

**ACCESS TO ESSENTIAL MEDICINES AND THE UTILISATION OF
COMPULSORY LICENSING AND PARALLEL IMPORTATION IN KENYA AND
SOUTH AFRICA**

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G62/66957/2011

**SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR
THE AWARD OF THE DEGREE OF MASTER OF LAWS LL.M (PUBLIC
INTERNATIONAL LAW) OF THE UNIVERSITY OF NAIROBI**

PREPARED UNDER THE SUPERVISION OF

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AT THE

UNIVERSITY OF NAIROBI

SCHOOL OF LAW

2013

DECLARATION

I, **Paul Omondi Ogendi**, hereby declares that the dissertation is an original work and has never been presented to any other institution. I also declare that all secondary information used has been duly acknowledged in this dissertation.

Signed

Date

Supervisor: Dr Celestine Musembi

Signature.....

Date.....

ACKNOWLEDGMENTS

I acknowledge the University of Nairobi LLM class of 2010. The journey was enjoyable because of your support and friendship.

I also acknowledge my supervisor Dr Celestine Musembi for your able guidance throughout the writing of this project. Your contributions were invaluable. Special thanks to Ms Pamela Ager and Mr Njaramba Gichuki the chair and the reader respectively of my thesis defence panel.

Lastly, I thank my family, relatives and friends for your patience and sacrifices without which this achievement would not have been possible.

DEDICATION

I dedicate this work to intellectual property and access to essential medicines actors in Kenya and South Africa.

LIST OF ABBREVIATIONS

ACA	Anti-Counterfeit Act
AIDS	Acquired Immunodeficiency Syndrome
ALP	AIDS Law Project
ARV	Antiretroviral
ART	Antiretroviral Treatment
AU	African Union
CESCR	Committee on Economic, Social and Cultural Rights
ESA	East and Southern Africa
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
MTCT	Mother-to-child-transmission
PULP	Pretoria University Law Press
TAC	Treatment Action Campaign
TRIPS	Trade Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
WHO	World Health Organization
WTO	World Trade Organization

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CHAPTER ONE

INTRODUCTION

1.1 Background

The Kenyan and South African Constitutions are unique mainly because they include, amongst many other innovations, justiciable socio-economic rights including the right to health¹. In this regard, in 2002, the South African Constitutional Court in the *Minister for Health and Others v Treatment Action Campaign and others*² (popularly known as the TAC case) was capacitated to uphold that the right to health encompasses access to essential medicines for everyone. In this particular case, the anti-retroviral drug, *Nevirapine*, was found to be an essential medicine in as far as it prevented mother-to-child-transmission (MTCT) during pregnancies. Accordingly, the failure by the South African government to make *Nevirapine* accessible to all pregnant women in South Africa was found to be a violation of the right to health as enshrined under the South African Constitution Section 27.

Similarly, in 2012, almost a decade after the TAC case, the Kenyan High Court in the *P.A.O and Others v Attorney General*³ (popularly known as the Patricia Asero case) also declared as unconstitutional certain provisions, specifically, sections 2, 32 and 34 of the Kenya Anti-Counterfeit Act (ACA)⁴. In reaching its verdict, the High Court took the view that the ACA was unconstitutional because it infringed on the

¹ See Article 43(a) and Section 27 of the Kenyan 2010 Constitution and the 1996 South African Constitution respectively.

² *Minister for Health and others v Treatment Action Campaign and others* 2002 5 SA 721 (CC). Also available at: <http://www.saflii.org/za/cases/ZACC/2002/16.html> (accessed 2 July 2012).

³ *Patricia Asero Ochieng and other v AG* Petition No. 409 of 2009. Also available at: <http://www.ip-watch.org/weblog/wp-content/uploads/2012/04/Kenya-Judgment-Petition-No-409-of-2009.pdf> (accessed 2 July 2012).

⁴ Anti-Counterfeit Act (ACA), Act No 13 of 2008.

constitutional rights to health, life and dignity of the three petitioners living positively with HIV and AIDS in Kenya. An analysis of the decision reveals maximum reliance on the right to health jurisprudence locally and internationally. This was made possible mainly by the fact that Article 43 of the Kenyan Constitution enshrines the right to health as justiciable. With the above provision, therefore, it was possible for the three petitioners to argue that the ACA, if implemented, would potentially restrict access to essential generic anti-retroviral drugs which was widely available and affordable in Kenya than branded medicines. In this respect, access to affordable generic antiretroviral (ARV) drugs was found to be a constitutional right to health.

From the above analysis, it is possible to protect access to essential medicines under the right to health framework. Kenya and South Africa are, therefore, legally obligated by their constitutional right to health and also the relevant court precedents discussed briefly previously to protect and guarantee access to essential medicines.

Generally, the concept of access to medicines has four elements as follows: non-discrimination; physical accessibility; economic accessibility (affordability); and information accessibility⁵. Illustratively, the *TAC* case, for instance, focused on non-discrimination and physical accessibility of *Nevirapine* since it was freely available in South Africa for the prevention of MTCT. In contrast, the *Patricia Asero* case focused on economic accessibility (affordability) since the crux of the petition emphasized on safeguarding access to the more affordable generic medicines in Kenya under the ACA framework.

Lastly, both Kenya and South Africa have firm commitments on the issue of the right to health and access to medicines as evidenced by their respective constitutions

⁵ General Comment No 14 8 November 2011 (UN Doc. E/C.12/2000/4) paragraph 12, <http://www.unhcr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En> (accessed 2 July 2012).

as well as solid court precedents that affirms the obligations of the government in this respect.

1.2 Problem statement

The role of laws and policies in enabling countries to respond to domestic challenges including public health cannot be overemphasized. The last three decades, for instance, have seen unprecedented suffering and deaths as a result of the HIV and AIDS scourge. Indeed, the HIV and AIDS scourge alongside tuberculosis and malaria remain a major threat to the realization of the right to health in most developing countries. Consequently, many countries are putting in place appropriate laws and policies to respond to the scourge including in the area of intellectual property right (IPR).

IPR is currently amongst the major barriers on the way of developing countries In as far as the HIV and AIDS scourge is concerned. In particular, efforts to scale up ARV drugs continue to be problematic due to prohibitive cost resulting partly from IPR protection. IPR protection contribute to the inaccessibility of medicines by for example making medicines expensive through remission of royalties and most importantly through restricting generic competition which has succeeded in reducing medicines prices by 99% elsewhere.⁶ Consequently, many people in developing countries continue to suffer from ill-health and avoidable deaths. It is crucial therefore to address IPR barrier in such a manner that it promotes the realization of the right to health and specifically access to medicines.⁷

⁶ India says “no” to policy that would block access to affordable medicines’ *MSF Access Campaign* 22 June 2011, <http://www.msfaaccess.org/about-us/media-room/press-releases/india-says-no-policy-would-block-access-affordable-medicines> (accessed 2 July 2012).

⁷ LR Helfer ‘Towards a human rights framework for intellectual property’ (2007) 40 *U.C. Davis Law Review* 973.

While progress has been registered at the international level with the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), less impact has been registered at the national level mainly because of limitations of domestic legislations.⁸ Most developing countries including Kenya and South Africa ‘have not or only partially [utilise] the flexibilities allowed by the TRIPS Agreement’ especially, compulsory licensing and parallel importation.⁹ As a result, the right to health and access to medicines situation in both countries is wanting.

This study seeks to understand what these TRIPS Agreement flexibilities are, and what avenues exist within these countries’ legal framework to argue for the utilization of these flexibilities, taking into account the various challenges that exist in each country, for the sake of realizing the right to health and access to essential medicines.

1.3 Hypothesis

The hypothesis of this study is that neither Kenya nor South Africa has taken full advantage of the flexibilities under the TRIPS Agreement to realize the right to health and access to medicines in their countries.

1.4 Literature review

By definition, intellectual property (IP) is an ‘intangible expression of an invention’.¹⁰ Patents together with trademarks, copyrights and trade secrets constitute IP regime that is characterized as ‘knowledge goods’ that encompasses, ‘inventions, ideas,

⁸ B Baker ‘Processes and issues for improving access to medicines: Willingness and ability to utilise TRIPS flexibilities in non-producing countries’ (2004) 19, http://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf (accessed on 2 July 2012).

⁹ MC Correa ‘Implication of the Doha Declaration on the TRIPS Agreement and Public Health’ (2002) 18, <http://www.who.int/medicinedocs/en/d/Js2301e/> (accessed 2 July 2012).

¹⁰ F Gurry ‘The evolution of technology and markets and the management of intellectual property rights’ (1996-1997) 72 *Chicago-Kent Law Review* 371.

information, artistic creations, music, brand names, celebrity persona, industrial secret, and customer lists'.¹¹

Knowledge goods are generally very costly to create for example, medicines, but copying is very easy once the idea is disclosed.¹² Therefore, the IP system, for example, the pharmaceutical patents, are aimed at protecting these ideas by granting monopoly rights to the patentee mainly in order to 'recoup its investment in discovering and developing the new drug.'¹³

The main role of an IP regime, therefore, is to protect ideas thus acting as an incentive for new inventions which according to utilitarian theory is a 'necessary trade-off to obtain the long term benefits.'¹⁴

There are also certain social costs that the society bears because of IPR systems. These include the fact that: it limits supplies in the market of patented subject matters; it often results into duplication since once granted other inventors will have no right on a similar patent and will have to rely on the owner of the first patent; and lastly, it delays innovation in terms of further research and development of existing ideas already patented.¹⁵

Importantly, IPRs is a form of law that intersects with many other areas of human well-being and human development including access to medicines, food, education, arts resulting from cultural heritage and virtually every aspect of

¹¹ JM Mueller *An introduction to patent law* (2003) 5.

¹² As above, 6.

¹³ As above.

¹⁴ As above, 22-23.

¹⁵ As above, pp 20-21.

humanity.¹⁶ In this respect, IPR should not act in order to prohibit the alleviation of poverty and the promotion of human development.¹⁷

Wong contends that the current evolving global development agenda on IPR presents a unique opportunity for countries to engage in IPR reforms in order to prioritize the meeting of basic needs in ‘food and health, increasing capabilities for education, attaining human rights, protecting cultural heritage and sustaining the environment for future generations’.¹⁸ Ultimately, however, a lot depends on how the developing countries implement or utilize the TRIPS Agreement flexibilities locally.¹⁹

Currently, there exist certain conflicts in implementing the TRIPs Agreement to serve as a catalyst for development. The main conflict though has taken the form of ‘private interest and profit motives of pharmaceutical companies’ versus ‘public health and social impact concerns of governments.’²⁰

The former category argues against patent exploitation. In their view, the problem of access to essential medicines in most developing countries lies mainly in the deficiency in government procurement as well as investment in research and development.²¹ And, that access to essential medicines is therefore greatly aided by the patent system which incentivizes the development of new drugs.²²

¹⁶ T Wong ‘Intellectual property through the lens of human development’ in T Wong & G Dutfield (eds) *Intellectual property and human development: Current trends and future scenarios* (2011) 1.

¹⁷ R Chandra ‘The role of national laws in reconciling constitutional rights to health with TRIPS obligations: an examination of the *Glivec* patent case in India’ in T Pogge, M Rimmer and K Rubenstein *Incentives for global public health: Patent law and access to essential medicines* (2010) 382.

¹⁸ Wong (n 16 above).

¹⁹ LM Opati ‘Intellectual property rights in health-Impact on access to drugs’ in M Wekesa and B Sihanya *Intellectual property rights in Kenya* (2009) 21. Available at http://www.kas.de/wf/doc/kas_18323-1522-2-30.pdf?110214131726 (accessed 3 July 2012).

²⁰ As above.

²¹ B Sihanya ‘Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya’ (2011),

The main argument for these proponents is that in public health pandemics such as that of HIV and AIDS where drug development is crucial, a patent protection system does more good than harm and vice versa. The challenges should be addressed via other channels identified above. Other possible strategies include: therapeutic value pricing; pooled procurement; negotiated procurement; planned donations; and government commitment.²³

This position may be in line with the Commission on Intellectual Property Rights (CIPR) report calling for a balance between price reduction (which is associated with patent exploitation) and actual drugs availability (which also means the retention of the patent incentives).²⁴

The latter category, on the other hand, argues for patent exploitation. According to these proponents, IPR is a major barrier on access and therefore its exploitation including by taking advantage of the TRIPS Agreement flexibilities is a more effective way of guaranteeing access to essential medicines particularly in developing countries. These proponents point out the TRIPS Agreement provisions on flexibilities, the Doha Declaration, the Paragraph 6 Decision, and the Chairperson's Statement on developing countries as a basis for their position.²⁵

According to Correa, the Doha Declaration was meant to clarify the existence of flexibilities under the TRIPS Agreement which could be utilized by developing

http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm (Accessed 3 August 2011)

²² Opati (n 19 above).

²³ As above.

²⁴ Report of the Commission on Intellectual Property Rights 'Integrating Intellectual Property Rights and Development Policy' (2002) 39, http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf (accessed 2 July 2012).

²⁵ SF Musungu & C Oh 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' (2005), http://digitalcollections.sit.edu/cgi/viewcontent.cgi?article=1856&context=isp_collection (accessed on 2 July 2012).

countries without attracting repercussions including legal challenges at the World Trade Organization (WTO) Dispute Settlement Unit (DSU).²⁶ Therefore, the implementation of the TRIPS Agreement also allows for the special treatment of pharmaceutical patents in the context of public health emergencies.²⁷

According to Gathii, the TRIPS Agreement patent system including that for the pharmaceutical sector must serve both the IP owners and the consumers. In his view, the TRIPS Agreement ought to be seen in the context of ‘balancing the interest of the industry in recovering its investments on the one hand, and the interests of consumers, and especially low-end consumers suffering from life-threatening illnesses on the other.’²⁸ Any view that emphasizes the TRIPS Agreement as an inflexible regime of exclusive patent rights protection will only legitimize market failure in the area of access to medicines for developing countries in an already anti-competitive international pharmaceutical sector favouring the first world.²⁹

Sadly, the existence of flexibilities at the international level has not actually translated into full benefits at the national level due to poor national implementation by most developing countries.³⁰ Musungu and Oh observes that most developing countries are yet to realize the benefits of these flexibilities because their domestic legislations do not provide for them.³¹ As a result, most of the developing countries are still unable to address their major public health challenges including that of HIV and AIDS.³²

²⁶ Correa (n 9 above), 16.

