potential breaches of the right to access affordable medicines that would result from adopting the proposed changes to intellectual property law and illustrate whether a full assessment should be conducted.

Walker, on his part, contends that screening involves identifying the potentially problematic areas in a trade agreement in relation to human rights.[156] He contends that an assessment in order to be meaningful should focus on trade measures, which are likely to have impact significantly on human rights.[157] Using literature review and expert judgment it is thus possible in this stage to establish 'the main causal links between a trade measure and the

[154] Forman & MacNaughton n 137 above, 11.
[155] As above.
[156] Walker n 150 above, 87.
[157] As above, 92.

subject theme of the assessment (economy, social development, environment) and assess the significance of any resulting impact using a limited number of significance criteria.'[158]

According to Walker, there is need to have a clear separation of the 'screening' stage and the 'scoping' stage because of the practical distinctions between the two stages.[159] Accordingly, one can screen-out unnecessary trade measures and as a separate step also clarify the scope of those measures that are to be subjected to subsequent assessment. In this regard, screening narrows the scope of the assessment in terms of the provisions while the later clarifies the content of the remaining provisions.[160] Be that as it may, this study does not see the significance of separating the two stages since they both deal with the identification of the problematic provisions and clarifying their substantive contents. The steps will be unduly prolonged if the two processes were to be contained in separate stages. In any case, it is necessary for one to know the contents of a provision before it can be singled out as problematic.

Since impact is a key factor in determining which provisions are subjected to an assessment, Walker lists four factors that can assist in determining this as follows:[161]

> the extent of existing human rights issues in the affected areas; the direction of changes compared to baseline conditions (positive or negative); the nature, magnitude, geographic extent, duration and reversibility of changes, including the likelihood of impacts having a cumulative effect; and the regulatory and institutional capacity to implement mitigation and enhancement measures.

The SHRC recognizes this stage and observes that a screening stage is mainly about subjecting a proposed policy to preliminary checks so that one can decide if a comprehensive impact assessment is needed or not.[162] The SHRC's report is particularly important because it recommends a list of best practice as follows:[163]

- At the very least, there should be a series of context-specific questions available to the decision-maker to prompt their thinking about whether a full HRIA is appropriate.

[158] As above.
[159] As above.
[160] As above.
[161] As above, 93.
[162] SHRC n 112 above, 5.
[163] As above, 6.

- Consideration should be given to sources of information/expertise through which screening decisions can be tested e.g. - selective secondary research and expert opinions.
- Training in screening processes should be a pre-requisite of making screening decisions
- A decision not to carry out a HRIA should be signed off at a senior level within the organization.

SHRC further notes that it is important to publish the result of the screening report in order to attract further inputs from human rights experts in case an issue has been missed.[164]

5.4.4.3 Scoping

The next step proposed by Forman and MacNaughton is the second step, which they note should first be assessed to be both feasible and necessary meaning that it is optional.[165] The purpose of the second step is to build on the first stage in terms of planning the assessment by among other things:[166]

> (1) identifying key actors to perform the assessment, (2) identifying key stakeholders and determining their respective roles in the assessment, (3) devising a work plan, timetable and budget for carrying out the assessment; (4) determining sources and methods of data collection; and (5) choosing indicators.

[164] As above
[165] Forman & MacNaughton n 137 above, 12.
[166] As above, 11-12. (1) Key Actors: The team conducting the assessment should be multidisciplinary, including people with knowledge and/or expertise of human rights and the right to health, TRIPS, public health, and economic modelling. Team members should be drawn from academia, domestic social groups, and international human rights bodies and should ensure independence from the executive. (2) Key stakeholders: Key stakeholders should include populations and/or communities likely to be most affected; policy-makers with direct responsibilities in relation to medicines and intellectual property provisions; social actors who will participate in the assessment and international actors who may contribute to the assessment. Importantly, participation of populations likely to be affected in the assessment should be considered more than simply as a source of evidence. Participation should be assured at all steps of the assessment. At this planning step, representatives of the people mostly likely to be impacted should be involved to ensure that their views are considered in designing the HRIA plan and budget, as important factors may be overlooked by establishing an assessment plan without including those most likely to impacted. (3) Work plan, timetable and budget: In developing the work plan, timetable and budget, actors should assess the actors, activities, duration, and beginning and end dates of each component of the HRIA, taking into account available resources and personnel, and the timelines for ensuring that HRIA results have maximum impact on trade negotiations. (4) Methods of data collection: Actors conducting the exercise will need to choose methods in accordance with resource availability and timeframes. In low-resource settings, methods may include analysis of existing studies, secondary sources, and economic modelling. Secondary sources should include existing literature exploring the impact of intellectual property rights on access to medicines.[166] (5) Choice of indicators: Potential indicators should be reflective of human rights, and should be both qualitative and quantitative.

Walker on the other hand equates the scoping stage to defining the terms of reference of an impact assessment with the following details:[167]

> describing in detail the elements of the policy or project to be assessed, identifying the negotiation or implementation of future scenarios to be assessed, identifying likely future impacts, identifying the indicators of measurement and significance criteria, as well as the data sources relied upon and the various assessment tools to be employed, identifying the stakeholders to be consulted and how to ensure popular participation.

In this regard, Walker notes that after narrowing the issues to be addressed at the 'screening' stage, the 'scoping' stage is supposed to provide details of how the impact assessment will be conducted by describing the following:[168]

> the trade measure under assessment and a range of potential negotiation scenarios; the geographical context and time horizons; an initial indication of the likely impacts; assessment priorities based on those likely impacts; indicators of impact and impact significance criteria; data collection and analysis techniques; and, a detailed consultation and participation plan.

On the part of SHRC, the best practice recommendations are that the scoping exercise must detail the following:[169]

> Who will undertake the assessment (see more detailed recommendations above); A description of the policy, its aims and why it has been developed; Who is affected by the policy; Possible human rights impacts of the proposal and indicators for how to measure those impacts; The evidence that exists to inform the assessment and any further evidence that needs to be found; and The timescale of the assessment.

This step appears to be crucial because it will be important in order to inform the size of research to be undertaken and assess the level of resources needed versus what is available.

5.4.4.4 Evidence collection

The third step which is information collection essentially builds on second stage by:

[167] Walker n 150 above, 87.
[168] As above, 93-94.
[169] As above.

(1) focusing on the trade-related intellectual property provisions that may have the greatest impact on the right to affordable medicines; and (2) gathering information on the potential right to health impacts of the proposed provisions.[170]

As the name suggests, this is where data collection is done before analysis can be undertaken.

Walker does not include this stage in his framework.

SHRC observes that the following are the best practice recommendations:[171]

- HRIA toolkits and guidance should include comprehensive sections on the sort of evidence that might be required (with specific examples) and where that evidence can be found (see Department of Health textbox above for details).
- HRIA training should include training in appropriate research methodologies
- Organizations should consider identifying someone to collect information as it becomes available. Smaller organizations could pool resources to develop a shared database.

5.4.4.5 Consultations

This procedure is only contained under the SHRC report and not the others. It is closely related to evidence collection since according to SHRC this step is supposed to cover the voices of persons to be affected by a policy decision so that they can also be incorporated in the impact assessment.[172]

According to SHRC, the best practice recommendations are as follows:[173]

- Consultation processes should ensure there is adequate opportunity to respond and for those responses to be taken into account in the formulation and modification of policy
- HRIAs should consider the full range of people who should be targeted by consultation processes (e.g. staff, service users, those effected by the policy and other stakeholders) and the best methods for consultation
- People undertaking HRIAs should have an understanding of the specific barriers to consultation that arise for particular groups and methods for dealing with them through appropriate training, and context specific guidance HRIA forms should ask for evidence of consultation with stakeholders not simply that consultation has taken place.

[170] Forman & MacNaughton n 137 above, 13.
[171] SHRC n 112 above, 7.
[172] As above, 7.
[173] As above.

5.4.4.6 Rights analysis

The next step is the rights analysis step. In this category, the data is analyzed as against human rights obligations to identify the implications of a policy measure proposed.[174] It is at this stage that the measures that may mitigate the identified impacts are also elaborated.[175] If necessary, this part may highlight measures that would improve the situation of access to medicines in a positive manner.[176]

Walker observes that analysis is about specifying the actual impact of a policy measure identified at the scoping stage using data. Accordingly,

> 'analysis' stage refers to the verification of the various cause-effect channels linking trade measures with potential impacts that were identified during the 'scoping' stage. Effectively, this stage is putting into practice the terms of reference elaborated during the 'scoping' stage. It essentially involves four principal steps: first, the collection of data; two, analysis of data by reference to impact indicators to see whether the likely positive or negative impacts identified in the 'scoping' stage are verified; third, an evaluation of those results giving them context and meaning and their implications for the enjoyment of human rights and the State's human rights obligations; and fourth, the compilation of an initial report.[177]

SHRC also contends that analysis is about establishing the human rights impact of a particular policy; In this step, human rights indicators are often utilized as the basis for analysis. Accordingly:[178]

> Indicators or questions should be developed at the scoping stage in order to ascertain what evidence should be gathered and then again at the analysis stage to determine whether there has been a human rights impact. Indicators need to be developed which are context specific and relevant to the human rights framework which is being employed Indicators should be designed to assist non-legal specialists in understanding the human rights obligations which are at the core of the assessment process

[174] Forman & MacNaughton n 137 above, 13.
[175] As above.
[176] As above.
[177] Walker n 150 above, 98.
[178] As above.

5.4.4.7 Finalization of the report and methods of implementation/ Conclusion of recommendations

Step five deals with the report, conclusions and recommendations. It is about finalizing the report using 'the analysis of impacts on the realization of State duties, health needs, and human experience.'[179] This is where proposals for policy reforms are made as well as strategies for implementation, monitoring, and evaluation.[180]

Walker observes that recommendations should consider what should be done to enhance the positive impact and reduce the negative impact identified in the analysis stage.[181] Walker further observes that this section might also encompass:

> a) Measures built into the trade agreement itself such as a modification of a trade measure, the inclusion of a safeguard mechanism or exception, changes to the timing of implementation; b) Measures included in a parallel agreement or side-letter to the agreement, such as interpretative statements or creation of institutional arrangements to help implement programmes of common interest to the parties to mitigate negative impacts or to monitor implementation of the agreement; c) Technical cooperation or capacity-building projects to improve infrastructure, access international institutions and human rights bodies, improve data collection and analysis and so on; d) National measures directed towards remedying market imperfections, such as pricing mechanisms, government support through subsidies, tax measures, microcredit schemes and so on; e) Regulatory measures, including the adoption of human rights legislation or regulations, private sector regulation, ratification of international instruments, consumer protection legislation and so on; f) Voluntary measures such as adoption of industry standards, codes of conduct, Eco labeling and fair trade schemes; g) Institutional measures to enhance public participation, improve transparency around trade negotiation and implementation of agreements including access to information, and to strengthen accountability mechanisms; h) Abandonment of the trade agreement, identification of 'no-go' areas or exclusion of certain trade measures.[182]

If possible, it is advisable to solicit for public views, especially from those directly to be affected, when developing recommendations and in the event that human rights norms are deficient in terms of providing appropriate guidance on what needs to be done to mitigate the negative impact identified.[183]

[179] Forman & MacNaughton n 137 above, 14.
[180] As above, 14.
[181] Walker n 150 above, 88.
[182] As above, 99-100.
[183] As above, 101.

SHRC notes that the conclusions and recommendations stage is where the results are clarified and the actions to be taken, including alternative proposals, as well as mitigating measures are clearly stated.[184] In terms of the best practice, the SHRC recommendations include:

- Making conclusions and recommendations should be highlighted as an integral part of the process of HRIA;
- HRIA toolkits and forms should include detailed guidance and questions that must be answered on the type of recommendations that might be appropriate including changes to the policy, mitigating actions;
- Where negative human rights impacts are identified then failure to recommend any action as a result should be fully justified;
- Where action is required, the person who will implement the recommendations should be identified, as well as the fact that they have been notified of the need for the change and the timescale within which this change will occur; and
- Recommendations should be signed off by a senior person in the organization undertaking the assessment, preferably with responsibility for decisions on the policy changes.