²⁷ As above, 42.

²⁸ JT Gathii ‘Rights, patents, markets and the global AIDS pandemic’ (2002) 14 *Florida Journal of International Law* 325.

²⁹ As above.

³⁰ Baker (n 8 above), 44.

³¹ Musungu & Oh (n 25 above).

³² As above, xxvii.

In East and Southern Africa (ESA), Zambia and Mauritius are the only developing countries that have made progress in taking advantage of the flexibilities under the TRIPS Agreement for the benefit of access to medicines in their countries.³³ What is more, Gathii contends that the HIV and AIDS scourge has only succeeded in re-creating the tensions that existed during the Uruguay Round between the developing and developed countries.³⁴ This point will be revisited later particularly with regards to South Africa's attempts to utilize compulsory licensing flexibility.

There are also new barriers being put on the path of patent exploitation on a regular basis. Illustratively, the already bad situation in developing countries has also been exacerbated by the proliferation of anti-counterfeiting legislations in ESA region which poses a limitation on the legal production and distribution of generic medicines.³⁵ Other barriers relate to bi-lateral trade agreements including the Economic Partnership Agreement (EPA) that is currently being negotiated in East Africa. Unfortunately, most countries including Kenya lack a strategy to adapt to new challenges in the IP system.³⁶ Similarly, from this study, both governments have not done enough to utilize fully the compulsory licensing and parallel importation flexibilities available under the TRIPS Agreement.

In a recent study on parallel importation and licensing options in Kenya, Nyaga observes that parallel importation commenced in earnest after the enactment of the

³³ Southern and Eastern Africa Trade, Information and Negotiation Institute (SEATINI) in the Regional Network for Equity in Health in East and Southern Africa (EQUINET) 'Implementation of the TRIPS Flexibilities by East and Southern African Countries: Status of Patent Law Reforms by 2010' (2010) 15, <http://www.equinet africa.org/bibl/docs/Diss80TRIPSupdate2010.pdf> (accessed 3 July 2012)

³⁴ JT Gathii 'The legal status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' (2002) 15(2) *Havard Journal of Law & Technology* 295.

³⁵ As above.

³⁶ R Lewis-Lettington & P Munyi 'Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study' (2004) 7, http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf (accessed on 3 July 2012).

Industrial Property Act in 2001 and has increased steadily since then thus improving access to essential medicines in Kenya.³⁷ It appears therefore that Kenya has made some commendable use of the parallel importation flexibility. In 2009, for example, out of an estimated US\$185 million drug market in Kenya, parallel importers constituted more than US\$ 37 Million market share for on- and off-patent drugs.³⁸ ARV drugs also form part of this market share which predominantly is supplied by Tanzania, Uganda, Burundi, Rwanda, Egypt, United Arabs Emirates, China and India. With regards to the ARV drugs, the government has taken over their supply and distribution which is usually for free since 2005.³⁹

With regard to licensing options, Kenya (and also South Africa) is yet to issue compulsory license or government use order despite putting in place relevant laws.⁴⁰ This study will inquire more into the specific reasons and challenges for this state of affairs even after the study was conducted in 2009.

It appears however that the country has benefited from voluntary licensing which is different from compulsory licensing that is involuntary in most cases. Currently, out of six voluntary licenses registered at the Kenya Industrial Property Institute (KIPI) register of voluntary licenses between 1997 and 2008, two were issued in the pharmaceutical sector including for *Nevirapine* for preventing PMTCT which was issued by Cosmos Limited for the East African Community on 26 October 2004.⁴¹

³⁷ JIM Nyaga 'Implementing parallel importation and licensing mechanisms to increase access to medicines in Kenya' unpublished LLM thesis Stanford Program in International Legal Studies, Stanford University, (2009) 47.

³⁸ As above 48.

³⁹ As above 53.

⁴⁰ As above 66.

⁴¹ As above.

There also exist other voluntary licenses including for the manufacturing of ARVs in Kenya.⁴²

However, Nyaga decries the unsustainability of donor funded HIV and AIDS interventions and observes that more effective implementation of other strategies including parallel importation and licensing options should be exploited.⁴³ The President of Kenya is also on record that Africa and specifically Kenya should take advantage of their ‘world-class pharmaceutical manufacturing facilities’ to ‘produce drugs to win in the war against HIV/AIDS, tuberculosis and malaria.’⁴⁴ In the author’s view, utilizing compulsory licensing flexibility under the TRIPS Agreement is a more sustainable option in guaranteeing access to affordable essential medicines in the country. This is because it can be used successfully by local generic manufacturers to promote generic competition.

In another study on Zimbabwe and South Africa, Sacco notes that ARVs in Zimbabwe produced under compulsory licensing are much cheaper than drugs in South Africa’s private sector including under voluntary licensing.⁴⁵ In this regard, compulsory licensing has a positive impact on medicines pricing than even voluntary licensing.

Parallel importation in South Africa is equally important. Many international non-governmental organizations working on emergency reliefs in the country rely heavily on parallel imports from Brazil to provide, for example, ARVs for the many

⁴² As above.

⁴³ As above, 28.

⁴⁴ ‘Foreign policy will favour Africa’ *The Standard* 16 July 2013.

⁴⁵ SF Sacco ‘A comparative study of the implementation in Zimbabwe and South Africa of the international law rules that allow compulsory licensing and parallel importation for HIV/AIDS drugs’ unpublished LLM (Human Rights and Democratisation in Africa) thesis, American University in Cairo, (2004) 39.

South Africans living with HIV and AIDS.⁴⁶ This study will also address the challenges faced by South Africa with respect to parallel importation owing to its importance in emergency relief.

In conclusion, this study will seek to update the knowledge on compulsory licensing and parallel importation in Kenya and South Africa using as a basis available research as reviewed above. In particular, it interrogates whether the unique right to health provisions under the Constitutions of 1996 and 2010 of South Africa and Kenya respectively have been used, satisfactorily, to promote the utilization of the TRIPS Agreement flexibilities particularly parallel importation and compulsory licensing locally. It also reviews the challenges faced by both countries in trying to achieve access to medicines via full utilization of these flexibilities. South Africa's right to health record being longer than Kenya's offers a useful counter point for drawing conclusions that can inform practice and reform interventions in this topic for the benefit of the entire East and Southern African (ESA) region.

1.4 Justification

The justifications for this study are as follows. First, this study is the first of its kind since it focuses on compulsory licensing and parallel importation in Kenya and South Africa. Both countries have enshrined the right to health under their Constitutions thereby prioritizing it.

Secondly, focusing on the gaps in these flexibilities in the law and policy in each country will inform appropriate legal and policy reforms in the future. Kenya in particular is obliged to reform its intellectual property rights laws in conformity with the East African Community (EAC) regional intellectual property policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of

⁴⁶ As above, 38.

national intellectual property legislation of 2013. South Africa is not left out since it has also enshrined the right to health in its Constitution. What is more South Africa (including Kenya) played an active role in putting together the Doha Declaration which authorizes the utilization of TRIPS Agreement flexibilities as a matter of right.

Lastly, by looking beyond the law for additional challenges that inhibit the full utilization of the TRIPS Agreement flexibilities provided under each country, the author hopes to influence broader action from all actors including policy makers, private sector and the broader international community.

1.5 Theoretical framework

This study is based on the broader property law subject and also the right to health. The two areas are discussed separately below beginning with the property law theories.

Generally, property law is about relationships amongst people in terms of control, use, and transfer of resources that have value.⁴⁷ This area of law concerns itself with both real and personal property that broadly refers to legal rights in land and structures on the land, and legal rights in movable objects and intangible resources including intellectual property rights respectively.⁴⁸

There exist debates about proper way to conceptualise and to adjudicate conflicts amongst property claimants however the different theories often employed in this regard include: traditional American Indian conception of property; first possession and labour; positivism and legal realism; rights, social contract and human

⁴⁷ JW Singer *Property law: Rules, policies and practices* (1993) xxxvii.

⁴⁸ As above.

flourishing, consequentialism, utilitarianism, and efficiency; and social relations approaches.⁴⁹

First, the traditional American Indian conception of property has two important practices especially concerning land. The first practice is that land is regarded as spiritual and the second is that property systems are more oriented to sharing. This theory however is not suitable for a theory in the area of intellectual property such as that being investigated in this study. This is because it focuses on tangible property such as land.

Second, the first possession and labour theory is perhaps the most widely accepted theory. The theory is commonly associated with Locke. However, in brief, it argues that one can acquire property rights by virtue of first possession (or occupancy), or through mixing labour with resources. Erbenznik observes that the ‘the self-ownership thesis, coupled with the mixing of one’s labor, and the necessity of doing so to improve one’s situation’ is a good justification for Locke’s exclusive property rights acquisition. However, she notes that the key issue in Locke’s theory is in its limits.⁵⁰ It is this acceptance that property rights must be limited that will inform the theory adopted for our study as will be discussed later.

Third, positivism and legal realism theorists argue on the basis of the law. Therefore, property rights are a creation of the law promulgated by the sovereign. In this regard, therefore, it makes sense to argue that Kenya’s and South Africa’s laws are deficient on the utilization of intellectual property rights. To some extent, this

⁴⁹ As above, 10-23.

⁵⁰ K Erbenznik ‘Does Lockean proviso commit us to global redistribution’ (undated) 6, http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=19&ved=OCHEQFjAIOAo&url=http%3A%2F%2Feconfaculty.gmu.edu%2Fpboettke%2Fworkshop%2Farchives%2Ffall06%2FPaper%2520Version%2520-%2520Lockean%2520Proviso.doc&ei=3OvnUbndE-To4QTrn4HwBg&usg=AFQjCNGSlgyZBUHake-2xrmuTS_u90tO7w&sig2=ejQi8rqMCMbBBhXK97qj5g&bvm=bv.49478099,d.bGE (accessed 18 July 2013).

theory is applicable in this study however, as will be discussed later, the mere fact that both Kenya and South Africa have provided in their laws for compulsory licensing has not translated into its utilisation.

Fourth, the rights, social contract, and human flourishing theorists put the interests of the individual first before other considerations including public policy. It argues for the balancing of interests with the individual rights at the centre. This theory is in favour of IPR protection and against the utilization of the TRIPS Agreement flexibilities.

Fifth, the consequentialism, utilitarianism and efficiency theorists focus on the consequences of alternative legal rules on behavior. According to these theorists, consequences are judged by comparing their costs and benefits with the goal of maximizing the aggregate level of human satisfaction and hence social utility. While this approach is desirable, this study does not conduct any analysis on the costs and benefits of utilizing TRIPS Agreement flexibilities.

Lastly, the social relations approaches views property rights as a delegation of sovereign power to individuals. In this regard, these rights should therefore be defined to accommodate the conflicting interests of social actors. This theory is also partly applicable however our study deals with an already defined area. Our focus therefore is on the utilization of the flexibilities.

As mentioned above, the Lockean natural rights theory is more appealing because of its ability to justify wide varying property systems.⁵¹ In this regard, scholars including this author have taken tremendous interest in the thrust of Lockean theory which the ‘reconciliation of strong private property rights with a

⁵¹ BG Damstedt ‘Limiting Locke: A natural law justification for the fair use doctrine’ (2003) 112 *The Yale Law Journal* 1179, 1180.

common of materials available for all'; a labourer should 'not take too many materials out of the common.'⁵²

The popularity of Locke's sufficiency proviso is reflected in the works of other authors. I will mention two. First, Widerquist refers to this phenomenon as the enough as good provision which justifies property rights limitation for the sake of securing the commons for others.⁵³ In this regard, Locke's sufficiency proviso is a justification for property rights limitation as being advocated in this study.

Secondly, Spitzlinger contends that, within the Lockean natural rights theory, one can legitimately exploit intellectual property rights to save lives.⁵⁴ In this regard, Locke's sufficiency proviso is a facilitator of patent exploitation particularly for life-saving purposes.

With regards to the right to health theory, developing countries hold the view that the strict constructions of the TRIPS Agreement 'fail to recognize the legitimate interests of intellectual property rights users; especially in the context of crises such as HIV/AIDS.'⁵⁵ Other scholars have argued for the centrality of access to medicines in realizing the 'Millenium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases.'⁵⁶

In this regard, access to medicines is therefore a fundamental component of the right to health and cannot be derogated from including via the IPRs. As a fundamental right, it also stresses on 'horrific injustice in the face of momentous suffering and loss

⁵² As above, 1181.

⁵³ K Widerquist 'Lockean theories of property: Justifications for unilateral appropriation' (2010) 2(1) *Public Reason* 10.

⁵⁴ R Spitzlinger 'On the idea of owning ideas: Applying Locke's labour appropriation theory to intellectual goods' (2011) 5 *Masaryk University Journal of Law and Technology* 282.

⁵⁵ Gathii (n 34 above).

⁵⁶ P Hunt and R Khosla 'The human right to medicines' (2008) 8 *Sur – International Journal on Human Rights* 99.

of life' due to HIV and AIDS, malaria and tuberculosis in developing countries.⁵⁷ To the extent that the TRIPS Agreement flexibilities also facilitate the realization of the right to health and access to medicines in developing country they remain crucial and must be implemented.⁵⁸

1.6 Research objectives

The following are the research objectives of this study:

1. To analyse the health rights and access to medicines obligations of Kenya and South Africa at the national, regional and international levels.
2. To analyse the extent to which Kenya and South Africa have utilized compulsory licensing for the right to health and access to essential medicines.
3. To analyse the extent to which Kenya and South Africa have utilized parallel importation for the right to health and access to essential medicines.