5.4.4.8 Preparation of report

This step is not listed by Forman and MacNaughton. Walker on the other hand lists as the last step the preparation of the report which will include the results of the impact assessment as well as its recommendations.[185] The report will also detail the monitoring and evaluation process.[186]

5.4.4.9 Publication

Publication of the report depends on its use. This stage should be last and preferably after the issues have been agreed upon. The SHRC also lists as best practice the following recommendations:[187]

- All HRIAs should be published including screening processes, full assessments and recommendations for action
- HRIA forms should be designed in order to promote transparency and provide a full record of the impact assessment process
- Individual HRIAs should be easy to access via a website and should be simple to find with a basic Google or other search engine search.

[184] SHRC n 112 above.
[185] Walker n 150 above, 89.
[186] As above.
[187] SHRC n 112 above, 57.

5.4.4.10 Evaluation and monitoring

With respect to evaluation and monitoring it is important to put in place benchmarks and indicators in order to monitor progress over a period of time including the long term period. It is crucial to also provide for the identity of the actors responsible to monitor progress at this step[188]

The framework methodology provided by Forman and MacNaughton is very useful especially in terms of provoking ideas on how best to fashion a context-specific HRIA such as for example in Kenya as contemplated in this study. However, the key question that has to be answered is: What is the main value-addition of the HRIA mechanism over a simple rights-compliance analysis using indicators and benchmarks as has been the main practice in the past as discussed in the previous Chapter? It will be demonstrated in this study that in the context of government legislation the non-substantive (this means the part that deals with processes as opposed to the substance) part of HRIA methodology is often the most important. What this means is that the rights compliance analysis usually achieves the same thing as is the process of evidence collection and rights analysis, which are two key steps in a HRIA mechanism.

According to Walker, evaluation and monitoring means that an assessment has to be done at a later stage to determine whether the objectives of the impact assessment has been realized or not.[189]

On its part, the SHRC regards monitoring and review as something that will ensure that the HRIA process is 'ongoing and cyclical review of policy' and not just a once in a lifetime event.[190] In this regard, the best practice recommendations include:[191]

- Post –assessment internal monitoring and review procedures should be set up to consider whether recommendations have been implemented and what the ongoing impacts of the policy or practice are.
- The Procedures should specify:

[188] As above.
[189] Walker n 150 above, 89.
[190] SHRC n 112 above, 41.
[191] As above, 57.

- who is responsible for monitoring the policy
- the date when the policy will be reviewed and what evidence would trigger an early review
- if there is any data which needs to be collected and how often it will be analyzed.
- how to continue to involve relevant groups and communities in the implementation and monitoring of the policy.

5.5 Conclusion

The main conclusion of this chapter is that human rights norms rely on human rights methodologies for implementation. There is a plethora of methodologies especially in the area of ESCRs. Most of the methodologies discussed above are best utilized to evaluate programmes and projects after or in the process of implementation of a project. However, the mechanism of HRIA is perhaps the only tool that can be utilized prior to the implementation of a policy or legislation to identify and mitigate the adverse impacts of trade policies, legislation and agreements. It works the same way as environmental or social impact assessment in the context of implementing development projects. To this extent, this tool is best suited to be used to resolve the adverse impacts of pharmaceutical trade policies. In the next chapter, the HRIA methodology is applied in the Kenyan country context in relation to pharmaceutical trade policies and access to medicines.

CHAPTER SIX: A CASE STUDY OF PHARMACEUTICAL TRADE POLICIES AND ACCESS TO MEDICINES IN KENYA

6.1 Introduction

The previous chapters demonstrated why developing countries may utilize human rights impact assessment (HRIA) methodology in order to resolve the adverse impacts of pharmaceutical trade policies on access to medicines in relation to the implementation of the Trade Related Intellectual Property Rights (TRIPs) Agreement. Specifically, it was argued that a market-based theory as opposed to human rights-based theory would be most appropriate in Kenya in terms of promoting the uptake of HRIA methodology by trade policy makers in government. The focus on market-based theories as a motivational theory for trade policymakers in government is informed by the free market ideology that is widely practiced in Kenya's trade sector. Therefore, as Coleman argues, the rational theory of morality provides an important framework to argue for the adoption of human rights without compromising the interests of the state or rather rationality by using the concept of market failure. In the previous chapters it also emerged that the implementation of the TRIPs Agreement in developing countries may potentially be classified as a situation of market failure in Kenya because of its adverse impacts on access to medicines in developing countries and as such according to the market theory of morality using human rights norms may be justified. In order to use human rights arguments, it is important to identify the appropriate framework, such as the right to health normative framework as it relates to the TRIPs Agreement and access to medicines. Lastly, the right to health framework can only be employed in a useful manner in relation to pharmaceutical trade policies and access to medicines if it can prevent *beforehand* the potential adverse impacts it may have on access to medicines. Consequently, this requires the use of the HRIA mechanism, which is functionally different from other methodologies that are available in relation to the implementation of economic, social and cultural rights (ESCRs). It emerges from the earlier review of the catalogue of ESCRs methodologies available that HRIA is perhaps the only instrument that can resolve *beforehand* the adverse impacts of pharmaceutical trade policies on access to medicines.

In the following chapters, the study narrows down the discussion to the Kenyan case study. Basically, there are two chapters dealing with the Kenyan country-context. The first one is this chapter which essentially demonstrates that Kenya has not used HRIA despite the fact that it continues to formulate pharmaceutical trade policies that may adversely impact on access to medicines locally especially in the area of anti-counterfeiting legislation. The next chapter then focuses on the reason why trade policy makers in Kenya have not implemented the HRIA mechanism despite the existence of a clear need especially in area of anti-counterfeiting legislation.

6.2 An introduction to the access to medicines and TRIPs Agreement flexibilities landscape in Kenya

This section will tackle the history of pharmaceutical patents in Kenya, incorporation of TRIPs Agreement flexibilities, threats to access to medicines, and local pharmaceutical manufacturing. The main argument advanced in this section is that Kenya's intellectual property rights framework has always been in favour of adopting a strong intellectual property rights protection framework as opposed to exploiting the available flexibilities in order to safeguard its human rights obligations including under the right to health and access to medicines. Essentially, therefore, Kenya is an example of a country that has taken its trade obligations or free market ideology seriously compared to its human rights obligations or egalitarianism. In this regard, from a historical standpoint, one may argue that market-based theories of HRIA may be more motivational to trade policy makers in Kenya as opposed to human rights-based theories because of the existence of a strong culture of free market ideology in the trade sector as opposed to egalitarianism.

6.2.1 History of pharmaceutical patents in Kenya

In Kenya, prior to the adoption of the TRIPS Agreement, the development of intellectual property rights rules and many other laws was mainly influenced by England by virtue of colonization. Until 1989, Kenya therefore recognized and protected in its territory the intellectual property rights rules of England and specifically the British Patents and Designs

Act, 1907.[1] Many countries had provision of patent laws entitled 'Reciprocal arrangements with the United Kingdom (UK) and other parts of His Majesty's dominions' to facilitate this.[2] The influence of colonialism is therefore critical in Kenya's intellectual property rights landscape since Kenya did not reserve the right not to protect pharmaceutical patents despite there being no obligation at the international level. The Kenyan historical experience therefore shows that Kenya has been an intellectual property rights maximalist in that it has always provided for higher protection of intellectual property rights in its territory. The above scenario also shows that Kenya has been heavily influenced by UK in terms of adopting free market ideology as opposed to egalitarianism. A free market ideology will therefore inadvertently prioritize trade rules at the expense of other obligations of the government.

In 1990, Kenya's intellectual property rights landscape changed significantly with the enactment of the Industrial Property Act,[3] which established the Kenya Industrial Property Organization (KIPO).[4] The establishment of KIPO is a significant development because it was now possible for Kenya to directly administer its own intellectual property rules. Under section 2 of the Act, industrial property rights were defined as patents, certificates for industrial designs and any other non-patentable creation, rationalization certificates and utility certificates. KIPO was established under section 3 to: '(a) to examine application for, and grant, industrial property rights; (b) to screen technology transfer agreements and licenses; (c) to provide patent information to the public; and (d) to promote inventiveness in Kenya.' Under sections 6 and 11 of the Act, there was no exception provided for pharmaceutical products as had been done by other developing countries. In particular, India's Patent Act, 1970 did not recognize product patents protection in drugs and food.[5] In fact, it is estimated that about 40 states had reserved the right to decide whether or not pharmaceutical patents should be protected in their respective jurisdictions.[6] Rather than

[1] M Wekesa 'An overview of the intellectual property rights (IPRS) regime In Kenya' in M Wekesa & B Sihanya *Intellectual property rights in Kenya* (2009) 7.
[2] See for instance the Patents and Designs Act No 11 of 1911, Bangladesh, section 78.
[3] Industrial Property Act, 1990 (Cap 509 Laws of Kenya).
[4] As above
[5] S Chaudhuri 'TRIPS and changes in pharmaceutical patent regime in India' (January 2005) 2, Working Paper No 535, http://www.who.int/hiv/amds/IDA_India-Patent-amendments-Sudip.pdf (accessed 12 March 2017).
[6] WHO Drug Information 'Intellectual property protection: Impact on public health' (Vol 19, No. 3, 2005) 238, http://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf (accessed 1 December 2016).

provide for complete exclusion section 12 of the Industrial Property Act, 1990 provided for temporary exclusion from patentability of certain products and processes. The section stated as follows:

> Inventions concerning certain kinds of products or processes for the manufacture of those products, may, by notice in the Gazette, be excluded from patentability for not more than ten years except that any such exclusion may be extended for further periods, each, period not exceeding ten years.

From the above quote, it is arguable that Kenya without expressly stating so could actually use the law to exclude from patentability product patent protection in drugs as was the case in India's Industrial Property Act, 1970. However, since this provision was never used by the government, the reluctance of the state to intervene, especially upscaling access to ARVs that were highly needed in the 1990s, contributed to many deaths in Kenya that could be prevented. The inability of the Kenyan government to take steps to protect its own people for fear of antagonizing its trade partners is a clear indication that Kenya has a strong free market ideology.

In 2002, Kenya repealed its Industrial Property Act, 1990 and replaced it with the Industrial Property Act, 2001. The TRIPs Agreement requires all its member states to provide minimum patent protection in all fields of technology including pharmaceutical patents.[7] The Industrial Property Act, 2001 also abolished the Kenya Industrial Property Organization and replaced it with the Kenya Industrial Property Institute (KIPI), which is a body corporate.[8] The function of KIPI are similar to that of KIPO as provided for under section 5 of the Act as follows:

> (a) consider applications for and grant industrial property rights; (b) screen technology transfer agreements and licenses; (c) provide to the public, industrial property information for technological and economic development; and (d) promote inventiveness and innovativeness in Kenya.

Section 22(1) provides for both product and process patents including pharmaceutical patents. The pharmaceutical patent protection for both processes and products in

[7] See generally Article 27 of the TRIPs Agreement, 1995.
[8] Section 3 of the Industrial Property Act, 2001.

developing countries including Kenya is therefore mandatory pursuant to Article 27 of the TRIPs Agreement, 1995.[9]

Compared to India, Kenya's policy space post-2005 is still incoherent in relation to access to medicines. Whilst both Kenya and India are required to be TRIPs-compliant post-2005, India has been able to make its patentability criteria strict in order to resolve the problem of 'ever-greening' of patents pursuant to India's Patent (Amendment) Act No 15 of 2005. 'Ever-greening' means that patents never expire due to the registration of a second or even third patent on the same product or invention.

6.2.2 Incorporation of the TRIPs Agreement flexibilities in Kenya and the success of parallel importation in Kenya

Since Kenya is not a net exporter of medicines, activism around access to medicines is focused on how to facilitate importation of medicines, and especially generics from other markets, where it could be cheaper than what is available in the Kenyan market. From this understanding, the issue of incorporation of TRIPs Agreement flexibilities in law becomes very important in order to secure the policy environment in favor of importation of generics. The above analogy explains why Kenya included a wide range of flexibilities into the Industrial Property Act, 2001. The first flexibility contained in the Act is government use under section 80.[10] The second flexibility contained in the Act is voluntary licensing under sections 69-70.[11] The third flexibility contained in the Act is compulsory licensing under

[9] Article 65(4) of the TRIPs Agreement allows for developing countries to further delaying of protection in relation to product patent to areas of technology not so protectable in its territory on the general date of application of the TRIPs Agreement. Article 27 of the TRIPs Agreement now imposes obligations in all fields of technology without exceptions.