1.7 Research question

The following are the research questions employed in this study:

1. What are the health rights and access to medicines obligations of Kenya and South Africa at the national, regional and international levels?
2. To what extent have Kenya and South Africa fully utilized compulsory licensing to guarantee the right to health and access to essential medicines?
3. To what extent have Kenya and South Africa fully utilized parallel importation to guarantee the right to health and access to essential medicines?

⁵⁷ A Yamin 'Not just a tragedy: Access to medications as a right under international law' (2006) 21 *B.U. Int'l L. J.* 370.

⁵⁸ As above.

1.8 Research methodology

The research was conducted mainly through desk based review of available and relevant literature. The author relied on both primary and secondary sources. Concerning primary sources, the author analysed available international, regional and domestic legal instruments. The use of email interviews was also employed. Concerning secondary sources books, journal articles and reports were also consulted.

1.9 Limitations

The key limitation in this study is that the study does not assess the suitability of other flexibilities and/or strategies outside the IPRs to disprove their efficacy in guaranteeing access to essential medicines in developing countries.

1.10 Chapters breakdown

The chapters in this study are divided in the following order. Chapter one is this introduction. It contains the background to the study, problem statement, research questions, and the theoretical framework amongst other things. Chapter two discusses the right to health obligations of Kenya and South Africa that must be balanced with IPRs protection. Chapter three discusses the utilization of compulsory licensing in Kenya and South Africa. Some of the challenges faced by both countries have also been explored. Chapter four discusses the utilization of parallel importation in Kenya and South Africa. Similarly, some of the challenges faced have also been analysed. Lastly, chapter five discusses the conclusions and recommendations of this study. It concludes that both Kenya and South Africa have done very well to utilize parallel importation but at the same time both countries have failed to grant even one compulsory licensing despite relevant laws being in place. Therefore, the utilization of compulsory licensing flexibility under the TRIPS Agreement and domestic laws presents the greatest challenge than parallel importation for both countries.

CHAPTER TWO

LINKING THE RIGHT TO HEALTH, ACCESS TO ESSENTIAL MEDICINES AND INTELLECTUAL PROPERTY IN KENYA AND SOUTH AFRICA

2.1 Introduction

This Chapter explores the right to health commitments in Kenya and South Africa at the national, regional and international levels. The right to health commitments for both countries is crucial in order to justify the obligation on the part of each government to utilize fully TRIPS Agreement flexibilities including compulsory licensing and parallel importation.

2.2 Right to health commitments in Kenya and South Africa

This part of the Chapter outlines the international, regional and national right to health commitments for both Kenya and South Africa.

2.2.1 International treaties

The starting point for any human rights discourse at the international level is the Universal Declaration of Human Rights (UDHR).⁵⁹ Despite the fact that it is generally non-binding and merely declaratory, it forms part of the International Bill of Rights. Others have observed that the violations on fundamental human values during World War II led to the international public opinion forcing the United Nations to be concerned about human rights and thus the UDHR.⁶⁰ In this regard, the first authority and guide on human rights is UDHR whose status has also grown to

⁵⁹ Universal Declaration of Human Rights, 10 December 1948, 217 A (III), <http://www.unhcr.org/refworld/docid/3ae6b3712c.html> (accessed 6 July 2012).

⁶⁰ V Dimitrijevic 'Customary law as an instrument for the protection of human rights' (ISPI working paper 7, 2006) 8, http://www.ispionline.it/it/documents/wp_7_2006.pdf (accessed 16 May 2013).

universal acceptance.⁶¹ It is now widely believed that the whole UDHR or some of its provisions have attained customary law status.⁶² Therefore the authoritative first reference to the right to health remains article 25(1) of the UDHR as follows:

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.

By virtue of being members of the United Nations (UN), Kenya and South Africa subscribe fully to the ideals and provisions of the UDHR including its commitment to the right to health.

Apart from the UDHR, both Kenya and South Africa are jointly and separately members of other legally binding international human rights treaties also codifying, in their texts, the right to health. Most prominently of these treaties and their provisions include: article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR),⁶³ article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW),⁶⁴ and article 24 of the Convention on the Rights of the Child.⁶⁵ However, it should be noted that while Kenya has ratified the

⁶¹ As above.

⁶² As above.

⁶³ UN General Assembly, *International Covenant on Economic, Social and Cultural Rights* Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, <http://www2.ohchr.org/english/law/cescr.htm> (accessed 3 July 2012). Kenya acceded to the ICESCR on 1 May 1972. South Africa however is yet to ratify the ICESCR.

⁶⁴ 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.unhcr.org/refworld/docid/3ae6b3970.html> (accessed 6 July 2012). Kenya ratified CEDAW on 09 March 1984. South Africa on the other hand ratified CEDAW in December 1995.

⁶⁵ UN General Assembly, *Convention on the Rights of the Child*, 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3, <http://www.unhcr.org/refworld/docid/3ae6b38f0.html> (accessed 6 July 2012). Kenya ratified the CRC on 30 July 1980. South Africa on the other hand ratified it in June 1995.

ICESCR, it is yet to ratify the Optional Protocol to the ICESCR⁶⁶ thereby denying individuals the right to present communications before the CESCR for action.⁶⁷ South Africa, unlike Kenya, is yet to ratify both the ICESCR and the Optional Protocol to the ICESCR contrary to the expectations of many peoples. This is because South Africa is internationally renowned for its leadership in the area of socio-economic rights having enshrined them in its Constitution in 1996. Indeed, many people view South Africa's role in adjudicating socio-economic rights as 'revolutionary and heroic.'⁶⁸ The government is yet to offer any official explanation on this issue⁶⁹ However Dugard explains that the non-ratification by South Africa of the ICESCR may be due to the following line of thought:

Failure to ratify the Covenant means that there will be little pressure on South Africa to conform with the jurisprudence of the CESCR with the result that South African law on social and economic rights will follow its own separate path. This is already illustrated by South Africa's deviance from the standard of the 'minimum core obligation'.⁷⁰

The Minimum core analysis was developed by the CESCR after years of extensive review of country report to come up with the 'floor' of socio-economic conditions.⁷¹ The South African Constitutional Court deviation may also be explained by their lack of the extensive information resources of the CESCR however, from their jurisprudence, they agree on the issue of having regard for the needs of the most vulnerable groups that is entitled to the protection of right in question as was affirmed in the *Government*

⁶⁶ Adopted through the General Assembly resolution A/RES/63/117 on 10 December 2008.

⁶⁷ Kenya National Commission on Human Rights (KNCHR) & Kenya UPR Stakeholders Coalition 'Universal Periodic Review (UPR) annual progress report 22nd September 2010-21st September 2011: An assessment by stakeholders of government's performance in implementation of UPR recommendations' (September 2011) 30.

⁶⁸ EC Christiansen 'Adjudicating non-justiciable rights: Socio-economic rights and the South African Constitutional Court' (2007) 38 *Col. Hum. Rts. L. Rev.* 321.

⁶⁹ J Dugard *International law: A South African perspective* (2011) 332.

⁷⁰ As above. South Africa has developed and currently utilizes the 'reasonableness test'.

⁷¹ Christiansen (n 68 above), 340.

of *Republic of South Africa v Grootboom* (*Grootboom case*)⁷² at the South African Constitutional Court.⁷³ The *Grootboom case* is indeed an improvement of the *Soobramoney v Minister of Health, KwaZulu-Natal* (*Soobramoney case*)⁷⁴ which failed to provide a remedy for the poor appellant who later died from renal failure.⁷⁵ Notwithstanding, Liebenberg posits that South Africa made reference to the jurisprudence of the CDESCR including its General Comment No 14 on the right to health during the negotiations that led to the adoption of the socio-economic rights in the Constitution.⁷⁶ Moreover, the South African Constitution section 233 allows every court when interpreting legislations to

prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law.

In this respect, it is not entirely accurate to assume that South Africa does not apply or observe the right to health provisions under the ICESCR. On the contrary, and as stated above, South African courts can only deviate from the international standards when they are offering a better interpretation beyond what is available at the international plane. Indeed, the ‘reasonableness test’ doctrine has gained traction in socio-economic rights litigation globally.

2.2.2 Regional treaties

Regional treaties ordinarily take the same legal status as international treaties. As noted above, both Kenya and South Africa have extensive obligations with regards to the right to health at the international level, the same position is also true at the

⁷² 2001 (1) SA 46 (CC).

⁷³ Christiansen (n 68 above), 340.

⁷⁴ 1998 (1) SA 765 (CC).

⁷⁵ Christiansen (n 68 above), 337.

⁷⁶ S Liebenberg ‘Adjudicating socio-economic rights under a transformative Constitution’ in M Langford *Social rights jurisprudence: Emerging trends in international and comparative law* (2008) 77, footnote 17.

regional level. As such, the following are some of the treaty provisions that codify the right to health at the regional level: Article 16 of the African Charter on Human and Peoples' Rights (African Charter);⁷⁷ article 14 of the Protocol to the African Charter on the Rights of the Women;⁷⁸ and article 14 of the Protocol to the African Charter on the Rights of the Child.⁷⁹ All these instruments are important.

Illustratively, the *Social Economic Rights Centre (SERAC) and Another v Nigeria*⁸⁰ deals also with the right to health regionally. In this case, the right to health included the obligation on the part of the state to desist from 'carrying out, sponsoring or tolerating any practice, policy or illegal measures violating the integrity of the individual.'⁸¹

2.2.3 National Constitutions

The national laws in any country enjoy a very special status compared to the international and regional treaties. In particular, the Constitution as the supreme law of the country is normally sacrosanct. Therefore, the fact that both Kenya and South Africa protects the right to health in their Constitutions speaks volumes on the importance of this right in each country.⁸² According to Biegon and Musila, the Bill of

⁷⁷ African Union *African Charter on Human and Peoples' Rights* adopted on 27 June 1981, CAB/LEG/67/3 rev., http://www.africa-union.org/official_documents/treaties_%20conventions_%20protocols/banjul%20charter.pdf (accessed 3 July 2012). Kenya acceded to the African Charter on 23 January 1992. South Africa ratified the African Charter on 09 July 1996.

⁷⁸ 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.unhcr.org/refworld/docid/3f4b139d4.html> [accessed 6 July 2012]. Kenya ratified the Protocol in October 2010. South Africa ratified it on 17 December 2004.

⁷⁹ African Union *Protocol to the African Charter on the Rights and Welfare of the Child* adopted in Addis Ababa, Ethiopia July 1990, OAU Doc. CAB/LEG/24.9?49 (1990), entered into force 29 November 1999, www.africa-union.org/root/au/Documents/Treaties/Text/A.%20C.%20ON%20THE%20RIGHT%20AND%20WELF%20OF%20CHILD.pdf (accessed 21 August 2012). Kenya acceded to the Protocol on 25 July 2000. Kenya ratified it on 25 July 2000. South Africa on the other hand ratified the Protocol on 07 January 2000.

⁸⁰ (2001) AHLR 60 ACHPR 2001.

⁸¹ As above, para 52.

⁸² See, Kenyan Constitution and South African Constitution (n 1 above).

rights, particularly in Kenya, is important for the following three reasons: It introduces new rights while re-orienting ‘old’ ones; it is a tool and vehicle through which society is to be transformed; and, lastly, the Bill of Rights is a central plank in the framework for validating all interpretation by subjecting all governmental policy – economic, social and cultural – to it.⁸³

The 1996 South African transformative Constitution under section 27(1)(a) provides that ‘[e]veryone has the right to have access to health care services, including reproductive health care.’ Under section 27(2), the South African government’s obligations in this regard is limited to ‘take reasonable measures, within its available resources, to achieve the progressive realization’ of the right to health. Comparatively, the equally progressive Kenyan Constitution of 2010 also extends protection of the right to health. Specifically, article 43(1) of the Kenyan Constitution provides that ‘[e]very person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.’ Under article 21(2), the obligations of the Kenyan government are limited to ‘take legislative, policy and other measures, including the setting of standards, to achieve the progressive realization of the rights guaranteed’ including the right to health. According to Mbazira, the limitation of rights clause under Article 24(1) is progressive since it shifts to the State the burden of justifying a limitation.⁸⁴ However, he also warns that Kenya will face certain challenges particularly arising from giving the rights

⁸³ J Biegon and G Musila ‘Socio-economic rights as one promise of a new constitutional era’ in J Biegon and G Musila *Judicial enforcement of socio-economic rights under the new constitution: Challenges and opportunities for Kenya* (2011) 4.

⁸⁴ C Mbazira ‘The judicial enforcement of the right to the highest attainable standard of health under the constitution of Kenya’ in J Biegon and G Musila *Judicial enforcement of socio-economic rights under the new constitution: Challenges and opportunities for Kenya* (2011) 130.

practical force due to limited resources and retrogressive thinking in the region that allocation of resources is a political rather than a judicial matter.⁸⁵

From a textual analysis of the relevant right to health provisions of both countries, firstly, South Africa on one part recognizes the right to 'have access to health care services'; while Kenya on the other part recognizes the right to the 'highest attainable standard of health, which includes the right to health care services'. Arguably, therefore, Kenya appears to have a slightly broader scope of the right to health than South Africa. Secondly, South Africa imposes an obligation on the government to take 'reasonable measures' while the Kenyan Constitution specifically implores on the Kenyan government to 'take legislative, policy and other measures, including setting of standards' to realize the right to health.' Kenya's Constitution therefore appears to have a greater degree of specificity than the South African Constitution which may be beneficial for the protection of the right to health in the country.

Both countries also have other relevant constitutional provisions codifying the right to health. In South Africa, section 28(1)(c) provides for the right to basic health care services for every child. Similarly, section 35(e) provides for detainees' and prisoners' right to 'adequate medical treatment'. On the other hand, the Kenyan Constitution article 53(c) recognizes the right to basic health care for children. Similarly, article 56(e) also provides for marginalized groups' access to health services. Lastly, article 46 obligates the government to protect the health of consumers in Kenya

It is however not clear whether these additional provisions impose an obligation separate or similar to the previous right to health provisions in both countries.

⁸⁵ As above, 132.

According to Liebenberg, the critical question to ask with regards to these other provisions is whether

these provisions impose direct obligation on the State to ensure the provision of a basic level of socio-economic rights...without the qualifications relating to reasonable measures, progressive realization and resource constraints.⁸⁶

According to Liebenberg, these other provisions do not impose a direct obligation on the State. Referring to the *TAC* case, she posits the following:⁸⁷

In *TAC*, the Court was dealing with children born to mothers who were too poor to afford private medical care and who were, as a result, dependent on State health care facilities. However, the Court did not conclude that these children enjoyed an *unqualified, direct claim* to the provision of health care services to support its finding that the government's rigid policy on Nevirapine was unreasonable because the policy excluded and harmed a particular vulnerable group.

Liebenberg seems to suggest that the right to health must be qualified irrespective of who is making a claim. However, special attention must be given to marginalized and vulnerable groups.

2.2.4 National laws

The protection of the right to health in Kenya and South Africa also extends to national legislations. In South Africa, for example, the principal health legislation is the National Health Act⁸⁸. The purpose of the Act is to 'protect, respect, promote and fulfil the rights of the people of South Africa to the progressive realisation of the constitutional right to access to health care services, including reproductive health

⁸⁶ Liebenberg (n 76 above) 86.

⁸⁷ As above, 87.

⁸⁸ National Health Act 61 of 2003, <http://www.info.gov.za/view/DownloadFileAction?id=68039> (accessed 3 July 2012)

care'. The National Health Act was intended to implement section 27 of the Constitution of South Africa on the right to health. It does so by regulating national, public and private, health care services in South Africa. The legislation also provides for patients' rights. Other relevant right to health legislation in South Africa include the Medicines and Related Substances Control Act⁸⁹. This particular legislation deals with access to essential medicines in general.

There also exists a policy framework on the right to health in South Africa. The most important one for the purposes of our study is the National Drug Policy (NDP) for South Africa. It aims at promoting the availability of safe and effective drugs at affordable prices through rationalising the drug pricing system in public and private sectors and promoting the use of generic medicines. Accordingly, the relevant provision of the NDP states that

[t]he availability of generic, essential drugs will be encouraged through the implementation of incentives that favour generic drugs and their production in the country.⁹⁰

Kenya's principal health legislation is yet to be enacted by the National Assembly.⁹¹ Once enacted, the health legislation will provide for the regulation of the health sector including access to essential medicines.⁹² The latest draft was withdrawn and a new one is yet to be publishes. However, in the latest draft, the purpose of the law has been stated as follows:

[T]o give effect to [a]rticle 43 of the Constitution; to provide for the maintenance and advancement of health and the provision of health services of the highest attainable standard; to provide for the powers, functions, and responsibilities of the Health

⁸⁹ Medicines and Related Substances Control Act, Act No. 101 of 1965, <http://www.info.gov.za/view/DownloadFileAction?id=71798> (accessed 3 July 2012)

⁹⁰ National Drug Policy of 1996, paragraph 4.2, <http://www.doh.gov.za/docs/policy/drugsjan1996.pdf> (accessed 6 July 2012)

⁹¹ Health Law Bill, 2012, <http://www.cickenya.org/legislation?page=1> (accessed 3 July 2012).

⁹² As above, parts 8, 9 & 10.

Council, the Health Services Authority, the National Health Inspectorate Service and the Council for Health Professionals and for other connected purposes.

A review of its clauses reveals controversial proposals. First, clause 57 devolves the procurement of medicines to the county governments. This move may affect negatively access since a central procurement system is better placed to negotiate for price reductions and discounts based on bulk purchases. Another clause that is controversial is clause 23 on the Kenya Health Service Authority which is supposed to perform an advisory function to the county and national governments. The main problem with the proposed body is that it is composed of a membership drawn from various government departments. The preferred alternative would be to have independent experts including in the area of access to medicines for maximum performance. Lastly, clause 102 on the powers of the cabinet secretary omits the power to apply for compulsory licensing and issue guideline on parallel importation. These powers would enable the office bearer to be an active participant in the exploitation of the TRIPS Agreement provisions as opposed to the current passive role the holder of the office plays.

The HIV and AIDS Prevention and Control Act (HAPCA) is also another relevant legislation that codifies the right to health.⁹³ In particular, section 19(2) of HAPCA provides for the access to health care services including ‘access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection.’

⁹³ HIV and AIDS Prevention and Control Act, Act No 14 of 2006, www.chr.up.ac.za/undp/domestic/docs/legislation_35.pdf (accessed 5 July 2012).

In terms of the policy framework, the Kenya National Drug Policy (KNDP)⁹⁴ states its goal as follows:⁹⁵

Use available resources to develop pharmaceutical services to meet the requirements of all Kenyans in the prevention, diagnosis and treatment of diseases using efficacious, high quality, safe and cost-effective pharmaceutical products.

In addition, one of the objectives of the KNDP is '[t]o provide drugs through the government, private, and non governments sectors at affordable prices'. The policy needs to be reviewed to promote the full utilization of the TRIPS Agreement flexibilities in Kenya. This would go a long way to secure the access to medicines situation in Kenya on a sustainable basis as well as realize the goal and the objective of KNDP as stated above.

In conclusion, from the above analysis, both Kenya and South Africa have extensive legislative and policy framework that favours the right to health and access to essential medicines in particular. The existence of favourable laws and policies on the right to health should influence positively the utilization of TRIPS Agreement flexibilities.

2.3 Access to medicines as a component of the right to health

Having established the strong commitments for Kenya and South Africa with regards to the right to health, it is imperative to establish the link between the right to health and access to essential medicines. This link is important in order to rely on the right to health narrative to justify the full utilization of TRIPS Agreement flexibilities including compulsory licensing and parallel importation. In order to achieve the stated

⁹⁴ Kenya National Drug Policy, 1994, <http://collections.infocollections.org/whocountry/en/d/Jh4332e/> (accessed 5 July 2012)

⁹⁵ As above, preamble.

objective, the author reviews numerous sources including at the international, regional and national levels.

2.3.1 International level - General Comment No 14

At the international level, the starting point for the interpretation of the right to health provisions under the ICESCR, Article 12 is the CESCR General Comment No 14 on the right to the highest attainable standard of health.⁹⁶ According to Biegon, this instrument has helped to water-down or dispel the claims that socio-economic rights including the right to health are vague and imprecise.⁹⁷ According to the General Comment No 14, health is a fundamental right indispensable for the exercise of other human rights and is realizable through ‘formulation of health policies, or the implementation of health programmes developed by the World Health Organization (WHO), or the adoption of specific legal instrument.’⁹⁸ The rights related to and dependent upon the right to health include the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement.⁹⁹ In terms of definition, the CESCR also acknowledged that the right to health

embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.¹⁰⁰

⁹⁶ E/C.12/2000/4.

⁹⁷ J Biegon ‘The inclusion of socio-economic rights in the 2010 Constitution: Conceptual and practical issues’ in J Biegon and GM Musila *Judicial enforcement of socio-economic rights under the new Constitution: Challenges and Opportunities* (2011) 22.

⁹⁸ Para 1.

⁹⁹ Para 3.

¹⁰⁰ Para 4.

However, the right to health does not mean the right to be healthy.¹⁰¹ This is because the State cannot guarantee protection against every possible causes of human ill health.¹⁰² However, the right to health has the following elements: availability; accessibility; acceptability; and quality.¹⁰³ With regards to access to essential medicines, General Comment No 14 provides that it forms part of the minimum core obligation under the right to health.¹⁰⁴ The implication of placing access to essential medicines under the minimum core obligations is that they are non-derogable and

¹⁰¹ Para 8.

¹⁰² As above.

¹⁰³ Para 12. The elements are explained as follows: (a) *Availability*. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs. (5)

(b) *Accessibility*. Health facilities, goods and services (6) have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:

Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds. (7)

Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS. Accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to buildings for persons with disabilities.

Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.

Information accessibility: accessibility includes the right to seek, receive and impart information and ideas (8) concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality.

(c) *Acceptability*. All 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.

(d) *Quality*. As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, *inter alia*, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

¹⁰⁴ Para 43(d).

must be implemented fully.¹⁰⁵ As such, all governments including Kenya that are part of the ICESCR should ensure that the World Health Organisation's (WHO) essential medicines list (including national essential medicines lists available in most countries) is implemented in a satisfactory manner.

2.3.2 Regional level - African resolution on access to medicines

As noted above, the African Charter provides for the right to health under its article 16. In order to interpret part of the African Charter provision on the right to health, members of the African Union (AU) adopted a Resolution on Access to Health and Needed Medicines in Africa.¹⁰⁶ This resolution is important because it recognizes that 'access to medicines is a fundamental component of the right to health' and that all members of the African Charter 'have an obligation to provide where appropriate needed medicines, or facilitate access to them.'¹⁰⁷ Illustratively, in *International Pen and other (on behalf of Saro-Wiwa) v Nigeria*,¹⁰⁸ the African Commission found that the denial of access to treatment and medications constituted a violation of Article 16 on the right to health.¹⁰⁹

2.3.3 National level - TAC case and Patricia Asero case

At the national level, the *TAC* and *Patricia Asero* cases are the relevant authorities on the right to health and access to essential medicines in South Africa and Kenya respectively. Since, these cases are not the subject matter of this study, they have been discussed in this part briefly. In the *TAC* case, the case was filed by a local non-

¹⁰⁵ General Comment No 3 (1990) para 10, UN DOC. E/1991/23, <http://www.unhcr.org/refworld/pdfid/4538838e10.pdf> (accessed 3 July 2012).

¹⁰⁶ Africa Union Resolution on Public Health and Needed Medicines, adopted in 2008. (ACHPR/Res. 141 (XXXVIII) 08), <http://www.chr.up.ac.za/index.php/ahrru-news.html> (accessed 3 July 2012).

¹⁰⁷ As above.

¹⁰⁸ *International Pen and other (on behalf of Saro-Wiwa) v Nigeria* (2000) AHRLR 212 (ACHPR 1998).

¹⁰⁹ As above, paras 104, 111 & 112.

governmental organization (NGO) in South Africa. The case challenged the policy of the government with regards to mother-to-child HIV transmission. The government had devised a pilot programme on a limited number of sites to distribute freely acquired *Nevirapine* known to reduce the transmission from HIV positive mothers to their children at birth. In this case, to start with, the government sought to rely on efficacy and safety of *Nevirapine* and lack of resources to defend its actions and restrictive policy on MTCT.¹¹⁰ The Court rejected the above justifications as unreasonable as follows:

[T]he failure to take measures without delay to permit and facilitate the use of the anti-retroviral drug, Nevirapine, throughout public health facilities in South Africa for the purpose of preventing MTCT of HIV was unreasonable.¹¹¹

In Kenya, in *Patricia Asero* case, the main issues brought by the petitioners composed of three persons living positively with HIV accompanied by NGOs including AIDS Law Project (ALP) were that the ACA was unconstitutional in as far as its sections 2, 32 and 34 violated the right to health, life and human dignity. The arguments by the government against the petition was that the proviso under section 2 of the ACA protecting access to essential goods including medicines as well as that the anti-counterfeit legislation in Kenya adopted the WHO definition of ‘counterfeiting’ was rejected since the Court observed that the ACA was highly eschewed in favour of intellectual property right protection and that the safeguards were therefore weak and unreliable.¹¹²

In particular, the key problem was that the definition of ‘counterfeiting’ was too broad to an extent that it also conflated counterfeit and generic medicines. To this extent, the legislation needed to delink patent application to cure this defect satisfactorily. The High Court went ahead to declare the anti-counterfeit legislation to

¹¹⁰ Liebenberg (n 76 above) 85.

¹¹¹As above.

¹¹² *Patricia Asero* case (n 3 above), para 77.

be unconstitutional. The *Patricia Asero* case has been described as a trail-blazer setting an important precedent in the region especially since the continued proliferation of anti-counterfeiting legislations.¹¹³ The decision has also managed to avert the death of millions of people in Kenya and other countries in the region relying on generic medicines sold or imported through Kenya.¹¹⁴

2.4 The Link between access to medicines and intellectual property

Having established that access to medicines is a core component of the right to health above, it is equally important to link access to medicines with intellectual property rights protection.¹¹⁵ Intellectual property rights (IPRs) protection is as old as the Declaration of the Rights of man and of Citizens where the interpretation of the right to property was found to also include a writer's work or copyright.¹¹⁶ Human rights treaty provisions, including articles 27 and 17 of the UDHR and ICESCR respectively, also recognizes some form of IPRs protection.

Undoubtedly, therefore IPRs protection and human rights have its first link on the human rights treaty provisions. However, there exist other links. Firstly, it is the conflict between the two areas of laws. The Resolution of the UN Sub-Commission on the Promotion and Protection of Human Rights¹¹⁷ pointed out that there exist notable conflicts between intellectual property rights enshrined under the TRIPS agreement

¹¹³ PO Ogendi 'Safeguarding access to essential generic medicines in Kenya's Anti-Counterfeit Act: Implementing *P.A.O & 2 Others v AG* decision' unpublished LLM (Human Rights and Democratisation in Africa) thesis, University of Lagos (2012) 21.

¹¹⁴ As above.

¹¹⁵ For more details on this subject refer to: LR Helfer 'Human rights and intellectual property: conflict or co-existence?' (2003) 5(1) *Minnesota intellectual property review* 47, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=459120; LR Helfer 'Towards a human rights framework for intellectual property' (2007) 40 U.C. Davis Law Review 971, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=891303 (accessed 3 October 2012); and PK Yu 'Reconceptualizing intellectual property interests in a human rights framework' (2007) 40 U.C. Davis Law review 1039, papers.ssrn.com/sol3/papers.cfm?abstract_id=927335 (accessed 3 October 2012).