[10] Section 80 (1) of the Act provides for the exploitation of the patented inventions by the Government or by third persons authorised by the Government as follows: 'Subject to this section, where: (a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of any other vital sector of the national economy so requires; or (b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive; the Minister may, upon application to him in the prescribed form and after consultation with the Institute and the owner of the patent, order that the protected invention shall be exploited by a Government Ministry, Department, agency or other person as the Minister may designate in the order, subject to the payment of adequate compensation to the owner of the patent in accordance with this section.'

[11] Section 69 of the Act elaborates the prohibited terms in licence contracts. Article 70 provides for the registration of the contract and issue of certificate.

sections 72 to 78.[12] The fourth flexibility contained in the Act is the 'early working' or 'Bollar' exceptions under section 54(II).[13] Accordingly,

> government use means that the government may legitimately appropriate a patent for its own legitimate purposes. Voluntary licensing relates to a situation where a patent owner licenses a third party to exploit his or her patent usually by way of royalty payment. Compulsory licensing relates to a situation where the government compulsorily acquires and licenses third parties to exploit an existing patent in line with existing requirements prescribed by law. Lastly, early working or the 'Bollar' provisions relate to exploitation of patents for research and/or marketing purposes but not for commercial purposes especially when the existing patent is due to expire.'[14]

From the above, it is clear that the participation of civil society partly ensured the incorporation of a robust list of flexibilities under the 2001 law. According to Harrington, each of these flexibilities could contribute to increased access of locally produced generics.[15]

However, in terms of practice, Kenya has not exploited fully all the flexibilities available in the IPA, 2001. Arguably, Kenya's strong free market ideology has also manifested itself in terms of the choice of flexibility employed to promote access to medicines, which is parallel importation. Harrington concedes that Kenya has obtained practical advantage using parallel importation provided for under Article 58(2), which provides for the integration of the international exhaustion principle as opposed to the restrictive national exhaustion principle.[16] Under this new regime, it is now possible to import and market cheaper branded products as well as generics even where a valid patent exists in Kenya.[17] Lettington and Munyi also hold the view that the new regime of parallel importation is indeed a best practice

[12] Section 76 of the Act provides that 'a compulsory licence may be transferred only with that part of the industrial undertaking or its goodwill, in which the relevant invention is used and no such transfer shall be valid until the consent of the Tribunal has been obtained.'
[13] Section 54(ii) provides that '[t]he owner of the patent shall have the right to preclude any person from exploiting the protected invention by any of the following acts- (a) when the patent has been granted in respect of a product – (ii) sticking such product for the purposes of offering it for sale, selling or using the product.
[14] J Harrington 'Access to essential medicines in Kenya: Intellectual property, anti-counterfeiting, and the right to health' in MF FBA, S Hawkes, & B Bennet (eds) *Law and global health* (2016) Oxford University Press. above, 98.
[15] As above.
[16] As above, 99. Section 36(a)(1) of the now repealed 1989 Industrial Property Act was reformed and replaced by the new section 58(2) of the 2001 Industrial Property Act which adopts international exhaustion principle as opposed to the previous national exhaustion principle section 58(2) therefore provides that '[t]he rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.'
[17] As above.

in Kenya and it has been responsible for lowering of commodity prices, improvement of medicines supply, and promotion of competition.[18] What Kenya has done is not to infringe property rights but exploit the variations in prices in the international market in order to respond to the challenge of high medicines prices.

On the flipside, however, a joint report by Ministry of Health and Pharmacy and Poisons Board claimed that parallel importation had not improved access to medicines locally.[19] The report however noted that the practice of parallel importation *may* be of utmost benefit to Kenya. In a recent study published by HAI regarding the price and availability of both locally produced and imported 31 medicines in both public and private outlets show that government procurement prices are slightly higher than international reference prices at 0.55 and 0.78 respectively and as such locally produced medicines were 30% cheaper than imports.[20] This position of the government could be explained by the fact that the regulatory framework to make parallel importation work best is almost non-existent, which has also contributed to the problem of counterfeiting and unethical trade practices.[21] Thus the government has recommended the review of the Pharmacy and Poisons Act[22] in order to accommodate the mechanism of parallel importation in line with the relevant intellectual property laws in Kenya and the TRIPs Agreement flexibilities.[23] In fact, the Pharmacy and Poisons Board has reportedly already elaborated a set of guidelines that is aimed at making medicines cheaper using the parallel importation framework.[24] However, overregulation of the parallel importation may achieve unintended consequences by, for example, making it hard to exploit the flexibility as is the case in relation to the utilization of the compulsory licensing flexibility.

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[18] R Lewis-Lettington & P Munyi *Willingness and ability to use TRIPs flexibilities: Kenya case study* (2004) 18.
[19] 'Taskforce report on parallel importation, counterfeits and illegal trade in pharmaceuticals' (undated joint report by the Ministry of Health and the Pharmacy and Poisons Board) 9, http://pharmacyboardkenya.org/downloads/?file=parallel_importation.doc (accessed 28 November 2016).
[20] HAI Report on prices & availability of locally produced and imported medicines in Kenya, Survey report July 2018, 11.
[21] As above, 7.
[22] Pharmacy and Poisons Act Cap 244.
[23] As above, 10.
[24] 'Kenya to allow imports of cheap drugs' *Standard Digital* (5 July 2016), https://www.standardmedia.co.ke/business/article/2000207535/kenya-to-allow-imports-of-cheap-drugs (accessed 28 November 2016).

6.2.3 Local pharmaceutical manufacturing and voluntary licensing in Kenya

In line with our thesis that Kenya indeed strongly subscribes to the free market ideology, Kenya has in the past negotiated voluntary licenses to try and ameliorate the access to medicines situation in the country. The approach by the government to pursue the voluntary as opposed to the compulsory license option is a further indication that Kenya is not yet willing to antagonize trade actors.

Consequently, the issue of local manufacturing of medicines, and in particular the ARVs, has also been canvassed in some literature. In this regard, despite the difficulties highlighted above in terms of the utilization of the licensing options in Kenya as compared to parallel importation, Kenya has in fact made attempts to manufacture medicines, especially ARVs, locally using the licensing options. Illustratively, in 2004, Kenya was able to obtain two voluntary licenses from GlaxoSmithKline (GSK) (for three technically different products zidovudine, lamivudine, and combir) and from BoehringerIngelheim for nevirapine, all of which were drugs essential for first line ARV treatment regimens.[25] The plan was to have Cosmos manufacture affordable ARVs for supply in Kenya but this plan was short-circuited because both GSK and Boehringer went ahead and reduced their ARV drugs prices in the Kenyan market, which subsequently meant that it was economically unviable for Cosmos to go ahead and produce and sell the generic versions in Kenya.[26] The problem as such is that Kenya is unable to guarantee greater access to medicines using the licensing options since the economies of scale are still a barrier to affordable medications. However, the long terms solution to the problem of access to medicines in Kenya and other developing countries is to promote local pharmaceutical companies to be able to manufacture affordable medicines. In the short term, local production may help lower prices of medicines from foreign companies because of competition including generic competition.

There are other factors that also undermined the viability of local manufacturing of ARVs as documented by Osewe, Nkrumah and Sackey. One of the issues raised by these three is that

[25] L Opati 'Intellectual property rights in health – impact on access to drugs' in M Wekesa & B Sihanya *Intellectual property rights in Kenya* (2009) 29.
[26] As above, 29-30.

the procurement system in Kenya, unlike that in Zimbabwe, is not supportive of local industries. In this regard, Cosmos failed to be given preferential treatment in terms of supplying ARVs in Kenya, which means that it was exposed to strong competition from all manufacturers in the world.[27] Perhaps the company would have done better if it was allowed preferential treatment in ARV supplies in Kenya. Another challenge that was notable is that the company had no WHO-prequalification and this therefore limited its ability to supply ARVs under the Global Fund programme. The Global Fund program is one of the largest funds available for antiretroviral therapy and as at 2017 it supported about 17.5 million people.[28] Its orders were therefore irregular and only came from the government, mission hospitals and some non-governmental organizations.[29] There was also the issue of economics of scale. It was estimated that the cost of bio-equivalence test for each ARV as well as the Active Pharmaceutical Ingredients (API) was high leading to serious financial obstacles for Cosmos.[30] Moreover, it was also estimated that 95 percent of the raw materials and about half of the packaging materials had to be supplied from outside meaning that its ARVs were more expensive than even those supplied under the Global Fund programme.[31]

It appears therefore that the approach by government to ensure medicines are available and accessible in the long run is through local manufacturing. In order to do so however it is crucial that issues relating to procurement and economies of scales should be addressed if this strategy is to be effective in terms of making medicines more affordable in the country. In the meantime, it appears that parallel importation is the main strategy that has delivered to some extent on lowering the prices of medicines. Other flexibilities such as compulsory licensing and reviewing the patentability criteria remain unexplored. All in all, from its choices it seems Kenya is not comfortable going against free trade ideals notwithstanding the welfare cost that comes with this position.

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[27] PL Osewe, YK Nkrumah & E Sackey *Improving access to medicines in Africa: Assessment of Trade-Related Aspects of Intellectual Property Rights (TRIPs) Flexibilities utilization* (2008) 34.
[28] https://www.theglobalfund.org/en/hivaids/ (accessed 31 October 2018). A company that is prequalified to supply drugs under the Global Fund programme is more likely to succeed in the market since many people on ARVs are currently supported under this programme including in Kenya.
[29] Osewe & others n 27 above.
[30] As above, 34-35.
[31] As above 35.

6.3 Threats to access to medicines in Kenya

The previous section demonstrated that Kenya is more predisposed to take its trade obligations more seriously than its human rights obligations. In this regard, Kenya has focused more on ensuring that it is compliant with its obligations under the TRIPs Agreement and sometimes even going beyond what is needed. It has also avoided by and large taking measures which may be interpreted as being anti-free trade such as compulsory licensing and instead focused on parallel importation which is based on competition from diverse sources of medicines. In this section, we further explore the threats to access to medicines in Kenya beyond the lack of full utilization of TRIPs Agreement flexibilities.

6.3.1 EU EAC EPA

Current statistics on access to medicines are not available. However, the threats to access to medicines in Kenya are diverse but this section focuses on potential threats emanating from intellectual property rights protection and enforcement. To begin with, the European Union East African Community Economic Partnership Agreement (EU EAC EPA) currently being negotiated has attracted some concerns regarding access. Kenya signed on to this Agreement on 1 September 2016 alongside Rwanda. On 27 September 2016, the Kenyan government deposited the instruments of ratification in Brussels after Parliament ratified EU EAC EPA on 20 September 2016, which means that it 'will continue to benefit from EC Market Access Regulation No 1528/2007 which governs the EU preferential market access regime for African, Caribbean and Pacific countries that have negotiated [EPA] with EU.'[32] With regards to intellectual property rights, Article 3(b)(IV) of EPA provides that Parties will conclude negotiations on intellectual property rights within five years upon entry into force of EPA. In this regard, the next five years will be crucial for access to medicines groups in Kenya and EAC assuming that the agreement enters into force.[33] The EPA entered into between EU and

[32] 'Kenya deposits instruments for ratification: Press statement by the Cabinet Secretary for Foreign Affairs on the deposition of instruments for ratification of the East African Community-European Union Economic Partnership Agreement' *Ministry of Foreign Affairs of Kenya*, 28 September 2016.
[33] For EPA to enter into force, it has to be signed on by all partners of the EAC. Currently, only two partners have signed EPA and as such it is not currently in force.

Southern African Development Community (SADC) may be indicative of what to expect.[34] Article 16 of this Agreement deals with cooperation in the area of intellectual property rights and provides as follows:

> 1. The Parties reaffirm their commitments under Article 46 of the Cotonou Agreement and their rights, obligations and flexibilities as set out in the Agreement on Trade-related Aspects of Intellectual Property, contained in Annex IC to the Agreement establishing the World Trade Organization ('TRIPS Agreement').
>
> 2. The Parties agree to grant and ensure adequate, effective and non-discriminatory protection of intellectual property rights ('IPRs'), and provide for measures for the enforcement of such rights against infringement thereof, in accordance with the provisions of the international agreements to which they are a party.
>
> 3. The Parties may cooperate in matters related to Geographical Indications ('GIs') in line with the provisions of Section 3 (Articles 22 to 24) of the TRIPS Agreement. The Parties recognize the importance of GIs and origin-linked products for sustainable agriculture and rural development.
>
> 4. The Parties agree that it is important to respond to reasonable requests to provide information and clarification to each other on GI and other IPR related matters. Without prejudice to the generality of such cooperation, the Parties may, by mutual agreement, involve international and regional organizations with expertise in the areas of GIs.
>
> 5. The Parties consider traditional knowledge as an important area and may cooperate on it in future.
>
> 6. The Parties may consider entering into negotiations on the protection of IPRs in future, and the SADC EPA states have as their ambition, and will endeavor, to negotiate as a collective. Should negotiations be launched, the EU will consider including provisions on cooperation and special and differential treatment.
>
> 7. If a Party that is not a party to a future agreement on protection of IPRs negotiated in accordance with paragraph 6 wishes to join, it may negotiate the terms of its entry to that agreement.
>
> 8. If any agreement emanating from negotiations envisaged in paragraphs 6 and 7 were to result in outcomes that prove to be incompatible with the future development of a SADC regional IPRs framework, Parties shall jointly endeavor to adjust this Agreement to bring it in line with that regional framework while ensuring a balance of benefits.

[34] 'Entry into force of the SADC-EU Economic Partnership Agreement (EPA) *tralac* 10 October 2016, https://www.tralac.org/news/article/10636-entry-into-force-of-the-sadc-eu-economic-partnership-agreement-epa.html (accessed 2 July 2018).

The emphasis on traditional knowledge and GI above shows the priorities of the SADC region in relation to intellectual property rights protection. However, paragraph 6 is essentially an opportunity for the EU to renegotiate intellectual property rights protection in the future in SADC. In this regard, there seems to be no major concessions being made by both the SADC and EU.

However, in relation to EU EAC EPA, the suggestion to open up intellectual property rules for discussions is in itself a matter of concern for access to medicines stakeholders. This is because Kenya is already compliant with the TRIPs Agreement and therefore re-opening the talks on intellectual property must be aimed at securing stronger intellectual property protection standards beyond what is required by the TRIPs Agreement. Kenya is also currently supporting the Continental Free Trade Agreement (CFTA) launched by the AU at the beginning of 2018, which may also be concerning if it adopts stronger intellectual property protection standards than is provided for under the TRIPs Agreement. Arguably, Kenya and other African countries may choose to focus on other intellectual property rights protection including traditional knowledge (TI) under this framework, which may be more beneficial to them than patents in terms of access to medicines.

Secondly, the Anti-Counterfeit Act, 2008 is another threat since it aims at reversing the gains already made under the Industrial Property Act, 2001 by making it hard to access generic medicines in the country. The argument against the Act is that it has stronger intellectual property including patent enforcement measures that may undermine access to medicines in the country. The details of this discourse will be explained in details in the next section.

The resulting situation in Kenya's intellectual property landscape is as follows:

> Patent protection is available through national filing, with a developed system of examination of applications. The law contains some key flexibilities, for example, compulsory licenses for failure to exploit or to meet demand, government use orders for public interest and anti-competitive purposes, and early working and research exceptions. Additionally, Kenya has one of the most liberal applications of the international exhaustion principle, permitting parallel importation of both branded and legitimately-marketed generic medicines. In

> addition Kenya has also adopted anti-counterfeiting legislation, widely regarded as TRIP-plus enforcement measures which militate against access to medicines."[35]

The key point to be noted from the above quote is that intellectual property rights rules in Kenya have gone beyond what is expressly required by the TRIPs Agreement at least in relation to the Anti-Counterfeit Act, 2008.

Consequently, the debate in the context of anti-counterfeit legislation in Kenya and elsewhere, and indeed with regards to intellectual property rules in general, has been mainly about the need to balance between the public policy objective of enforcing intellectual property rights as required by the TRIPs Agreement and ensuring that intellectual property rights enforcement does not become a barrier to legitimate (generic) trade and human development, which is important in relation to human rights. This position is summarized as follows:

> Intellectual property rights infringement and the need for effective enforcement is probably one of the most important public policy issues in the current discourse on the governance of intellectual property system. Designing appropriate policies and laws to promote effective and adequate protection of IPRs while ensuring that enforcement measures and procedures do not themselves become barriers to legitimate trade and that such measures do not negatively impact efforts to promote human development is the key challenge.[36]

The challenge of anti-counterfeiting legislation is indeed concerning since the enforcement of intellectual property rights may further restrict access to generic medicines in the country. The broad definition of counterfeit goods under the anti-counterfeit legislation is unnecessary at least in relation to what the TRIPs Agreement requires and should be avoided by trade policy makers in government.

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[35] Global Commission on HIV and the Law 'Regional Issue Brief: Intellectual property rights and access to medicines' (4 August 2012, Pretoria, South Africa), www.hivlawcommission.org/index.php/regional-dialogues-main/.../download (accessed 1 December 2016).

[36] SF Musungu 'IPR infringements and enforcement – Accounting for socio-economic, technical and development variables' Advisory Committee on Enforcement, Sixth Session, Geneva, December 1 – 2, 2010 [WIPO/ACE/6/10], http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_6/wipo_ace_6_10.pdf (accessed 1 December 2016).

6.3.2 Anti-Counterfeiting law and criminal enforcement measures in Kenya

The previous section introduced the issue of access to medicines in Kenya and located some of the threats to the TRIPs-plus measures contained specifically under the Anti-Counterfeit Act, 2008. This section will explain in details why the Act is a threat on access to medicines in Kenya and then discuss the opposition it has received specifically from civil society members.

In 2008, Kenya enacted an Anti-Counterfeiting Act after a long campaign by manufacturers for more effective intellectual property rights enforcement in Kenya.'[37] The Ministry of Trade and Industrialization embarked on the drafting of the legislation in consultation with various stakeholders and especially the Kenya Association of Manufacturers (KAM).[38] The influence of the KAM in the final text was evident because the legislation succeeded in providing for greater intellectual property rights enforcement. However, almost immediately after it was enacted, it was subjected to a constitutional challenge, using the repealed constitution. Three petitioners living positively with HIV and AIDS between eight and 19 years approached the High Court to complain about the potential impact of the legislation on access to ARVs.[39] At a later date, after the enactment of the 2010 Constitution, the petition was amended by relying on among others the constitutional right to health. Harrington argues that the justiciability of the constitutional right to health under the new Constitution was crucial in opening up the courts as an alternative forum within which the distinctive needs of persons living with HIV and AIDS could be given voice.[40]

In the petition, it was contended that the enactment of the Industrial Property Act in 2001 made medicines 'widely available', which fact enabled the government and other partners such as *Médecines sans Frontières (MSF)* to provide ARVs to the petitioners 'free of charge'.[41] Relying on experiences of the Netherlands and Germany with regards to the danger of

[37] J Harrington 'Access to essential medicines in Kenya: Intellectual property, anti-counterfeiting, and the right to health' in MF FBA, S Hawkes, & B Bennet (eds) *Law and global health* (2016), 103.
[38] As above, 105.
[39] As above, 108. The previous constitution was used in this regard and specifically relying on its provision on the right to life among others.
[40] As above, 116.
[41] *PAO & 2 Others v AG & 2Others* [2012] eKLR, para 9.

seizure of generic medicines on account of the anti-counterfeiting war, the petitioners asked 'the government to consider the Act again and redraft it'.[42] In summary, the arguments of the petitioners are summarized under paragraph 14 of the decision as follows:

> They state that the government has failed to acknowledge and specifically exempt generic drugs and medicines from the definition of counterfeit goods in the Act; it has failed to provide a clear definition of counterfeit goods under section 2 of the Act by defining counterfeit goods in the section in such a manner as would allow generic drugs to be included in the said definition thereby effectively prohibiting importation and manufacture of generic drugs and medicines in Kenya; it has also failed to take into account the provisions of the HIV and AIDS Prevention and Control Act, 2006 in so far as the petitioners have accrued rights under the said Act and have acquired a legitimate expectation that those rights will be protected; it has failed to clarify the application of the Industrial Property Act, 2001 in so far as the Act allows for exceptions necessary to make generic drugs available in Kenya; it has imposed an undue and unnecessary burden on the consumers of generic drugs and medicines of proving that generic drugs and medicines are not counterfeit goods as defined by the Act.

In support of the petition, according to the United Nations (UN) Special Rapporteur on the right to the highest attainable standard of physical and mental health (Special Rapporteur), the Act would endanger generic access in the country. In this regard, he argued that the Act which was meant to prohibit counterfeiting trade in Kenya would in the process endanger the right to health and the right to life as enshrined under Articles 43 and 26 of the Constitution respectively.[43] The problem of the Act was to be found in the definition of counterfeit drugs under section 2 of the Act most likely included generic medicines produced in Kenya and abroad and that this would interfere with its manufacturing, sale, and distribution especially of generic versions of patented drugs.[44] In terms of consequences, it would lead to seizures of legitimate generics as counterfeits. With regards to this point, the Special Rapporteur averred as follows:[45]

> This would lead to a situation in which medicines that are approved by regulatory authorities as being safe and effective are seized on the grounds that they are "counterfeit"; generic medicines destined for importation to Kenya being seized due to the uncertainty surrounding possible infringement of the Act upon delivery; significant delays of shipments of imported generic drugs at ports of entry to Kenya for inspection or legal clarification purposes; seizure of medicines at Kenyan ports by customs officials and police officers who are not specially trained to recognize the difference between counterfeit and generic products and an increase

[42] As above, para 22-23.
[43] As above, para 34.
[44] As above.
[45] As above, para 36.

> in the price of ARVs within Kenya which would make them expensive and financially inaccessible to those who need them.

On the side of the Respondent, the government relied on two main arguments. The first one was that the anti-counterfeit legislation will save lives in Kenya including those of the petitioners by protecting citizens against counterfeit medicines.[46] They argued in this regard that the definition employed in the Act was similar to that provided by the World Health Organization (WHO).[47] The second argument put forward by the government was that the *proviso* to section 2 of the Act gives the Industrial Property Act priority over the Anti-Counterfeit Act and in case of conflict, as is presently contented, the *proviso* would be sufficient enough to preserve the gains made with regards to generic medicines in the country.[48] In other words, the safeguards being requested by the petitioners had already been adequately provided for.

In terms of analysis, the learned Judge started by acknowledging the socio-economic context of the case and concluded that persons infected with HIV would succumb to opportunistic infections if they had no access to medical intervention and treatment.[49] The learned Judge observed that many HIV patients just like the petitioners were heavily dependent on the more affordable generics for their lifelong treatment.[50] The Judge referred to paragraph 4 of the CESCR General Comment. 14, which states that the drafting of Article 12(2) of the ICESCR rejected the definition of health as contained in the WHO Constitution's preamble and 'embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life….'[51] According to the Judge, this imply 'a situation in which people have access to the medication they require to remain healthy. If the state fails to put in place such conditions, then it has violated or is likely to violate the right to health of its citizens.'[52] The

[46] As above, para 39.
[47] As above.
[48] As above, para 41.
[49] As above, para 50.
[50] As above.
[51] General Comment 14: The right to the highest attainable standard of health (Art. 12), Adopted at the Twenty-second session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4), para 4.
[52] *PAO* n 41 above, para 63.