¹¹⁶ R Ostergard 'Intellectual property: A universal Human Right' in Wong (n 24 above) 267.

¹¹⁷ Res 2001/21, UN ESCOR, Sub-Commission on Human Rights un doc. e/2001/23-6/cn/sub.2/res/2001/21 (2001).

and international human rights law occasioned by the failure of the intellectual property rights regime to integrate in itself ‘the fundamental nature and indivisibility of all human rights’.¹¹⁸

The problem here is that IPRs protection has largely ignored human rights. Accordingly, General Comment No 17 paragraph 2 points out that the main difference between human rights and IPRs is that the latter ‘are generally of a temporary nature and can be revoked, licensed or assigned to someone else’.¹¹⁹ The revocation, licensing and assignment can be undertaken by the State as part of its obligations, according to paragraph 35, in order to prevent unreasonable high cost of medicines.¹²⁰ Paragraph 35 makes it clear that intellectual property rights are not necessarily human rights while at the same time noting that human rights are a ‘timeless expressions of fundamental entitlements of the human person’.

Correa observes that countries like India which has taken advantage of the TRIPS Agreement flexibilities enjoy up to 41 times cheaper prices than countries which do not utilize TRIPS Agreement flexibilities.¹²¹ This has been made possible due to the existence of sufficient political will that is missing in many other developing countries including Kenya and South Africa. Globally, access to generic drugs and competition has helped reduce global medicines prices from US\$ 10,000 per patient per year to less than US\$ 350 per patient per year for a first line combination ARVs therapy.¹²² This massive price difference between the generic and branded medicines has led to accusations that some pharmaceutical companies are abusing their dominance in the

¹¹⁸ As above.

¹¹⁹ General Comment No 17 on the right of everyone to benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he or she is the author 12 January 2006 (UN Doc. E/C.12/GC/17), <http://www.unhcr.org/refworld/pdfid/441543594.pdf> (accessed on 3 September 2012).

¹²⁰ As above.

¹²¹ C Correa *Intellectual property rights, the WTO and developing countries: The TRIPS Agreement and policy options* (2002) 35.

¹²² C Perez-Cassas et al., “Accessing ARVs: untangling the web of price reductions for developing countries”, (2001) 3.

market.¹²³ To the extent that IPRs promote monopolization, it is a barrier on the realization of the right to health in developing countries. The UN Special Rapporteur on the Rights to Health observes that

a product patent enables a patentee to set high prices. Higher standard of patent protection, which can reduce the number of easily granted patents, can facilitate competition and lower the prices of medicines. Lower standards of patent protection, however, which can increase the number of easily granted patents can lead to higher prices. Generic competition in the field of pharmaceuticals has the potential to significantly lower prices and increase access.¹²⁴

Lastly, during the 23rd session of the Human Rights Council (HRC) conducted on 11 June 2013 adopted a resolution on access to medicines in the context of the right to health¹²⁵ further affirming the link between access to medicines and intellectual property. The resolution observed the need for states to utilize fully TRIPS Agreement flexibilities for the benefit of access to medicines.¹²⁶

2.5 Conclusion

From the above analysis, the study has been able to achieve three objectives. First, the study has described in considerable details that both Kenya and South Africa have numerous right to health obligations at the national, regional and international levels that justifies the utilization of TRIPS Agreement flexibilities. Secondly, the study has

¹²³ E t Hoen *The global politics of pharmaceutical monopoly power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (2009) 25.

¹²⁴ 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2009) para 19. UN DOC. A/HRC/11/12. Available at <http://www2.ohchr.org/english/issues/health/right/visits.htm> (accessed 3 July 2012).

¹²⁵ Resolution on access to medicines in the context of the right to health, UN Doc A/HRC/23/L.10/Rev.1, http://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/23/L.10/rev.1 (accessed 16 July 2013).

¹²⁶ Paragraph 5(h).

established that access to essential medicines forms part of the non-derogable core elements of the right to health. In this regard, Kenya and South Africa must ensure that access to essential medicines is not compromised. Lastly, the study has succeeded in showing that IPRs have an impact on access to medicines through promoting monopolization. Evidence elsewhere, has supported the promotion of generic medicines competition which has succeeded in reducing considerably medicines prices. The challenge however remains how to make available generic competitions. In the following chapters, we discuss two ways, compulsory licensing and parallel importation, as legally acceptable means of promoting generic competition in Kenya and South Africa respectively in order to promote access to medicines.

CHAPTER THREE

COMPUSLORY LICENSING IN KENYA AND SOUTH AFRICA

3.1 Introduction

This Chapter is concerned with the full utilization of compulsory licensing flexibility under the TRIPS Agreement. Its key objective is to analyse the legal and policy environment around the subject matter with the aim of establishing whether conditions are right for the full utilization of compulsory licensing in Kenya and South Africa. Also addressed in this Chapter are the advantages as well as the challenges associated with the utilization of compulsory licensing in Kenya and South Africa.

3.2 Compulsory licensing and the TRIPS Agreement

Compulsory licensing is arguably the most important TRIPS Agreement flexibility. Compulsory licensing is by definition a ‘non-voluntary license...to a third party to exploit a patented invention, without the authority of the patent holder.’¹²⁷ In effect, therefore, compulsory licenses are the only flexibility that goes against the patent system.¹²⁸ It is also the only flexibility that allows relevant public authorities to grant companies, private sector and/or individuals the authority to ‘use the rights of the patent — to make, use, sell or import a product under patent (i.e. a patented product or a product made by a patented process)...provided certain procedures and conditions are fulfilled’.¹²⁹ Compulsory licenses have been vehemently opposed because it may

¹²⁷ Musungu & Oh (n 25 above) 27.

¹²⁸ CA Cotropia ‘Compulsory licensing under TRIPS and the Supreme Court of the United States Decision in *eBay v MercExchange*’ in T Takenaka *Patent law and theory: A handbook of contemporary research* (2008) 560.

¹²⁹ ‘Compulsory licensing’ *World Trade Organisation*, http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm (accessed 19 November 2012).

‘destroy the incentive to innovate’.¹³⁰ This argument has been used successful to ensure that compulsory licenses are used at very minimal levels globally. In fact, both Kenya and South Africa have not attempted to utilize this flexibility despite providing for it in their national legislations.

Perhaps, it would be important to revisit the actual reasons why compulsory licensing should be embraced by developing countries. The reference point is the Doha Declaration on Public Health and the TRIPS Agreement (Doha Declaration) paragraph 5(b) which encourages the use of compulsory licenses. In effect, paragraph 5(b) also clarifies that members have the ‘freedom to determine the grounds for the granting of compulsory licences.’

These grounds are many and varied but the following grounds have been cited in the past: refusal by a patent owner to licence on reasonable commercial terms; public interest including public health; public health and nutrition including ensuring availability and affordability of medicines; national emergency or situation of extreme urgency including war, famine, and natural catastrophe; the need to correct anti-competitive practices; dependent patent where a new invention requires the use of pre-existing patented invention for working; and failure to exploit or insufficiency of working.¹³¹ This list is by no means exhaustive.

As such, developing countries are free to explore other justifications in order to take advantage of compulsory licensing flexibility. Other reasons may include promotion of local pharmaceutical capacity and also responding to regional and/or international emergency situations.

¹³⁰ R Rozek and R Rainey ‘Broad-based compulsory licensing of pharmaceutical technologies: Unsound public policy’ (2001) 4 *Journal of World Intellectual Property* 469.

¹³¹ As above, pp 28-31.

3.2.1 Minimum procedural requirements under the TRIPS Agreement

While compulsory licensing is the most important flexibility, it also comes with certain conditions which must be met. These conditions may be responsible to some extent for the poor utilization of this flexibility in most developing countries.

Internationally, article 31 of the TRIPS Agreement enlists the minimum conditions that must be fulfilled before any State can utilize compulsory licenses for any purpose. The key conditions that must be fulfilled are that the patent owner must be equitably remunerated and also that the acquisition must be for strictly non-commercial use and for the benefit of the public. In my opinion, the latter condition should be amended to allow for promotion of local and regional manufacturing capacity.

This will have the effect of promoting competition and thereby reducing over-reliance on the compulsory licensing flexibility to respond to public health emergencies since medicines will be widely and cheaply available. Notwithstanding, Nyaga also notes that compulsory licensing is more advantageous if it forms part of a direct government policy for the provision of free or subsidized medications to patients.¹³² My argument to respond to this observation is that most governments today have pledged to provide affordable medical care for its citizens. In order to implement this pledge, the government will need to find sustainable ways of addressing medicines' prices and availability. One such way is to encourage the utilization of compulsory licensing for the promotion of local or regional manufacturing capacity at least for the major diseases that afflict developing countries.

¹³² Nyaga (n 34 above), 22.

Article 31 is divided into many subsections. First, article 31(a) stipulates that each case of compulsory licensing must be ‘considered on its individual merits’.¹³³

Second, article 31(b) requires that one pursues as a precondition express authorization from a patent owner on reasonable commercial terms. The only exceptions to this provision are in cases of ‘national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. In such cases, a patent owner must be informed promptly. In cases where express authorization was sought and granted by the patent owner, upon assessment, competent authorities may refuse to terminate the compulsory license ‘if and when the conditions which led to such authorization are likely to recur’ in cases where the period of exploitation agreed upon by both parties expires.¹³⁴

Third, compulsory licenses that are successfully granted must be limited in scope and duration taking into account the ‘purpose for which it was granted’.¹³⁵ This requires that the purpose of the compulsory license must be clearly defined and the timelines for exploitation must be clearly defined. In this regard, a compulsory license cannot be given for abstract and/or unclear reasons.

Fourth, compulsory licenses once granted must be made available for everyone to exploit.¹³⁶ In other words, it should be non-exclusive. Anyone who has the capacity to take advantage of the license must be allowed to benefit from the license including the patent owner.

¹³³ Article 31(a) of the TRIPS Agreement, 1995.

¹³⁴ Article 31(k) of the TRIPS Agreement.

¹³⁵ Article 31(c) of the TRIPS Agreement.

¹³⁶ Article 32(d) of the TRIPS Agreement.

Fifth, compulsory licenses cannot be assigned by any other enterprises unless it receives a grant from the State or enjoys similar goodwill.¹³⁷

Sixth, the utilization of compulsory licensing must consider the commercial interest of patent owners and ideally its use should be limited for predominantly domestic consumption.¹³⁸ This condition may also be suspended in cases where a compulsory license is granted to correct anti-competitive practices.¹³⁹

In a challenge by developing countries at the World Trade Organization (WTO) TRIPS Agreement General Council a Decision of 30 August 2003 now allows for limited exportation and importation of pharmaceutical products for WTO Members with insufficient or no manufacturing capacities particularly for the benefit of least-developed countries (LDCs).¹⁴⁰

Seventh, a compulsory license ceases to exist when the ‘circumstances which led to it cease to exist and are unlikely to recur’.¹⁴¹

Eighth, adequate remuneration shall be paid to the patent owner with due regard to the economic value of the license.¹⁴² The amount of remuneration to be given may also take into account the need to correct anti-competitive practices.¹⁴³

Ninth, the legality of compulsory licenses can be challenged in court or through ‘other independent review by a distinct higher authority’.¹⁴⁴ This also applies in cases

¹³⁷ Article 31(e) of the TRIPS Agreement.

¹³⁸ Article 31(f) of the TRIPS Agreement.

¹³⁹ Article 31(k) of the TRIPS Agreement.

¹⁴⁰ This Decision is for the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on the utilization of the compulsory license as a flexibility.

¹⁴¹ Article 31(g) of the TRIPS Agreement.

¹⁴² Article 31(h) of the TRIPS Agreement.

¹⁴³ Article 31(k) of the TRIPS Agreement.

¹⁴⁴ Article 31(i) of the TRIPS Agreement.

of conflicts on remuneration.¹⁴⁵ And, last, where a compulsory license is issued to permit the exploitation of a second patent, the following additional conditions are provided for:

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Despite the complexities around the grant of compulsory licensing, the WTO Dispute Settlement Body (DSB) has not had an opportunity to set a precedent as to whether it is legal under the TRIPS Agreement.¹⁴⁶ The closest opportunity came when America disputed as illegal under the TRIPS Agreement the South African move to empower its Minister for Health to be able to issue compulsory licenses for pharmaceuticals.¹⁴⁷ The Indian case is also a good case that should be resolved by the DSB considering that America has been very unhappy with India's move to grant compulsory license on Bayer's cancer drug Nexavar.

Moving forward, because of the high stakes and increasing confusion involved in this subject, it is perhaps the time to bring a dispute before the DSB instead of relying on other diplomatic and legal measures to solve such disputes.¹⁴⁸

3.3 A brief description of the compulsory licensing legal framework in Kenya

In Kenya, there exist elaborate provisions with regards to compulsory licensing under the Industrial Property Act (IPA).¹⁴⁹ Specifically, sections 72 to 78 outline the

¹⁴⁵ Article 31(j) of the TRIPS Agreement.

¹⁴⁶ SM Ford 'Compulsory licensing provisions under the TRIPs Agreement: Balancing pills and patents' (2000) 15(4) *American International Law Review* 956.

¹⁴⁷ As above, 950.