Judge further quoted paragraph 35 of the CESCR General Comment 17[53] with regards to the obligations of the government to prevent unreasonably high prices.[54] In this regard, the Judge observed that, in accordance with the State's negative obligations under the right to health, it would be a violation for the state to put in place a legislation whose impact would be to make essential medicines unaffordable.[55] This means that states are required to refrain from taking measures that will jeopardize the right to health including access to generic medicines. The Judge also noted the intricate link of the right to health, life and dignity especially in the context of HIV and AIDS.[56]

Having clarified the obligations of the government with regards to the right to health, the Judge turned her focus to the legislation at hand. She observed that it was meant to bolster intellectual property rights in Kenya by introducing criminal sanctions for infringement since Kenya had complied with TRIPs Agreement under its IPA 2001.[57] The main issue before the Judge was thus 'whether the implementation of the Act will result in the violation of the constitutional rights of the petitioners as a result of the provisions of section 2 of the Act.'[58]

In terms of the defenses provided by the Respondent, the Judge noted that section 2 of the Act definition was beyond what was provided by the WHO. She noted that by specifically adding to the WHO definition of counterfeit medicines definition the words '…whether or not such products have correct ingredients…' and '…have sufficient active ingredients…', generic medicines was directly targeted since generics usually have the correct active ingredient as the branded product.[59] The Judge also concluded, while referring to sections 32-34 of the Act that, contrary to what was asserted by the Respondent, the primary intention of the legislation was not to safeguard consumers from counterfeit medicine because minimal emphasis was put on issues of standards and quality.[60] She observed that the issue of

[53] General Comment 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literally or artistic production of which he or she is the author, [UN Doc. E/C.12/G.C./17].
[54] *PAO* n 41 above, para 64.
[55] As above, para 66.
[56] As above, para 56.
[57] As above, para 70.
[58] As above, para 71.
[59] As above, paras 72-78.
[60] As above, para 82.

consumer protection may have been a collateral issue in the minds of the drafters judging by the *proviso* in section 2, which alludes to the rights of the consumers especially of generic medicines.[61]

From the foregoing, it appears that by including a *proviso* under section 2 of the Act the government thought it had adequately discharged its obligations under the right to health. This was not to be the case as noted subsequently. The Judge rejected the argument that the *proviso* was adequate to safeguard generic medicines as made available by the Industrial Property Act, 2001 and observed that in fact the anti-counterfeiting legislation was a threat to access to essential generic medicines in Kenya as discussed under paragraphs 84- 86 of the *PAO* decision.[62] Consequently, the Judge ruled in favor of the petitioners and granted all their prayers and also gave a decision to the effect that the Act should be amended and

[61] As above, para 85.

[62] The contents of the relevant paragraphs are reproduced below for ease of reference:

84. However, the right to life, dignity and health of people like the petitioners who are infected with the HIV virus cannot be secured by a vague proviso in a situation where those charged with the responsibility of enforcement of the law may not have a clear understanding of the difference between generic and counterfeit medicine. The primary concern of the respondent should be the interests of the petitioners and others infected with HIV AND AIDS to whom it owes the duty to ensure access to appropriate health care and essential medicines. It would be in violation of the state's obligations to the petitioners with respect to their right to life and health to have included in legislation ambiguous provisions subject to the interpretation of intellectual property holders and customs officials when such provisions relate to access to medicines essential for the petitioners' survival. There can be no room for ambiguity where the right to health and life of the petitioners and the many other Kenyans who are affected by HIV and AIDS are at stake.

85. Further, contrary to the respondents' counsel's assertion, the Anti-Counterfeit Act, being later in time, would prevail over the Industrial Property Act in the event of a conflict, and the proviso to Section 2 may not be of much help to the petitioners. Should the Act be implemented as it is, the danger that it poses to the right of the petitioners to access essential medicine which they require on a daily basis in order to sustain life is far greater and more critical than the protection of the intellectual property rights that the Act seeks to protect. The right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders.

86. While such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners. As the Committee on Economic Social and Cultural rights notes at paragraph 35 of General Comment. 17.

'Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education. Moreover, states parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights.

……states parties should also consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions.

especially it's the definition of counterfeit medicines under section 2.[63] Since the decision was not appealed against within the stipulated time, its application has been 'permanently suspended' as it relates to generic medicines importation in Kenya.[64] If properly implemented, this decision will help to preserve the current levels of availability of affordable medication in Kenya.[65] The permanent solution however remains putting in place appropriate amendments that are capable of adequately safeguarding the right to health and in particular access to generic medicines in Kenya.

As such, a comprehensive agenda aimed at safeguarding the right to health in anti-counterfeit legislation is justifiable. According to El Said and Kapczynski, the new push that conflates IP enforcement and drug quality control represents a new threat on access to medicines by targeting the generic supply chain.[66] The two authors further contend that the 'most extreme measure' of the legislation in Kenya was its extra-territorial application in terms of obliging enforcement authorities locally to 'take measures against generic medicines that are lawfully in Kenyan market on the basis that they infringe patents in other countries.'[67] They advise that the issues of drug quality, safety and efficacy should be

[63] The relevant paragraphs of the *P.A.O* decision are reproduced below for ease of reference:
87. In view of the matters set out above, I find that Sections 2, 32 and 34 of the Anti-Counterfeit Act threaten to violate the right to life of the petitioners as protected by Article 26 (1), the right to human dignity guaranteed under Article 28 and the right to the highest attainable standard of health guaranteed under Article 43 (1) and grant the declarations sought as follows:
(a) The fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43(1) of the Constitution encompasses access to affordable and essential drugs and medicines including generic drugs and medicines.
(b) In so far as the Anti-Counterfeit Act, 2008 severely limits or threatens to limit access to affordable and essential drugs and medicines including generic medicines for HIV and AIDSHIV and AIDS, it infringes on the petitioners' right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43(1) of the Constitution.
(c) Enforcement of the Anti-Counterfeit Act, 2008 in so far as it affects access to affordable and essential drugs and medication particularly generic drugs is a breach of the petitioners' right to life, human dignity and health guaranteed under the Constitution.
88. It is incumbent on the state to reconsider the provisions of section 2 of the Anti-Counterfeit Act alongside its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of petitioners and others dependent on generic medicines are not put in jeopardy.
[64] Harrington n 37 above, 113.
[65] As above.
[66] M El Said & A Kapczynski 'Access to medicines: The role of intellectual property law and policy (2011) 13, 15, Working paper prepared for the Third meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7 - 9 July 2011.
[67] As above, 16.

separated from issues of IP enforcement and that the former should be led by a well-resourced and trained local drug regulatory institution.[68]

6.3.3 Analysis of the Anti-Counterfeiting Act amendments

Pursuant to paragraph 88 of the *PAO* decision, the learned Judge recommends the review of especially section 2 of the Anti-Counterfeit Act in order to get rid of its defects that potentially infringes on the constitutional rights of the petitioners. This section thus focuses on the amendments of the anti-counterfeiting legislation in 2014.

Despite the positive effects the decision has had in the region, it is arguable whether the same positive feedback has been registered locally. In 2013, a technical meeting was held in Kenya by various stakeholders to discuss the anti-counterfeit legislation in light of the *PAO* decision. In this meeting, the experts allowed technical discussions of the legislation leading to: the identification of potential threats that the Act had on access to medicines; a unanimous position on the appropriate scope and operation of the Act; and a unanimous amendment on the proposed reviewed definition of counterfeiting.[69] In terms of approach, the technical team sought to align the Anti-Counterfeit Act with the TRIPs provisions. In this regard, the technical team proposed that anti-counterfeiting law should be limited to counterfeit trademarks and copyright piracy as provided for under Article 51 of the TRIPs. Similarly, the team recommended that, in line with Article 61 of the TRIPs, criminal measures should be limited to 'willful cases' done in 'commercial scale'.[70] Alongside other proposals, the recommendations of the technical team were to be subjected to national civil society endorsement and subsequently shared with the Anti-Counterfeit Agency and the Parliament to aide in the amendment process of the Act.[71]

A number of civil society organizations working around issues of intellectual property and access to medicines held a consultative meeting in order to harmonize their positions and to present a common position paper detailing the amendments they deemed appropriate in the

[68] As above, 15-16.
[69] 'Anti-Counterfeit Act and access to medicines in Kenya: Outcome of the technical meeting' Held at Maanzoni lodge in Machakos County, 26 November 2013, 4.
[70] As above, 6-7.
[71] As above, 8.

anti-counterfeiting legislation in order to safeguard access to affordable medications.[72] Unfortunately, the civil society position paper played a minimal role if the amendments discussed above are anything to go by.[73] In fact, it is doubtful as to whether it was seriously considered despite representatives of the civil society groups attending a number of meetings in the context of the Kenya's anti-counterfeiting law review.[74] Even more worrying is that government departments were complicit when the intellectual property rights and enforcement agenda was being championed in Kenya despite the warning that it may adversely impact access to affordable medications as protected under the right to health and thus the need for appropriate safeguards to be put in place. A good example of government complicity has been the failed attempts by the government to amend relevant laws in order to limit the full utilization of the parallel importation flexibility under the TRIPs Agreement.

In 2014, the anti-counterfeiting legislation was amended by way of supplementary legislation. However, most of the suggestions proffered by the civil society actors as advised by the technical team were ignored. Perhaps, the only positive measure that was adopted in line with the judgment of the High Court in *PAO* was the removal, of the extra-territorial application of the anti-counterfeiting legislation.[75] This is because it had been argued that the protection of intellectual property rights beyond those protected in Kenya violates the territoriality principle.[76] Unfortunately, other critical measures proposed by civil society organizations to be put in place failed to see the light of the day and in particular the

[72] The meeting was organized by the author of this thesis in 2013 amongst other stakeholders. The report of the meeting is on file with the author.
[73] Despite the fact that the proposals were made available to the anti-counterfeiting agency as a matter of knowledge since the current author worked on the document as well, the final amendments adopted do not reveal any evidence of the optimal utilization of the proposals therein.
[74] As the programme manager at the AIDS Law Project, this author sent various lawyers to represent the civil society position during the meetings organized by ACA. Copies of the letters in file at ALP.
[75] It should be noted that the argument presented in this study is not that there have been no amendments of the 2008 Anti-Counterfeit Act No 13 of 2008 but that the amendments were not meant to implement the judgment of the High Court of Kenya to safeguard access to affordable medicines. Looking at the 2014 Kenya Gazette Supplement No 75 (National Assembly Bills No. 24), which contains the amendments that have now been signed into law provides as follows. Section 2 will be amended to delete extraterritorial application of intellectual property rights. Section 16 of the law has been amended to establish the Intellectual Property and Enforcement Coordination Advisory Committee. Finally, section 34 empowers the Executive Director of the Anti-counterfeiting Agency to make orders, which have the same effect as High Court decrees or orders. Clearly, it will be argued, these amendments did not address the core of the issues involved in the case at hand.
[76] This principle requires that only intellectual property registered within a territory should be protected.

suggestion to delink patents from anti-counterfeiting legislation in order to safeguard access generic medicines was ignored due to the influence of the private sector on the process of amendments in particular.[77] The ability of the private sector to influence government officials coupled with the apparent ignorance of trade policy makers on trade and human rights issues (discussed in details in chapter 7) means that civil society organizations in Kenya have to work twice as hard to promote access to medicines in the country. The proposal to delink patents from the anti-counterfeiting legislation is critical since the current definition of counterfeiting under section 2 of the Anti-Counterfeit Act 'makes it possible to classify generic medicines as counterfeit medicines.'[78]

From the foregoing, it appears that the review of the Kenyan anti-counterfeiting legislation even though expected to comply with the judgment by the High Court of Kenya in *PAO.* case, failed to satisfactorily safeguard the right to health on access to medicine as aptly captured by HRC resolution 23/14 discussed above under the section on right to health and accessibility. Most of the amendments adopted were biased in favor of trade as well as intellectual property rights enforcement and it is doubtful that the right to health concerns were sufficiently integrated in the final amendments. For instance, section 16 of the anti-counterfeiting law as amended establishes another body, namely, Intellectual Property and Enforcement Coordination Advisory Committee (IPECAC). Similarly, section 34 as amended empowers the Executive Director of the Anti-Counterfeiting Agency (ACA) to be able make orders, which have the same effect as the High Court decrees or orders. Clearly, these amendments did not address the core of the issues raised in the *PAO* judgment, which is to safeguard access to affordable medicines in accordance with the right to health obligations of the government of Kenya. If they did address the right to health concerns, they barely scratched the surface of the problem.

[77] Interview with Jacinta Nyachae, March 2017. It should be noted that a key ask for civil society actors in Kenya and beyond was to delink patents from the anti-counterfeiting legislation. It was thought that since the scope of the anti-counterfeit legislation covered patents it was TRIPS-plus, a term used to connote measures that go beyond what is required by the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.
[78] 'The Kenya Anti-Counterfeit regulation 2010' 26 October 2010 Coulson Harney Advocates, http://www.iracm.com/wp-content/uploads/2013/01/kenyan-anti-counterfeit-regulation-2010-9231.pdf (accessed 25 April 2016).