¹⁴⁸ As above, 968.

requirements for the exercise of compulsory licensing. However, the starting point is section 58(5) which allows for the limitation of patent rights on the grounds of ‘provisions on compulsory licenses for reasons of public interest or based on interdependence of patents’. In this respect, public interest and interdependence of patents are the justifications acceptable in Kenya. Unlike other countries that rely on the courts, compulsory licenses in Kenya are granted by the Tribunal and registered by the Managing Director of Kenya Industrial Property Institute (KIPI).¹⁵⁰

As seen above, Kenya has at least two grounds for the grant of compulsory licenses including “supply on reasonable terms” and “interdependence of patents”.¹⁵¹ The first ground for granting compulsory licensing in Kenya is basically invoked when there is a failure to work an earlier patent. As such, if four years after the filing of a patent or three years after a patent has been granted there are no supplies in the market on reasonable terms without any justification another person may apply for a compulsory license in Kenya.¹⁵² The second ground for granting compulsory licenses is where there are interdependent patents. In this case, an owner of a subsequent patent may apply to the Tribunal for a compulsory license with respect to an earlier patent to enable him work his patent. However, the precondition is that the invention must constitute a more ‘important technical advance of considerable economic significance’ in relation to the earlier patent.¹⁵³ If the owner of the first patent so desires, he may also request and obtain a cross-license on the earlier patent.¹⁵⁴ The first patent once acquired cannot be assigned unless it is assigned together with the second patent.¹⁵⁵

¹⁴⁹ Industrial Property Act, Act No. 3 of 2001 Laws of Kenya.

¹⁵⁰ See sections 75(1) and 78 of the IPA.

¹⁵¹ Lewis-Lettington & Munyi (n 36 above), 22.

¹⁵² Section 72(1) of the IPA.

¹⁵³ Section 73(1) of the IPA.

¹⁵⁴ Section 73(2) of the IPA.

¹⁵⁵ Section 73(3) of the IPA.

Other preconditions for granting compulsory licenses are also contained under section 74 of the IPA as follows. One, the person requesting the license must prove that he was ‘unable to obtain the license on reasonable commercial terms’.¹⁵⁶ However, this condition does not apply with respect to national emergencies.¹⁵⁷ Two, there must also be guarantees to work the patent or remedy the circumstances that led to the request of the license.¹⁵⁸

The most controversial requirement however that needs urgent reforms to align it with the latest developments under the TRIPS Agreement is the restriction imposed on compulsory licenses in Kenya for predominantly domestic supply. In this regard, Kenya cannot export or import pharmaceutical products in line with the Paragraph 6 Decision of August 2003.¹⁵⁹ Undoubtedly, this restriction would limit the full utilization of compulsory licensing in Kenya.¹⁶⁰ Also, while the TRIPS Agreement sets ‘adequate remuneration’ for compulsory licenses Kenya requires ‘remuneration which is equitable’.¹⁶¹ Lastly, in Kenya, a compulsory license may be substituted by a favourable contractual license from the patentee.¹⁶²

3.4 A brief description of the compulsory licensing legal framework in South Africa

In South Africa, both the Patent Act¹⁶³ and the Medicines and Related Substances Control Amendment (RSCA) Act¹⁶⁴ provides for compulsory licenses. The relevant

¹⁵⁶ Section 74(1)(a) of the IPA.

¹⁵⁷ Section 74(2) of the IPA.

¹⁵⁸ Section 74(1)(b) of the IPA.

¹⁵⁹ Section 75(2)(b) of the IPA. The paragraph 6 Decision was a solution to the provision under the TRIPS Agreement that required products resulting from a grant of a compulsory license must be predominantly for domestic supply.

¹⁶⁰ COMESA *Sector strategy for access to medicines in COMESA* (2011) 17. File available with the author.

¹⁶¹ Section 75(2)(e) of the IPA.

¹⁶² Section 76(3) of the IPA.

¹⁶³ No 57 of 1978.

¹⁶⁴ No 90 of 1997.

sections in the Patent Act are sections 52 to 59 while the RSCA provides for compulsory licensing under section 5(c). The general requirements of compulsory licensing are the same as those found in Kenya. In this part, we focus on the variations between the two countries. The Patent Act section 37(5) allows for the limitation of patent rights and the utilization of compulsory licensing for ‘public interest or based on interdependence of patents’. Generally speaking, South Africa’s provisions relating to non-working of patents are more elaborate than Kenya’s meaning that South Africa has more grounds for non-working than Kenya, thus making it easier to grant compulsory licenses.¹⁶⁵ Unlike Kenya, it is the courts that grant compulsory licenses. Compulsory licenses in South Africa are granted by the courts in the interest of ‘the establishment or development of industrial or commercial activities.’¹⁶⁶ For interdependent patents, the requirement is that if the two patents serve similar purposes, upon request, the owner of the earlier patent may also benefit from compulsory license on the later patent.¹⁶⁷ Under section 54 of the Patent Act, products considered of vital importance may be put under compulsory license by an order from the Minister. The products must be of vital importance to the defence, economy and public health of South Africa. Lastly, section 56(2)(d) of the Patent Act provides for the equitable remuneration of the patent owner.

3.5 Comparative analysis

It is noteworthy that the legal framework with regard to compulsory license in Kenya and South Africa are largely similar. This part highlights at least three major differences in the two countries legal systems.

First, as stated above, Kenya’s compulsory licensing process is handled by a Tribunal, the Industrial Property Tribunal. However, in South Africa, the process is

¹⁶⁵ Section 52 of the Patent Act, 1987.

¹⁶⁶ Section 52(iv) of the Patent Act.

¹⁶⁷ Section 53(2) of the Patent Act.

handled by the courts. Both options are within the discretion of each country pursuant to the relevant provisions of the TRIPS Agreement. According to Baker, the court process in developing countries is undesirable because they are ‘more costly, delayed and burdensome procedure, reducing the likelihood that non-governmental applicants, especially generic companies, would pursue compulsory licenses.’¹⁶⁸ Ordinarily, expedited independent procedures before a panel or a tribunal are to be preferred to the potentially lengthy and expensive court process.¹⁶⁹

Second, South Africa has the most progressive provision under section 54 of the Patent Act. Under this section, compulsory licenses may be issued on various grounds including for purposes of public health by way of a notice in the *Gazette* by the Minister. This provision therefore allows for an alternative process of exercising compulsory licensing flexibility other than through the court process. This method is known as government use order. Kenya on the other hand has a provision waiving the requirement to obtain permission from a patent owner in cases of national emergencies under section 74(2). Section 80 on government use order requires that before the exploitation of a patented invention for public interest reasons an application to the Managing Director of KIPi must be done in a prescribed form.¹⁷⁰

Third, it is unfortunate that Kenya is yet to reform its law in line with the Doha Declaration paragraph 6 and the August 2003 Decision to allow for minimum imports and exports of essential medicines especially for the benefit of LDCs in the East African Community (EAC) region. The IPA section 75(2) still retains the provision that requires that compulsory licenses are granted for predominantly local supply. No such restrictive provision is contained in the South African law therefore allowing it the

¹⁶⁸ Email interview with B Baker, 11 October 2012.

¹⁶⁹ *Good practice guide: Improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement* United Nations Development Programme (UNDP) HIV/AIDS (2010) 30.

¹⁷⁰ Section 80(1) of the IPA.

latitude to supply limited exports to LDCs in the Southern African region. Compulsory licenses have worked well recently in Brazil, Ecuador and Thailand for domestic production or import of ARVs and other essential medicines.¹⁷¹

Notwithstanding, the UNDP observes that an appropriate legal framework should contain the following features: define what constitutes 'adequate remuneration', provide for strict timelines for negotiations and a clean default policy in favour of the issuance of a compulsory license; it should adopt expedited independent procedures and not the courts which sometimes end up being lengthy in process and expensive; and lastly, the possibility of delaying the compulsory license should be eliminated by providing that any challenge of the validity of the compulsory license would not stay the operation of the license.¹⁷²

3.6 Advantages and disadvantages of compulsory licensing for limited imports and exports¹⁷³

Pursuant to the TRIPS Agreement, paragraph 7 of the Doha Declaration, and the 30 August 2003 Decision by members who have limited or no manufacturing capacity as is the case in the sub-Saharan region may benefit from limited imports and exports after applying to the TRIPS Council. In this regard, the following are the advantages and disadvantages of utilizing this option for particularly LDCs. Developing countries like Kenya and South Africa may also wish to consider their laws and policies to promote the utilization of compulsory licensing in their countries.

3.6.1 Advantages

The following are the general advantages of compulsory licensing particularly for limited import and exports as outlined by Baker.

¹⁷¹ UNDP (n 168 above) 30.

¹⁷² As above.

¹⁷³ See, Baker (n 8 above), 26.

- i. Compulsory licenses to import generics can instantly meet demand depending on the producer(s)'s manufacturing capacity and on the registration status of the medicine.
- ii. With sufficient economies-of-scale based on demand from multiple nations, generic producers with export compulsory licenses should be able to produce medicines at greatly reduced prices (subject to countervailing possibility of abusive pricing). Large-scale manufacturers might also be able to establish more efficient product distribution systems.
- iii. Multiple compulsory licenses can be issued and each license can permit patented medicines to be combined to ensure development and registration of rational fixed-dose combination medicines that will ease patient compliance with complex treatment regimes.

In simple terms, the advantages of allowing for imports and exports are threefold: to meet local market demands; reduce medicines prices; and facilitate research and development of new medicines that are easy to use.

3.6.2 Disadvantages

The following are the general disadvantages of compulsory licensing particularly for limited imports and exports as articulated by Baker.

- i. The exporter will be permitted to export small amounts only. Unless it has a large internal domestic market for the medicine, quantities for export might prove to be inadequate;
- ii. Foreign manufacture does not increase local pharmaceutical capacity and economic self-reliance in the importing country;
- iii. There is some risk that major pharmaceuticals might simply buy out low-profit competing generic manufacturers eliminating established sources of supply;

- iv. Issuing compulsory licenses is procedurally burdensome. Because of these procedural burdens and because of pressure from certain developed countries, developing countries seem unwilling thus far to issue compulsory licenses.¹⁷⁴
- v. Widespread use of compulsory licenses for imports might deter the development of a domestic pharmaceutical industry, but only if that industry is highly dependent on the domestic market.

3.7 General challenges

The challenges of using this mode of flexibility especially in developing countries have comprehensively been discussed by Ley.¹⁷⁵ The challenges have also been reproduced in this study for ease of reference. Ley categorizes the challenges associated with compulsory licensing into three distinct parts as follows: legal; technical; and research and development challenges.

To begin with the legal challenges, he observes that the amount of remuneration and payment of royalties to patent owners is problematic since there are no set criteria or guidelines under the TRIPS Agreement for addressing the same. The results are that the grant of a compulsory license may suffer many protracted legal battles making it grossly undesirable.

Secondly, another legal concern relates to the poor state of manufacturing capacity in most developing countries making them dependant on developed countries.

Thirdly, the lack of incorporation of TRIPS flexibilities to the domestic legislations of most developing countries hampers the utilization of compulsory

¹⁷⁴ For example, neither Kenya nor Malawi has done so, and so far only Mozambique, Zimbabwe and Malaysia have issued compulsory licenses or government use orders.

¹⁷⁵ B Ley 'Patent rights and access to medicines: Are patents really the only barrier for good health care in developing countries?' in M Sinjela (eds) *Human Rights and intellectual property rights: Tensions and convergences* (2007) 114-117.

licensing flexibility. Fortunately, both Kenya and South Africa have incorporated compulsory licensing in their relevant patent laws.

Fourthly, the fear of the impact on foreign direct investment (FDI) has made many countries unwilling or unable to utilize compulsory licensing as a legitimate flexibility. It is noteworthy that this fear is unfounded since no research has been able to link intellectual property rights protection to FDI.

Lastly, the erosion of requisite incentive to stimulate local research and development as a result of compulsory licensing makes most countries jittery about the actual implication of compulsory licensing on access to essential medicines.

The technical problems associated with compulsory licensing according to Ley are as follows. One, if royalties are exorbitant it would not be attractive to private investors' especially generic manufacturers due to the unattractive profits. The possibility of this situation inevitably makes government investment the only safe bet especially in times of national emergencies.

Another technical challenge is that most diseases in developing countries are unique requiring development of new drugs as opposed to exploitation of existing patents. Indeed, most diseases in developing countries are under-researched and therefore fewer medicines are developed for exploitation. In essence, therefore, Ley seems to suggest that the focus should be on drug development and not patent exploitation. However, the author of this paper is of the view that the two can go hand in hand. As such, it is possible to promote the development of new drugs and at the same time maximize access of existing drugs especially to eradicate the public health pandemics like that of HIV and AIDS, malaria and tuberculosis.

The last challenges relate broadly to concerns of research and development. Accordingly, there are arguments that suggest that the cost of medicines in most countries is mainly influenced by marketing which is three times the cost of research

and development. As such, marketing is a bigger factor on the affordability of medicine in developing countries than patents. According to this position, patents should not be targeted because their impact on prices of medicines is minimal. However, evidence in Brazil and Thailand suggest that generic competition has had positive impact on the affordability of medicines without taking into account the marketing options.¹⁷⁶

The second point is that research and development of new medicines follow market opportunities which make developing countries comparatively unattractive. In this regard, two systems should be developed in order to effectively take advantage of compulsory licensing flexibility in a manner that benefits developing countries. The first system should deal with medicines for globalized diseases which can easily and sufficiently be marketed for profits. The second system should be for unique diseases that do not have adequate market like those found in most developing countries. Having a single compulsory licensing system for both categories of medicines is therefore undesirable like in the case in Kenya and South Africa. It is implicit in the above position that perhaps compulsory licensing should be designed to address the challenges of drug development as well. It is therefore not enough to ignore the reality that patents play a big role in drug development. In this regard, in dealing with unique diseases drug development should be prioritized than their patent exploitation.

3.8 Specific challenges

3.8.1 Kenya¹⁷⁷

In Kenya, there are five challenges on the use of compulsory licensing. Nyaga discusses the main challenges including: inability to supply the government due to lack of WHO prequalification; stringent licensing preconditions; small market size;

¹⁷⁶ UNDP (n 160 above).