In fact, it is possible to argue that as a result of the amendments discussed above the situation of access to affordable medicines is even more precarious since the enforcement of intellectual property rights framework in Kenya has been greatly enhanced. Specifically, both the institutional capacity and the efficiency of the system has been boosted because of the establishment of a new institutions, IPECAC, as well as the provisions enhancing the powers of the Executive Director of the ACA to act in similar vein as a judicial officer. In essence, therefore, access to medicines is still under attack in Kenya and this time round the problem is much bigger than before. Put differently, instead of safeguarding access to medicines, the amendments boosted Kenya's intellectual property rights enforcement mechanism that may jeopardize generic medicines access.

Suffice to note, the relevant government agencies that were in charge of the process of reviewing and amending the anti-counterfeiting legislation in Kenya took a very hostile stance against issues raised in support of safeguarding access to affordable medicines by civil society organizations.[79] It appears as if pro-intellectual property rights enforcement interest groups successfully hijacked the *PAO & 2 Others v. AG* judgment and used it to further strengthen the enforcement framework for intellectual property rights in Kenya as opposed to safeguarding access to affordable medicines as ordered by the Judge despite numerous interventions from the civil society organizations.

In light of the apparent failure to achieve any meaningful progress in the implementation of the *PAO* judgment in line with the right to health framework since April 2012 when the judgment was handed down, it is arguably the right time for access to medicines actors to think of alternative strategies. The pro-intellectual property rights interest groups, which comprises of mainly pharmaceutical companies, are very strong both at the national and international fronts and in this manner they have currently succeeded in frustrating any meaningful reforms in the context of the anti-counterfeiting legislation in Kenya. Through government acquiescence, they have failed to sufficiently accommodate alternative views

[79] In 2013, a group of activists engaged the Anti-counterfeiting Agency director in a war of words in twitter under the hash-tag #TellACABoss online debate, '#TelACABoss', https://ipkenya.wordpress.com/2013/10/04/tellacaboss-online-debate-balancing-protection-of-public-health-and-intellectual-property-in-kenya/ (accessed 22 April 2014).

from specifically pro-access to medicines human rights interest groups and this situation has manifested itself in the adoption of more stringent enforcement measures in the context of the anti-counterfeit legislation review process as discussed above.

6.3.4 The Statute Law (Miscellaneous Amendment) Bill, 2018

As contended in the previous section, in 2013, the Anti-Counterfeit Act, 2008 was subjected to a series of amendments including in relation to the extra-territorial application of the legislation under section 2.

In 2014, the Act was amended to remove the extraterritorial application of the legislation through supplementary legislation, the Kenya Gazette Supplement No 75 (National Assembly Bills No. 24). The effect of this amendment was to restrict the Anti-Counterfeit Act, 2008 from applying beyond the intellectual property rights recognized and protected in Kenya. This amendment was important because first IP protection is usually territorial in nature and should not be universal because it is not required by the TRIPs Agreement. Secondly, in the context of access to medicines, the amendment was equally important especially if Kenya was to continue enjoying the benefits of the trade in parallel importation that is one of the flexibilities under the TRIPs Agreement currently codified under Industrial Property Act, 2001 and has been instrumental in promoting greater access to affordable medicines by exploiting the international exhaustion principles.

In 2018, however, the issue of anti-counterfeit legislation has arisen again and this time there appears to be an agenda to extend IP protection and enforcement beyond Kenya. Through the less visible The Statute Law (Miscellaneous Amendment) Bill, 2018, there are amendments which are aimed at reversing the scope of IP enforcement under section 2.

The Statute Law (Miscellaneous Amendment) Bill, 2018 proposes among other things ‘to insert the words "any item that bears an intellectual property right" immediately after the word "counterfeiting" in the definition of "counterfeit goods".’ The current definition of the counterfeit good is as follows: ‘"counterfeit goods" means goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting.’ Once enacted, the new definition of counterfeit good will be as follows: "counterfeit goods" means ‘goods

that are the result of counterfeiting, and includes any means used for purposes of counterfeiting; any item that bears an intellectual property right.'

The issues that arises are two. First, the current amendment proposed once again fails to implement the *PAO decision* in terms of reducing the scope of counterfeiting goods. Implementing the decision would have been achieved by proposing amendment to define counterfeit goods as products resulting from counterfeiting and then defining counterfeiting as willful copyright piracy and counterfeit trademark on a commercial scale in accordance with the TRIPs Agreement. Second, the amendment as currently proposed will also give the Anti-Counterfeit Authority more power to enforce IP protected outside the country. Therefore, any amendment to be introduced should end with intellectual property rights protected in Kenya to restrict the application of the anti-counterfeit legislation outside the country.

From the above, it appears that the agenda to ignore human rights concerns in trade policy development is still alive and more vigilance is needed to arrest the trend.

6.4 The implementation of human rights impact assessment in Kenya

Throughout the IPA, 2001 and Anti-Counterfeit Act, 2008 as well as EU EAC EPA, various strategies have been employed by especially the civil society groups in the country. In this regard, litigation appears to be the most dominant and effective method in relation to challenging the adverse impacts of pharmaceutical trade policies. There have also been legal literacy trainings by AIDS Law Project (ALP) targeting communities and especially persons living with HIV and AIDS to be able to advocate for their own medicines. This strategy was coupled by campaigns both at the national and international context. A number of studies, papers, policy briefs and reports have also been adequately utilized in this context. However, neither the government nor non-governmental organizations have implemented HRIA in Kenya so far. This thesis does not aim to explain why this methodology has not yet been popular but the next chapter will explore the preparedness of trade policy makers in relation to the use of this instrument in particular.

6.5 Conclusion

To begin with, Kenya has two main trade laws on intellectual property rights and specifically pharmaceutical patents and access to medicines. The first one is the Industrial Property Act, 2001 adopted in 2001. This legislation is key because prior to its enactment, the access to medicines' movement in the country, working closely with trade policy makers, successfully ensured that the TRIPS Agreement flexibilities were incorporated into the Industrial Property Act, 2001.[80] The result of this is that the present legislation has been without many controversies because it largely complies with the right to health norms, which requires the full incorporation of TRIPs Agreement flexibilities in such legislation.[81] In particular, the incorporation of the TRIPs Agreement legislation has facilitated the government of Kenya to be able to leverage on the available licensing systems including compulsory and government licensing system as well as parallel importation flexibilities to achieve lower prices for medicines in the country for the benefit of the general population.

However, in 2008, the Parliament of Kenya enacted the Anti-Counterfeit Act, 2008, which is now threatening to reverse the gains already made under the Industrial Property Act. Unlike the Industrial Property Act, 2001, the Anti-Counterfeit Act, 2008 is more expansive in terms of providing for stronger intellectual property rights protection and enforcement. In particular, the legislation has included patents as a counterfeit or public safety issue meaning that generic medicines are predisposed to attract the criminal and civil measures proposed in the legislation. As expected, this development has attracted a lot of opposition from many quarters including civil society organizations because of its potential to adversely impact on the issue of access to medicines in Kenya. Following a court challenge, in 2012, the Kenyan High Court declared the Anti-Counterfeit Act unconstitutional in so far as it infringed upon the rights to life, health, and dignity. In this regard, the discourse on access to medicines in Kenya is focused on the Anti-Counterfeit Act, 2008. This discourse has remained unconcluded even after amendments to the Anti-Counterfeit legislation was passed by Parliament in 2015. This lack of progress in relation to trade and human rights in the context of the Anti-Counterfeit legislation and an absence of a HRIA conducted in Kenya before

[80] Harrington n 14 above, 97.
[81] See HRC resolution 23/14 on the right to health and access to medicines [A/HRC/Res/23/14].

reveals a deeper issue, which is the preparedness of trade policy makers to implement human rights. This issue is tackled in the next chapter.

CHAPTER SEVEN: ASSESSING THE PREPAREDNESS IN TERMS OF KNOWLEDGE AND ATTITUDE OF TRADE POLICY MAKERS IN KENYA

7.1 Introduction

The previous chapter focused on the problem of access to medicines in Kenya in relation to trade policy and located it in the anti-counterfeit legislation as well as the impending European Union East African Community Economic Partnership Agreement (EU EAC EPA). The chapter also underscored the fact that there has not been any process to develop or implement the mechanism of human rights impact assessment (HRIA) despite the fact that it is capable of resolving *beforehand* the adverse impacts of pharmaceutical trade policies. However, as will be demonstrated in this chapter, the implementation of the HRIA may also be dependent on the preparedness of trade policy makers in terms of their knowledge and attitude. This chapter therefore specifically analyses the trade policy making process in Kenya and links it to the overall thesis of this study which is that the government through its trade policy makers have not yet implemented the HRIA as a routine process because they do not perceive it as being in conformity with free market ideology, which includes the predisposition to act rationally and efficiently in line with the state's interests. In the context of free market, state officials see their role as securing state interests by adopting utility-maximizing behaviour or acting in a rational manner. HRIA sadly is still not seen by trade policy makers as being capable of securing the interest of the state even in relation to the growing body of evidence that is linking access to medicines challenges in developing countries to policy incoherence at the national level in relation to the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement implementation challenges. This challenge is manifested in domestic pharmaceutical trade policies that have continued to be enacted relying on nothing but future promise of developed economies market access and not rational behavior *per se*.

7.2 The role of actors in relation to the issues of EU EAC EPA and anti-counterfeit legislation

As noted in the previous chapter, the challenges to access to medicines remain current and pressing in Kenya however those in charge of trade policy making seem oblivious of their

obligations in this regard. Why is it that despite the guidance by the judiciary, the executive is still interested in pursuing the same agenda as before, which is strengthening intellectual property protection and enforcement at the expense of human rights and access to medicines? As it will become clear in this section, the knowledge about human rights is accessible to trade policy makers but they are not motivated to apply it in their work as expected. This speaks to the need to market HRIA in a manner that is attractive to trade policy makers in Kenya, which, this thesis proposes, can be achieved by using the rational theory of morality. This theory may resonate with the culture in the trade sector, which is to secure the interests of the state in the most efficient or rational manner. As observed by Coleman, using human rights in a situation of perfect market is inefficient or irrational. Therefore, it is crucial to explain to trade policy makers that what pertains in Kenya in relation to the implementation of TRIPs Agreement is not securing any interests of the government and actually represents a situation of market failure since medicines have remained unaffordable to the majority poor. Using human rights is therefore logical, efficient and rational since it will safeguard the interests of the Kenyan government, as opposed to those of foreign multinationals and in favour of developed countries.

Through the expert interviews conducted in the course of this study, several factors emerged to prove that indeed trade policy makers had knowledge or access to the knowledge related to human rights and trade. According to Kyalo, the level of awareness of trade and human rights issues from the perspective of trade policy makers can be measured from the fact that the East African Community (EAC) economic partnership agreement (EPA) is currently at a stalemate.[1] This means that the trade policy makers actually know the issues at stake.[2] He however attributes this stagnation to challenges and resistance mounted by especially small scale farmers backed by civil society groups as opposed to concerns about access to medicines considerations per se.[3] It is submitted however that the access to medicines agenda in the region as reflected in the EAC intellectual property policy may have

[1] Interview with Felix Kyalo on 9 March 2018 (UG Country Rep, IDLO).
[2] As above.
[3] As above.

contributed to the resistance witnessed in the context of the EU EAC EPA.[4] It is therefore plausible to note that both the efforts of small scale farmers as well as the efforts of access to medicines advocates, have contributed to the stalemate currently being witnessed in the EU EAC EPA.

However, the fact that trade policy makers know about health and access to medicines has not influenced them to change their behavior. Munyi notes that during the negotiations of the Anti-Counterfeit Act, 2008 in Kenya civil society proposals were largely ignored and the only concession given to them was the *proviso* under section 2 attempting to exempt medicines from the application of the Anti-Counterfeit Act.[5] The fact that the civil society launched a court challenge immediately after the enactment of the legislation reveals that the concession given to them was unsatisfactory and the main issue was the inclusion of patents under the definition of anti-counterfeiting under the Act.[6] The subsequent amendments has failed to review this sowing a lack of interest on the part of trade policy makers to accommodate human rights concerns.[7] This is particularly concerning because trade policy makers have participated in various trainings organized by the Judicial Training Institute (JTI) in order to implement the decision of *PAO* case.[8] One interviewee defended the inclusion of patents in the anti-counterfeiting legislation noting that public safety was important especially when medicines are coming from some developing countries where counterfeiting is rampant.[9]

It emerges from the above that knowledge about human rights norms *per se* is not sufficient to change the behavior of trade policy makers. It may be necessary to have proper civil society organizing as is the case with EPA. Indeed one interviewee noted that unlike in 2001, the access to medicines movement in Kenya was not properly organized since many individuals have joined the executive, judiciary and private sector thus weakening the

[4] EAC 'Regional intellectual property policy on the utilization of public health-related WTO-TRIPs Flexibilities and the approximation of national intellectual property legislation (2013).
[5] Interview with Peter Munyi on 15 March 2018 (International Trade Lecturer, UoN).
[6] As above. See also the *PAO & 2 Others v AG & 2 Others* [2012] eKLR.
[7] Interview with Allan Maleche on 14 March 2018 (Executive Director, KELIN).
[8] As above.
[9] Interview with Judy Ouma, 6 March 2018 (Former Trade Negotiator, Economist and USIU-Africa Lecturer).

movement.[10] The interviewee further lamented that there is a dearth of resources to conduct access to medicines advocacy at the national level but it remains under-utilized in relevant offices.[11] The situation however appears to be changing since some funding is coming back into the sector. This funding aims to assist in terms of implementing programmes on TRIPs flexibilities in Kenya and Uganda, through the civil society organizations KELIN and CEHURD respectively, in line with the ARIPO recommendations calling for policy coherence in ARIPO countries to achieve access to medicines following the Report of the Secretary General's High Level Panel on Access to Medicines, 2016.[12] The implementation of these kind of programs should however be complemented by a sound trade development policy so that the two strategies can be jointly responsible for achieving access to medicines in Kenya.

7.3 The process of trade policy development within the Ministry of Trade in Kenya

Apart from the actors, the process of trade policy development is also important. It is in the process that the methodology of HRIA belongs and should be implemented. As demonstrated below, the process of trade policy making in Kenya still assumes the situation of perfect market and is blind to market failures. It is because of this that the HRIA as a tool has been seen as being unnecessary in trade negotiations. In order to change this, the trade process should be able to identify and deal with situations of market failures, which means the availability of more adverse impacts than actual benefits for a country in relation to a particular trade measure.

It is important to note that the administration of intellectual property rights in Kenya faces severe institutional problems.[13] The problem is further exacerbated by the fact that many

[10] Interview with Jacinta Nyachae, 23 March 2017 (Executive Director, ALP).
[11] As above.
[12] Interview with Allan Maleche n 7 above. See also the High-level meeting on promoting policy coherence on health technology innovation and access in the ARIPO region, 1-3 November, 2017, Lilongwe, Malawi.
[13] B Sihanya *Intellectual property and investment law in Kenya and Africa: Translating technology for sustainable development* (2016) 619 Sihanya Mentoring & Innovative Layering, Nairobi & Siaya.

government institutions are unable to attract and retain a multidisciplinary work force and in many cases they lose their best workforce to transnational organizations.[14]

Before embarking on trade policy making it is important to clarify that pharmaceutical trade policies are usually viewed as trade policies and not health policies. However, as noted by Wangai, health providers may not be able to do much in health care facilities without medicines.[15] Despite the importance of medicines in health, the Ministry of Health has no mandate over the trade aspects of medicines including issues of intellectual property rights protection. However as noted by Wangai, the Ministry of Health has some role to play when it comes to regulation of medicines and currently the Pharmacy and Poisons Board is responsible for guaranteeing the quality of medicines in the country.[16] According to Dr Wangai, Kenya aims at establishing the Kenya Food and Drug Agency which will be responsible to regulate medicine and other non-pharmaceutical products being used in the health sector.[17] It therefore appears that the Ministry of Health is focused on quality assurance as opposed to trade. This may explain the lack of clear collaboration between the Ministry of Health and Ministry of Trade including in the area of medicines.[18] It is submitted therefore that the Ministry of Health has very limited role to play in terms of making medicines affordable in the country especially in relation to the adverse impacts of pharmaceutical trade policies despite the fact that they stand to be most affected when medicines are inaccessible. The relevant ministry that is directly responsible for policies that have is the Ministry of Trade through its trade policy development process as canvassed below.

In Kenya, the trade policy development process, including in the area of intellectual property rights, is largely a participatory process coordinated at the Ministry of Trade supported by other government departments.[19] As such, trade policy in Kenya is not an exclusive function

[14] As above.
[15] Interview with Dr Mary Wangai on 23 May 2018 (Ministry of Health, Department of Regulation and Standards).
[16] As above.
[17] As above.
[18] As above.
[19] Interview with Bramah L Kaleve on 17 April 2018 (Principal Trade Development Officer, Ministry of Trade).

for the Ministry of Trade. It should be noted however that international trade is coordinated by the Ministry of Foreign Affairs an International Trade since 2017.[20]

According to Kaleve, the process of trade policy development begins with a preparatory meeting organized by the Ministry of Trade in the country involving various stakeholders usually government ministries and other departments to be affected in a particular trade process.[21] The various stakeholders are then usually required to develop position papers in relation to the trade proposals that are on the table in a manner that will safeguard the interests of the government in the trade negotiation process.[22] The position paper is then compiled by trade experts or officials from the ministry of trade and the position paper then forms the basis for negotiations.[23] At the multilateral level, the process is a bit different since there is usually a peer review process or trade policy review process that is usually done in order to ensure that the proposals made do not negatively impact international trade.[24] The government then has to reach out to a government department that is affected to provide information that may be required to address any queries raised.[25] It is submitted that the peer review process is a good practice in as far as implementation of trade obligations is concerned and a similar practice in relation to human rights may be useful. In the alternative, Munyi notes that there needs to be a checklist akin to that used by the Dutch negotiators to check whether all elements have been complied with by an agreement before it is signed or enacted into law.[26]

However, since the thesis focuses on trade policy at the national level, it is crucial to understand if there are safeguards in the trade policy development process in relation to human rights. Kaleve notes that human rights is usually introduced through specific trade instruments for instance the African Growth and Opportunity Act (AGOA) and the Cotonou Framework for EPA negotiations have specific clauses addressing human rights in trade

[20] Interview with Leah Aywa Baraza on 15 May 2018 (Deputy Chief State Counsel, International Law Division).
[21] Interview with Bramah L Kaleve n 19 above.
[22] As above.
[23] As above.
[24] As above.
[25] As above.
[26] Interview with Peter Munyi on 15 March 2018 (International Trade Lecturer, University of Nairobi).

policy.[27] However, the Ministry of Trade has no internal mechanism to address human rights concerns in trade should it be necessary.[28] The trade experts are mainly individuals qualified in law, economics, trade development and business. [29] However, the Ministry of Trade officials often attend seminars organized by civil society on trade and human rights. [30] It is submitted that more seminars and trainings targeting trade policy makers may help narrow the capacity gap in terms of trade and human rights. This is especially because as noted by Kaleve, human rights do not form part of the work plan of the Ministry of Trade and it is unlikely that the Ministry will streamline it because the variable value on productivity is minimal.[31] It is submitted that the above position is generally understood using market theories aiming at increasing the Pareto-efficiency. However, as argued in chapter two and three, there are circumstances, including market failure, that may actually require inefficient response from the government especially when it relates to the implementation of international intellectual property rights rules.

The role played by the Ministry of Trade in terms of the integration of the TRIPs Agreement flexibilities serves as a good lesson in relation to access to medicines agenda. In 2001, the role of trade policy makers including Minister Biwott was instrumental in the incorporation of TRIPs Agreement flexibilities under the Industrial Property Act, 2001.[32] During this time, it should be noted that the momentum was also in favor of developing countries since the Doha Declaration was also adopted. In the period after the Doha Declaration many developing countries have become less assertive especially at the national level. The agency of the Doha Declaration serves to show that trade policy makers are actually desirous of tools that they can use to act in the best interest of the government.

At the present moment, the influence of the Doha Declaration is waning at the national level. Trade policy makers have therefore become very unpredictable since trade policy makers are usually assertive in Geneva but they don't follow up their 'talk' in Geneva with

[27] Interview with Bramah L Kaleve n 19 above.
[28] As above.
[29] As above.
[30] As above.
[31] As above.
[32] Interview with Peter Munyi n 26 above.

appropriate actions in terms of implementation back at home.[33] It appears therefore that a national tool that is able to remind trade policy makers of their obligations including under human rights such as the HRIA may be an appropriate solution. It is therefore important to show that the HRIA methodology is actually a tool that serves rather than frustrate the interests of the government since trade policy development is usually about maximizing the interest of the state.

In the absence of a clear integration of human rights norms and methodologies in the context of mainstream trade policy development process, it is useful to also look at the role of the Office of the Attorney General (AG) as well as the KNCHR in relation to trade and human rights.

7.4 Other relevant government departments

Ideally, the implementation of HRIA should be undertaken by legal offices in government. It is these offices that actually have access to information regarding the nature of interests the government as. For instance, the trade department may not be in the know about the interests of the government under human rights. Therefore, where the Ministry of Trade fails, the other government departments supporting the trade policy development process should be able to act accordingly.

According to Ouma, when the government negotiates a trade agreement with other countries the relevant line ministries often do provide position papers in trade, health and agriculture.[34] She notes that the legal issues relating to trade negotiations are mainly handled by the treaty department in the office of the Attorney General (AG) of Kenya.[35] It therefore appears that the AG has the final say on the legality of a legislation or trade agreement.

Accordingly, in doing its work, the AG is usually involved to make sure that the legal limits are observed in relation to the obligations of the government both at the international and national levels.[36] In doing its work, the AG office relies on the request, proposals or

[33] As above.
[34] Interview with Judy Ouma n 9 above.
[35] As above.
[36] Interview with Leah Aywa Baraza on 15 May 2018 (Deputy Chief State Counsel, International Law Division).

documents presented to it by the Ministry of Trade. So far the office of the AG has yet to receive any request from the Ministry of Trade to evaluate a particular trade agreement from a human rights perspective even though it is true that the capacity may be low in the department in relation to human rights.[37] In this regard, the AG's office is usually focused on complying with the Constitution of Kenya and the WTO obligations and not human rights including the constitutional human rights provisions.[38] It is submitted that many government departments including the legal departments are oblivious to their obligations in relation to trade and human rights. Indeed, Aywa notes that the stakeholders who usually participate in trade are non-human rights specialists and therefore it is usually difficult for these people to understand the human rights issues in trade; so far trade and human rights is viewed separately.[39]

Indeed, the sentiments expressed above in relation to the general perception in government about the separateness of trade and human rights is also reflected in the work of the Department of Justice under the AG's office. The department is responsible for reporting on human rights violations in collaboration with other government departments including the KNCHR. Korir notes that there has not been any complaint in relation to human rights and trade.[40] Korir further notes that the main problem is that the policy makers in many government departments are still operating under the old constitutional framework, which had limited human rights in it and excludes socio-economic rights.[41] It therefore emerges that the quality of policy makers in government today have not adjusted to the new constitutional dispensation which also protects the right to health, including in the trade context.[42] However, the link between human rights and trade is still unclear for many officials in the Department of Justice.[43]

[37] As above.
[38] As above.
[39] As above.
[40] Interview with Stephen Kibet Korir on 3 May 2018 (State Counsel, Department of Justice, Human Rights Division).
[41] As above.
[42] As above.
[43] As above.