¹⁷⁷ This part builds on the challenges discussed by Nyaga in her thesis. See, Nyaga (n 37 above), 69-73

high cost of production; and insufficient manufacturing capacity. In this study, the author re-evaluates the above challenges and attempts to establish their current status. In this regard, the author relies on recent developments to determine whether the challenges still persist or have been addressed.

a) WHO Prequalification

Before any medicine can be supplied in the market, the manufacturer has to meet certain prequalification criteria set by the World Health Organisation (WHO). The WHO prequalification system is aimed at guaranteeing medicines quality, safety and efficacy.¹⁷⁸ The cost of doing bio-equivalence tests for each product is prohibitive to most manufacturing companies resulting into incapacity to produce such medicines to supply the government including under the Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund), the United States' President's Emergency Plan for AIDS Relief (PEPFAR) and other similar donor initiatives.¹⁷⁹ The only option therefore is for the government to purchase the medicines without the WHO prequalification but this option is largely unsustainable since a huge chunk of money for the purchasing of medicines is donor-funded.¹⁸⁰

What has changed since 2009 when Nyaga conducted her research? In November 2011, the WHO issued a WHO prequalification to Universal Corporation based in Kenya making it the second pharmaceutical company to receive such a qualification after Luzira Drug Factory in Uganda owned by Quality Chemicals in conjunction with CIPLA, an Indian company.¹⁸¹ The ARV Lamozido has been approved for use by the Global Fund, PEPFAR and MSF therefore making it available for use

¹⁷⁸ See <http://www.who.int/topics/prequalification/en/> (accessed 17 May 2013).

¹⁷⁹ Nyaga (n 37 above), 23

¹⁸⁰ As above, 72-73.

¹⁸¹ 'Kenya: ARVs to cost 30 percent less as WHO clears manufacturer' *The Star* 2 November 2011, allafrica.com/stories/201111021334.html.

domestically and also for exports.¹⁸² By acquiring WHO pre-qualification, Universal Corporation may further promote competition in the region by introducing generics and therefore ultimately benefiting the majority poor through price reductions. However, it should be noted that other pharmaceutical companies should apply for similar pre-qualifications to pave way for local production of ARVs and other essential medicines including those under compulsory licensing.

b) Stringent licensing preconditions

The reality in Kenya is that most companies have inadequate manufacturing technological capacity which translates in to their inability to comply with the Current Good Manufacturing Practices (cGMP) which are very stringent.¹⁸³ cGMP is currently being enforced by Pharmacy and Poisons Board in Kenya. As a result, the perception that has been created is that most generic companies consider complying with cGMP an expensive undertaking that can only be met by high investment companies. cGMP, in their view, would make medicines prices high and therefore unprofitable. Surprisingly, available research show that out of about '30 registered pharmaceutical companies in Kenya, only three meet the cGMP standards. About six others had potential but for the rest, there is no hope.'¹⁸⁴ Unfortunately, these conditions are important in order to guarantee the safety and quality of medicines. The only solution therefore would be to merge the capital of the small companies in order to meet the exorbitant cost of cGMP. cGMP may be classified as a technical barrier. Therefore, companies must device mechanisms that will enable them meet the set standards even as they angle themselves to produce generic medicines.

¹⁸² As above.

¹⁸³ Nyaga (n 34 above), 71.

¹⁸⁴ As above, 72.

c) Small market size

The issue of market size is of great concern since prices are also impacted by the economies of scale factor. Illustratively, most companies including Cosmos Limited in Kenya while negotiating for a (voluntary) license always insist on an expanded market to include the entire East African Community members in order to be able to make economic sense.¹⁸⁵ Essentially, a wider market connotes better economies of scale which also has a positive impact on the affordability of medicines. The same logic applies with regards to compulsory licenses. Such a license should ideally be able to serve the wider EAC as opposed to the Kenyan market alone. The coming into effect of the East African Common Market protocol on 1 July 2010 is perhaps a big opportunity which if properly harnessed may address this legitimate challenge by enabling access to a bigger market.

d) High cost of raw materials and production

Most generic companies in Kenya do not pursue compulsory licensing because even if they acquire one, the cost of raw materials including active pharmaceutical ingredients and excipients are prohibitive.¹⁸⁶ As expected, most companies also rely on imports from Brazil, India and China for their generic manufacturing. This means that the raw materials and the cost of production is generally out of reach for these companies. This problem can only be solved if the government promoted the prospecting of genetic resources for medicinal purposes. In addition, the prices of raw materials should be regulated internationally to allow for local production in developing countries by for example allowing for differential pricing.

¹⁸⁵ Nyaga (n 37 above), 70.

¹⁸⁶ Nyaga (n 37 above), 70.

e) Insufficient manufacturing capacity

Insufficient manufacturing capacity is perhaps the most significant factor constraining licensing activities in Kenya. According to Nyaga's findings, for example, only three pharmaceutical companies had the capacity to manufacture ARVs in Kenya despite the fact that Roche was willing to grant a voluntary license.¹⁸⁷ Comparatively, Kenya may boast of 'well developed domestic pharmaceutical manufacturing industries'.¹⁸⁸ However, most of the generic manufacturers in the country do not have the necessary technology to engage in medicines production for local and external consumption. In order to address this problem, Vision 2030 seeks to focus on industrialization which would greatly remedy the current situation.

3.8.2 South Africa

While South Africa shares some of the above challenges, this part focuses on two major challenges: lack of political will; and legal challenges from multinational corporations and foreign governments.

a) Political will

According to Sacco, the genesis of this particular problem may be traced back to the time when the former President Thabo Mbeki denied the existence of HIV and AIDS as a major disease in South Africa. Another indicator can also be discerned from the TAC case when the government had to be literally sued in order to provide *Nevirapine* for pregnant women despite the fact that the drug was freely available. In this respect, it is fair to conclude that the South African government lacks sufficient political will and has to be pushed by external forces in order to provide access to essential medicines for its people.¹⁸⁹ This problem is not only unique in South Africa but also in Kenya

¹⁸⁷ Nyaga (n 34 above), 69.

¹⁸⁸ Opati (n 19 above), 14.

¹⁸⁹ Sacco (n 45 above), 42.

going by the recent dragging of feet by the government to implement the High Court case of *Patricia Asero*. Perhaps, it is high time the lack of political will was addressed head-on by for example ensuring that they are part of political parties' manifestos since it is a major challenge on the utilization of TRIPS flexibilities in general and compulsory licenses in particular.

b) Legal sanctions

This particular challenge emerged sometime in 1997 after the government amended its Medicines and Related Substances Act to allow for greater government powers for issuing compulsory licenses. Immediately after that amendment was passed, the South African government suffered a series of legal sanctions. First, it found itself in the United States 301 watch list.¹⁹⁰ Secondly, about 39 pharmaceutical companies sued the South African government and only withdrew the case in 2001 after concerted domestic and international pressure.¹⁹¹ Currently, the use of legal sanctions has reduced due to stronger civil society movements. It is therefore incumbent that these networks of civil society actors be sustained in order to reduce the legal backlash on subsequent government that is acting in the best interest of its people.

3.9 Conclusion

In conclusion, from the above analysis, the author has established two major points. First, both Kenya and South Africa have elaborate patent laws that also provides for the utilization of compulsory licensing under certain conditions. Two, the existence of the provisions on compulsory licensing is not a guarantee that they will be used. In

¹⁹⁰ This is a list prepared annually by the Office of the United States Trade Representatives (USTR) under section 301 of the Trade Act of 1974. The US lists countries which do not provide adequate and effective protection of intellectual property rights or fair and equitable market access to US persons relying on intellectual property rights.

¹⁹¹ Some of the organizations that protested the move include the Medicines sans Frontiers (MSF) which supplies ARVs to millions of people living with HIV and AIDS.

this regard, the study has discussed some of the challenges that affect the utilization of compulsory licensing with a view to encouraging solutions beyond the law.

CHAPTER FOUR

PARALLEL IMPORTATION IN KENYA AND SOUTH AFRICA

4.1 Introduction

This chapter discusses the legal framework for parallel importation in Kenya and South Africa. In addition, it also discusses some challenges associated with the use of parallel importation as allowable flexibility under the TRIPS Agreement in both countries.

4.2 Parallel importation under the TRIPS Agreement

The provisions relating to parallel importation are specifically contained under article 6 of the TRIPS Agreement. Article 6 of the TRIPS Agreement provides for the exhaustion of intellectual property rights (IPRs) as follows:

[f]or the purpose of dispute settlement under this Agreement...nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.

In essence therefore the TRIPS Agreement is essentially silent on the question of parallel importation. It is as such upon the respective WTO members to adopt the most favourable exhaustion principle that responds to their circumstances and needs. Exhaustion principle is important since it determines when an IPRs holder ceases to exercise control over use and disposition of goods therefore allowing free transfer of goods within and across borders as is the case with parallel importation.¹⁹² However,

¹⁹² See <http://michaeldizon.wordpress.com/2009/01/20/doctrine-of-exhaustion-of-intellectual-property-rights/>, (accessed 17 May 2013).

the exhaustion principle adopted by any country is subject to the other TRIPS Agreement provisions on national treatment and most-favoured nation principles.¹⁹³

By definition, parallel importation means:

[P]roducts that have been made and marketed by the patent owner in one country, which have subsequently been imported by a third party into another country, without the patent owner's consent.¹⁹⁴

Mac Gillivray also observes that parallel importation is not about the physical attributes of a product but rather the distribution process for products in the market without direct authorization of the owner of an intellectual property right.¹⁹⁵ In this regard therefore it can be described as a

parallel trade, sometimes referred to as the 'grey market', consists of trade in genuine trademark (or other intellectual property) protected goods that take place without the consent of the trademark owner. Official channel goods reach the final customer through the intermediaries and distribution networks that are designed by the trademark owner, from some layer of the authorised channel. This can either be directly from the manufacturer, from an intermediary (wholesaler or middleman) or from authorised retailers.¹⁹⁶

In terms of the rationale, Baker contends that parallel importation promotes 'pricing equity by allowing importation of patented product marketed more cheaply in another country'.¹⁹⁷

¹⁹³ Article 6 of the TRIPS Agreement, 1995.

¹⁹⁴ 'Parallel importation,' <http://www.drugterm.com/country/world.htm> (accessed on 22/10/2011 at 6:19pm)

¹⁹⁵ RA MacGillivray *Parallel importation* (2010) 7.

¹⁹⁶ As above.

¹⁹⁷ Baker (n 8 above), 22.

4.3 Legal framework for parallel importation in Kenya

Kenya like many other countries have taken advantage of article 6 to adopt the most favourable system of international exhaustion to effectively allow for the widest possible latitude for taking advantage of parallel importation flexibility under the TRIPS Agreement. In effect, this means that Kenya can import any product including essential medicines as long as they have been released legally in any market. In this regard, section 58(2) of the Kenyan Industrial Property Act (IPA) provides that

the 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.

There are those who hold the view that the specific words, ‘by the patent owner, or with his consent’ are implied in the above provision.¹⁹⁸ However, the failure to expressly include those words means that medicines produced by means of an involuntary acquisition may be supplied in Kenya. This is particularly so because the previously proposed Intellectual Property Bill of 2001 made it mandatory for the patentee to grant authorization before one could utilize parallel importation as a flexibility in Kenya. Therefore, a look at the then provision had the following additional words at the end of section 58(2) of the current IPA, ‘by the owner of the patent or with his express consent’. These words were deleted subsequently. Musungu has argued that if the provision was enacted as it was previously, this ‘would have restricted parallel imports with the requirement of “express consent” of the patent holder before a patented product is imported.’¹⁹⁹

Undoubtedly, the above provision has enabled Kenya to be a major beneficiary of parallel importation. In fact, the bulk of medicines used in Kenya currently are generics imported from foreign countries under the enabling parallel importation

¹⁹⁸ Adams & Adams *Practical guide to intellectual property in Africa* (2012) 232.

¹⁹⁹ Musungu & Oh (n 25 above), 51.

framework. The benefits have been tremendous. Kenya is touted as a best practice in this regard. In 2002, for example, the successful use of parallel importation helped reduce medicines prices by up to 40%-65% because of generic competition.²⁰⁰ The market share commanded by pharmaceutical parallel imports was between 30% and 35% thus representing a significant market portion.²⁰¹

4.4 Parallel importation in South Africa

Comparatively, the provisions of parallel importation in South Africa were included much earlier than in Kenya. Section 37(2) of the South African Patent Act provides for parallel importation of patented products on condition that the medicines are being marketed in South Africa or with the consent of a patent owner. Therefore, while South Africa allows for an international exhaustion principle it limits the scope by imposing the requirements that the medicines should be at the time of importation being marketed in South Africa or that the patentee must consent. By and large therefore, the South African provisions are not as broad as the Kenyan legislation. In addition, South Africa has also enacted the Medicines and Related Substances Control Amendment Act²⁰². This Act was further amended in 1997 to further improve the provisions relating to parallel importation in the country. Section 15(c), in particular, provides that

[t]he Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

a) Notwithstanding anything to the contrary contained in the Patent Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which

²⁰⁰ Lewis-Lettington & Munyi (n 36 above), 17.

²⁰¹ Nyaga (n 37 above), 48.

²⁰² Medicines and Related Substances Control Amendment Act, Act No 101 of 1965.

has been put onto the market by the owner of the medicine, or with his or her consent;

- b) Prescribe the condition to which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by another person other than the person who is a holder of a registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- c) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

Under the above amendments, the Minister has been given additional powers to circumvent the bottleneck identified above. Paragraph (a) above allows for the Minister to Act with regards to access to medicines but making sure that at the same time he or she does not to contravene the rights of the medicines already being marketed in the country legally. This provision allows for parallel importation but at the same time protecting commercial interests in the country. Paragraph (b) allows for dealing with trademark challenges by way of a regulation. Kenya is yet to address the trademark challenges and has in the past suffered setbacks in parallel importation. This was the subject matter in a 2007 case of *Lords Healthcare Limited v Salama Pharmaceutical Limited*²⁰³. In this case, the plaintiff sought an injunction to bar the defendant from importing the product 'Budecort-200' inhaler. The plaintiff relied on the trademark law which they argued was being infringed by the defendant. The defendant in his defence relied on, *inter alia*, parallel importation. While dismissing the case, the Judge made no reference to parallel importation and instead noted the following:

²⁰³ [2008] eKLR.

the evidence which has been availed before me is not sufficient for this court to come to the conclusion that *prima facie* the plaintiff has any exclusive rights to the use of the word 'Budecort', the alleged infringement by the defendant being anchored on the existence of the plaintiff's exclusive rights, and the existence of the exclusive rights being doubtful, no *prima facie* case has been established.