However, taking into account the above process of trade negotiations, which involves various line ministries including the office of the AG, it is perplexing that the KNCHR, which is mandated to advise the government on human rights issues, plays no active role to support the office of the AG.[44] At the moment, even the relevant ESCRs department under the KNCHR is yet to roll out a specific programme on trade and human rights and it admits that it has not collaborated in the area of pharmaceutical trade policies in the past with other government departments.[45] The department however currently focuses on business and human rights especially focusing on extractive industries and some of the activities being implemented include the putting in place of a national action plan and policies in this area.[46] The area of access to medicines has therefore been neglected by KNCHR and as such the KNCHR has failed to push for and monitor compliance in terms of the implementation of the constitutional right to health including the decision in the *PAO* case on anti-counterfeit legislation in Kenya.[47]

From the above, it appears that the lack of input of the office of the AG, both the international law department and the department of justice, as well as from the KNCHR, may have contributed to the low profile of human rights in the process of trade development and negotiations. The KNCHR working closely with the office of the AG may thus help prop the human rights agenda in trade including the implementation of HRIA. However, the use of the HRIA tool is still best optimized if the Ministry of Trade and its agencies including the ACA and KIPI[48] were capacitated to integrate the tool as a routine process in their work, especially because pharmaceutical trade policies are actually in fact trade as opposed to health or human rights policies. This is the true spirit of the current constitutional framework which binds all state and non-state officials and recognizes that every state organ has a fundamental duty to observe respect, protect, promote and fulfil the human rights protected

[44] Interview with Maina Mutua, 30 March 2017 (Head of ECOSOC Department, KNCHR).
[45] As above.
[46] Interview with George Morara, 14 March 2018 (Vice Chairperson, KNCHR).
[47] As above.
[48] Telephone interviews with anonymous individuals at KIPI and ACA on 5 July 2018. In this interview it also emerged that these agencies do engage in trade policy development process especially in relation to the work they do but still there is no clear appreciation of the link between human rights and trade.

under the constitution.[49] It will also be in line with the current government priorities and interests, which include the political commitment to UHC found in the SDGs.

7.6 Conclusion

There are several conclusions that arises from the foregoing. The first one is that the trade policy development process is a multi-stakeholders process and is coordinated by the Ministry of Trade. The Office of the AG is also a critical player in this process especially in relation to legal compliance. It is argued therefore that rather than wait for a compliance audit to be conducted by the AG, human rights should and can be integrated as a routine process by the trade policy makers at the Ministry of Trade. In this regard, the Ministry of Trade is primarily responsible for the development of the appropriate trade policies at least domestically. However, the function of doing the same at the international level was transferred to the Ministry of Foreign Affairs and International Trade in 2017. This study focused on trade policy development process at the national as opposed to international level.

Secondly, trade policy makers in Kenya have the primarily responsibility to ensure that the policies they develop at the national level are in line with the international and constitutional right to health and the current government's commitment to achieve UHC in Kenya. In this regard, the trade policies developed and collated by the Ministry of Trade should in principle promote rather than undermine the realization of access to medicines in the country for the above reasons.

Thirdly, the Ministry of Health has limited mandate over the process of trade policy development including in relation to intellectual property rights and access to medicines even though healthcare providers may not carry out their duties without medicines. The role of the Ministry of Health, through the Pharmacy and Poisons Board, is to regulate the quality and safety of pharmaceutical products in the country and not the trade in medicines.

Fourthly, the link between trade and human rights is still unknown by many trade policy makers including at the Ministry of Trade. Surprisingly, even the capacity that existed earlier

[49] Article 21(1) of the Constitution, 2010.

in the civil society sector has eroded and it is currently very hard to find dedicated officials working in the area of right to health and access to medicines.[50]

Lastly, the Ministry of Trade should take advantage of the numerous opportunities to learn about the obligations of the government in relation to human rights and trade in medicines. The opportunities for learning about human rights and trade has become even more readily available in the aftermath of the *PAO* case in Kenya including through the JTI.

[50] Interview with Allan Maleche n 12 above.

CHAPTER EIGHT: CONCLUSION AND RECOMMENDATIONS

8.1 Conclusion

The greatest preoccupation of access to medicines actors has been how to ensure that trade is fair as opposed to free. In this regard, the actors have emphasized on the concept of fair trade as opposed to free trade, which is currently the dominant model advanced by the WTO in relation to the globalization and trade liberalization agenda. The trade rules advanced by the WTO have focused mainly on the concept of free trade without necessarily taking into account the fairness of the trading system. This has been made possible by the fact that many agreements reached at the WTO level are contractual in nature meaning that each member has to negotiate for what is best for itself. The result is that more developed and powerful economies have been able to influence the trading system in a manner that disproportionately serves their interest without taking into account the interest of the weak and poor countries. These rules have in turn presented unique challenges at the national level including in terms of lack of access to medicines for many people in developing countries.

In all of the rules adopted by the WTO, the TRIPs Agreement has been most controversial. This is because the TRIPs Agreement, which deals with international rules for intellectual property rights, has set minimum standards for intellectual property rights protection. One minimum obligation imposed by the TRIPs Agreement is the protection of process and product patents in all fields of technologies including in the pharmaceutical sector. This approach has presented unique challenges in developing countries in relation to the realization of access to medicines. The pharmaceutical trade policies that are enacted at the national level due to the effects of international intellectual property rights rules including TRIPs Agreement, has made the government powerless in terms of responding in a manner that can promote the realization of access to medicines.

In this regard, various responses have been implemented including suggestions to integrate HRIA in the process of trade policy making. The process of trade policy making is often dominated by free market ideology and in this regard human rights norms and

methodologies including HRIA has not found easy uptake in the trade sector. This thesis therefore sought to answer the question how the mechanism of HRIA could be implemented in Kenya specifically. This question is informed by the fact that if the implementation of the mechanism of HRIA is to be successful it must be able to overcome the unique circumstances of each country. It is therefore not possible to provide a general approach to developing countries to guide them on how to implement the mechanism of HRIA. Each country must be analyzed separately and appropriate recommendations made.

Consequently, in order to understand the situation in Kenya, the study utilized the following research to guide this study. The first question analyzed the theoretical approaches that may be used to underpin the mechanism of HRIA in trade policy making. The main approach was to look for a theory that appeals to trade actors directly. In this regard, apart from the human rights theories, market theories were also considered. The second question on the other hand focused on the problem of TRIPs Agreement as well as FTAs and how it has generally failed to serve the interests of developing countries. In particular, the issue of pharmaceutical patent on medicine prices and the problem of neglected diseases have been canvassed in detail. The question also covers the approaches that could be employed to respond to the problems discussed above in terms of investment in health as well as utilization of human rights norms. The third question tackles the issue of right to health norms by discussing how the norms cover trade issues including in relation to international intellectual property rules. It also covers other aspects such as the obligation of the government and violations. The fourth question addresses the issue of ESCRs measurement. It discusses the relevant methodologies that have been considered in different contexts in terms of the implementation of ESCRs including HRIAs. However, more emphasis is given to analyzing the HRIA mechanism. The fifth question discusses the issue of HRIA, pharmaceutical trade policies and access to medicines in the Kenyan context and in particular elaborates on the issue of the anti-counterfeiting legislation. The last question covers issue of preparedness in terms of knowledge and attitude of trade policy makers to utilize human rights in trade policy making.

It emerges, as the general conclusion, that the implementation of the mechanism of HRIA in Kenya will require finding a way to bring on board trade policy makers as the primary implementers.

As mentioned above, some of the unique characteristics observed in Kenya are related to the appropriate theoretical framework used to underpin the use of HRIA methodology. In this regard, the use of human rights theories should be complemented by market theories such as semiotic methods and rational theory of morality in order to be attractive to trade policy makers in Kenya.

Other challenges are more complicated since they have nothing to do with the theoretical or technical qualities of the HRIA tool but the preparedness, or to be more precise, the knowledge and the attitude of trade policy makers who are primarily responsible in making trade rules. In general, the analysis locates the main characteristic that may impact the positive implementation of the tool is the attitude of trade policy makers. It is only when trade policy makers view human rights favorably that progress can be made in this regard.

The conclusion that the attitude of trade policy makers are at the heart of the problem is supported by many facts. One main fact is the inability to resolve the issues associated with the Anti-Counterfeit legislation. From the time this legislation was proposed it appeared as if the government was unaware of human rights norms applicable despite the fact that NGOs working on these issues were involved meaning that the source of information was available. Even assuming that NGOs were unavailable in the amendment process, the *PAO* decision of the High Court should have been implemented as a matter of law. The failure to get it right after both the CSO input as well as the court process strongly supports the thesis that the attitude of trade policy makers may be at stake.

This conclusion is important because it can inform the kind of interventions to be implemented and specifically capacity development. In this regard, it is no longer defensible that developing countries blame foreign states for their lack of access to medicines when it can be established that they are not even prepared to take advantage of the small

opportunities they have to promote access to medicines in Kenya including through integrating the HRIA mechanism as a routine process in trade.

The experience of the High Court challenge on Anti-Counterfeit Act, 2008 shows that more work needs to be done in order to convince trade policy makers that human rights actually has a positive role to play in resolving the adverse impacts of pharmaceutical trade policies on access to medicines.

Lastly, the government can do itself more service if it takes seriously its obligations under human rights without compromising the obligations in trade. This can be done through using the right to health norms, which are adequate to resolve the conundrum between trade obligations and access to medicines. Failure to appreciate the role of human rights in trade by policy makers means that some trade policies that will be adopted by the government will restrict the ability of the government to realize access to medicines at the national level and this situation spells doom for the entire population in terms of access to medicines.

8.2 Recommendations

In terms of recommendations, what do the above conclusions portend? The conclusion in this study necessitates a different approach to access to medicines advocacy. It is no longer tenable to prove theories and facts but it may be more beneficial to focus on and work towards changing the attitudes of individuals responsible for making decisions that matter. In this regard, the access to medicines movement in Kenya should transcend beyond debating the theory and substance of access to medicines and look at the limitations that exists in terms of the people that have the power to make a difference. How can this be achieved?

1) There is need to integrate human rights into the training and development of trade policy makers so that it is clear that this is not an imposition from outside but a useful paradigm to solve important policy decisions. A good entry point would be for instance to review the curriculum that is currently being used to train trade policy makers in Kenya but also not forgetting the need to update the knowledge of current

trade officials on their role in relation to promoting access to medicines under the constitutional right to health. This knowledge should be able to impact positively on the ongoing anti-counterfeiting agenda as well as the potential negotiations under EU EAC EPA on intellectual property protection.

2) There is also need to acknowledge the limitations of human rights. In this regard, human rights norms can be easily sold through emphasizing its relevance in specific circumstances such as market failure as is the case with the TRIPs Agreement and access to medicines in developing countries. Once the market corrects itself and is able to equitably provide for the needs of everyone it may not be necessary to insist on the implementation of human rights norms in relation to pharmaceutical trade policies since there would be no adverse impacts to identify and mitigate in the first place.
3) There is also a need for human rights actors to adopt trade lenses when discussing human rights and trade issues for maximum impact in terms of communication. The problem that has made it impossible to make progress in regards to human rights and trade is that the promoters of human rights usually focus on converting trade policy makers into human rights experts, which is almost impossible or undesirable. It is possible to promote human rights by using market theories such as the rational theory of morality.
4) Human rights actors should also link their interventions with the affected communities for maximum impact. The community support is crucial in terms of motivating the trade policy makers to behave in an appropriate manner. The fact that HRIA has a strong element of participation is therefore a positive thing in this regard. The relevance of HRIA in this regard is particularly emphasized in the methodology section and specifically its step on consultations.

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Interviews

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236. Interview with Bramah L Kaleve on 17 April 2018 (Principal Trade Development Officer, Ministry of Trade).

237. Interview with Dr Mary Wangai on 23 May 2018 (Ministry of Health, Department of Regulation and Standards).

238. Interview with Felix Kyalo on 9 March 2018 (UG Country Rep, IDLO).

239. Interview with George Morara, 14 March 2018 (Vice Chairperson, KNCHR)

240. Interview with Jacinta Nyachae, 23 March 2017 (Executive Director, ALP).

241. Interview with Judy Ouma, 6 March 2018 (Former Trade Negotiator, Economist and USIU-Africa Lecturer).

242. Interview with Leah Aywa Baraza on 15 May 2018 (Deputy Chief State Counsel, International Law Division).

243. Interview with Maina Mutua, 30 March 2017 (Head of ECOSOC Department, KNCHR).

244. Interview with Peter Munyi on 15 March 2018 (International Trade Lecturer, UoN).

245. Interview with Stephen Kibet Korir on 3 May 2018 (State Counsel, Department of Justice, Human Rights Division).

246. Telephone interviews with anonymous individuals at KIPI and ACA on 5 July 2018.