It is clear from the above decision that parallel imports may be hindered by way of trademark law. This situation was addressed in South Africa however Kenya is yet to address the same.

4.5 General Challenges²⁰⁴

Apart from the specific challenges discussed after this section, the following are general challenges that have made the utilization of parallel importation difficult in most developing countries as summarized by Leys.

The first problem relates to the issue of quality. It is a known fact that parallel importation in general allows a country to take advantage of price differentials in different markets by putting in place appropriate system of IP rights exhaustion. The difference in price may be as a result of lower transaction cost due to good infrastructure. The most prominent concern however is that marketing of similar products under different brand names does not guarantee that the quality is the same.

The second concern relates to the effect of parallel importation on differential pricing. According to Ley, developing countries account for only 20 per cent of the pharmaceutical market. However, they may be forced to buy medicines under a uniform pricing system at the same price as a consumer in developed nations. In this regard, a market-specific differential pricing based on per capita income should be encouraged as opposed to parallel importation. He argues that, theoretically, parallel

²⁰⁴ Ley (n 166 above) 119-121.

importation may undermine public health by allowing pharmaceutical companies to set ‘one uniform higher price’ based on a consumer in developed countries.

Third, there is evidence that due to higher bargaining power, some pharmaceutical companies sometimes charge even higher prices in developing countries especially in those countries where medicines prices are negotiated through state-run or controlled insurance companies. Therefore, developing countries will end up paying higher medicines prices due to their weak negotiating power even under parallel importation system.

Fourth, some countries like South Africa applying the ‘External Reference’ system means that pharmaceutical companies will, in their best interest, maintain high prices even in LDCs in order not to upset its international prices. Most developing countries including South Africa apply external reference pricing to both on-patent and off-patent medicines.²⁰⁵ The immediate impact with such a system is to impose a single price worldwide with countries benefiting from lower prices unable to do so in the future.²⁰⁶ Ultimately the use of parallel importation may not have any significant benefits including affordability of medicines. However, in principle, external reference pricing should be assessed based on the ‘objectives of universal medicine availability, affordability, equitable access and rational use of medicines.’²⁰⁷

Lastly, while most developed countries have or are in the process of zero-rating import duties on medicines, most developing duties still retain high import duties and tariffs. The effect on this is that even if medicines are imported cheaply this would not translate into actual benefits for the locals.²⁰⁸ In Pakistan, successful consumer

²⁰⁵ WHO/HAI project on medicines prices and availability ‘External reference pricing’ (Review series on pharmaceutical pricing policies and interventions working paper 1, 2011) 19, <http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf> (accessed 20 May 2013).

²⁰⁶ As above.

²⁰⁷ As above, 20.

²⁰⁸ WHO/HAI project on medicines prices and availability ‘Sales taxes on medicines’ (Review series on pharmaceutical pricing policies and interventions working paper 5, 2011) 17,

advocacy resulted into a 15% sales tax removal.²⁰⁹ However, the experience in Peru showed that removal of taxes does not automatically translate into benefits for patients unless supporting regulation including on retail mark-ups is implemented.²¹⁰

4.6 Specific challenges

4.6.1 Kenya

There exist at least three main challenges facing Kenya's parallel importation: the potential existence of TRIPS Agreement violation; the implied license theory; ambiguity in laws; and the anti-counterfeiting legislations.

a) Potential violation of the TRIPS Agreement

Kenya has certain international obligations under the TRIPS Agreement. Baker observes that Kenya's provision on parallel importation may be in violation of article 28(1) of the TRIPS Agreement. He explains his point by observing that:

One country, Kenya, has adopted a very robust parallel importation rule that not only permits parallel importation of patented medicines previously sold abroad, but also permits parallel importation of any generic legitimately marketed abroad, including those produced where there is no conflicting patent. Unfortunately, this last option might be interpreted to conflict with the Kenyan patent bar and might be interpreted to violate article 28(1) of the TRIPS Agreement as well.²¹¹

Article 28(1) of the TRIPS Agreement provide for exclusive rights of patent holders: 'making, using offering for sale, selling, or importing.' These rights may however be violated by a compulsory licensee and importer.²¹² This is because parallel importation of generic medicines produced in third countries under compulsory licensing deviates

<http://www.haiweb.org/medicineprices/05062011/Taxes%20final%20May2011.pdf> (accessed 20 May 2013).

²⁰⁹ As above, 18-19.

²¹⁰ As above, 19.

²¹¹ Baker (n 8 above), 22.

²¹² Email interview with B Baker, 20 May 2013.

from the traditional understanding of the exhaustion doctrine.²¹³ Carlos however argues to the contrary and observes that compulsory licensees can make sales under parallel importation in full compliance with the TRIPS Agreement.²¹⁴ Notwithstanding, therefore, it is possible that Kenya's provision on parallel importation may be challenged at the WTO with regard to its provisions on parallel importation depending on its source. However, it is important to note that no such challenge has ever been preferred in the past.

b) Implied license theory

Implied license theory simply means that the exhaustion of IPRs ultimately rests on the discretion of the title-holder.²¹⁵ This theory was illustrated in a Kenyan case of *Beecham Group v. International Products Ltd*²¹⁶ where importation of certain products by a distributor in Kenya was stopped by the High Court since the supplier, Bristol-Meyers, had no authority from the patent holder to sell goods in infringement of the Kenyan patent. The distributor could therefore not acquire better rights than those of Bristol-Meyers.

c) ambiguity in the law

There exists ambiguity in relation to the law relating to parallel importation in Kenya. This is because crucial laws such as the Trademarks Act²¹⁷ and Pharmacy and Poisons Act²¹⁸ do not provide for parallel importation despite the fact that they

²¹³ East African Community 'Regional intellectual property policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation' (2013) 8. Available with the author on file.

²¹⁴ As above.

²¹⁵ C Correa 'The TRIPS Agreement and developing countries' (undated) 450, <http://web.cenet.org.cn/upfile/109807.pdf> (accessed 20 May 2013).

²¹⁶ As quoted above. No citation available.

²¹⁷ Trademark Act, Cap 506 Laws of Kenya.

²¹⁸ Pharmacy and Poisons Act, Cap 44 Laws of Kenya.

regulate the pharmaceutical products industry in Kenya.²¹⁹ The Trademarks Act in particular has been used in the past to frustrate parallel importation as noted above. This was a subject matter of a recent court case *Lords Healthcare Limited v Salama Pharmaceuticals Limited*.²²⁰ This case concerned the supplying of a parallel imported inhaler for asthma patients in Kenya under the trademark Budercort-200. Lord sued the defendant for patent infringement while the defendant sought to rely on parallel importation provisions as his defence. The failure to *gazette* and operationalize the 2006 draft parallel importation guidelines is a major factor contributing to this confusion.²²¹

d) Anti-counterfeiting legislation

In 2009, Kenya enacted the Anti-Counterfeit Act²²² which conflated generic medicines with counterfeits. In this regard, the legislation, if implemented, would have affected the importation of generic medicines in Kenya including by the exploitation of parallel importation provisions in the law. Luckily, the legislation, as enacted, has been declared unconstitutional by the High Court on 20 April 2012 following a successful petition by three persons living positively with HIV and AIDS.²²³ However, it is yet to be seen whether the government will amend the law to exempt generic medicines from its application.²²⁴

4.6.2 South Africa

In South Africa, the main challenge seems to be their constitutional democracy expectations as explained below.

²¹⁹ Nyaga (n 37 above), 58.

²²⁰ High Court of Kenya, Nairobi (Milimani Commercial Courts) Civil Suit No. 334 of 2007.

²²¹ As above.

²²² Anti-Counterfeit Act, Act No 13 of 2008.

²²³ See *P.A.O & 2 Others v AG & Another (2012) eKLR*.

²²⁴ For a detailed analysis on this issue, see, Ogendi (n 118 above).

a) Challenges of constitutional democracy

According to Vawda, the 1997 and 2008 amendments of the Medicines and Related Substances Act introduced major changes towards making medicines more affordable in South Africa. The amendments achieved their objectives by: permitting parallel importation of 'cheaper branded medicines from countries where they are sold more cheaply; allowing generic substitution of off-patent medicines with cheaper high quality generics; and introducing pricing committee'.²²⁵ However, the main challenge was that the amendments failed to

grasp the nettle of aligning the legislation to the norms of a modern constitutional democracy. It has failed to introduce greater transparency and accountability in the regulatory process, has failed to safeguard the autonomy of the regulatory authority from interference by the executive, has not promoted measures in the medicines' registration and delivery process which promote access, and has not removed those which impede it.

It seems therefore from Vawda's position that South Africa's impressive parallel importation provisions are inhibited by lack of transparency in the system and political interference. Vawda concludes that as a result of these constitutional democracy challenges the amendments failed to achieve a regulatory environment that can facilitate medicine and health care access in an 'open, transparent and accountable manner'.²²⁶

4.7 Conclusion

In conclusion, comparatively, parallel importation appears to work better for both countries and especially for Kenya. Unlike its compulsory licensing counterpart,

²²⁵ YA Vawda 'Ensuring access through the Medicines and Related Substances Amendment Act 72 of 2008' (2009) *South African Law Journal* 667-668.

²²⁶ As above, 677.

parallel importation is not heavily restricted by certain pre-conditions making it easy to utilize at the national level for the benefit of access to medicines.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

This Chapter discusses the conclusions and recommendations of this study. It begins with recommendations/conclusions for Kenya and then South Africa.

5.1 Conclusions

The conclusions of this study are briefly stated as follows.

5.1.1 Kenya

Firstly, while Kenya has provided for the highest protection of the right to health nationally it is yet to enact the national health legislation in order to effectively implement the right to health. The lack of the Health Law has impeded the development of a legal framework for the full realization of the right to health in Kenya including access to essential medicines. Notwithstanding, the HIV and AIDS Prevention and Control Act is the only legislation that has expressly implemented the right to health care for persons living with HIV and AIDS.

Secondly, Kenya has ratified most international human rights instruments enshrining the right to health including the ICESCR. However, it is yet to ratify the Optional Protocol which would amongst other things allow for individual communications. This has therefore severely impeded the protection of ESCRs internationally including the right to health.

Thirdly, the *Patricia Asero* case confirmed that the right to health enshrined in the Constitution and other legislations also encompasses access to essential medicines. In this case, the anti-counterfeit legislation that sought to restrain access was declared unconstitutional.

Fourthly, under General Comment No 17 of the CESCRs, Kenya has the obligation to ensure that medicines' prices are not exorbitant. It is therefore imperative that Kenya secures access to the affordable generic medicines for its patients since they are cheaper than branded medicines.

Fifthly, Kenya has elaborate provisions relating to compulsory licensing under its Industrial Property Act. Compulsory licenses are granted on two grounds in Kenya which is 'supply on reasonable terms' and 'interdependent patents'. However, despite other challenges stated under Chapter 3, the requirement that compulsory licenses should be predominantly for domestic supply is most problematic since it fails to incorporate new developments that allow for limited importation and exportations pursuant to the Paragraph 6 Decision.

Sixthly, Kenya's provisions on parallel importation are ambiguous especially with regard to the Trademarks Act and the Pharmacy and Poisons Board. This is further exacerbated by lack of guidelines for parallel importation in Kenya.

5.1.2 South Africa

Firstly, South Africa has the most elaborate constitutional and legislative provisions on the right to health and access to essential medicines nationally. The Constitution entrenches the right to health under its section. The National Health Act is also the principal legislation for the implementation of the right to health.

Secondly, regionally, South Africa has stronger commitment as illustrated by its membership to most core instruments. This is a good development since South Africa has been at the forefront championing the agenda of African Union (AU) in the continent by providing both technical and financial support.

Thirdly, South Africa is yet to implement the ICESCR contrary to many peoples' expectations. However, this has not impeded its efforts in terms of the protection of ESCRs nationally since the courts are allowed to refer to international jurisprudence while deciding cases. However, it has impeded accountability and input at the international level.

Fourthly, the *TAC* case confirmed the obligations of the government with regards to the right to health to make accessible essential medicines including Nevirapine in particular for the vulnerable poor South African mothers dependent on the public health system. It reiterated that the government's programme must be reasonable and comprehensive.

Fifthly, South Africa is not bound by General Comment No 17 to protect medicines prices. However, its Constitution and the court's jurisprudence secures the right to health including affordable health care and essential medicines.

Sixthly, South Africa has tremendous provisions for compulsory licensing. However, out of all the challenges, the court process is undesirable since, according to Baker, it is more costly, delayed and burdensome compared to the Tribunal process in Kenya.

Lastly, on parallel importation, South Africa introduced far reaching reforms in its laws. However, Vawda notes that the reforms are yet to satisfy the standard required of a constitutional democracy since it has, *inter alia*, failed to promote measures in the medicines registration and delivery process which promotes access.

5.1.3 Evaluative conclusions

Firstly, the utilization of TRIPS Agreement flexibilities is largely dependent on the technicalities in form of pre-conditions imposed before it. Therefore, both countries

find it easier to utilize parallel importation due to lesser restrictions than compulsory licensing.

Secondly, the laws in both countries provide for TRIPS Agreement flexibilities of parallel importation and compulsory licensing. However, challenges outside the law including trade sanctions and lack of manufacturing capacity are the biggest obstacles for the utilization of compulsory licensing in South Africa and Kenya respectively.

Lastly, the existence of the right to health in the constitutions of both countries has made it easier for actors in both countries to enforce the right to health and advocate for access to medicines.

5.2 Recommendations

The recommendations of this study are as follows.

5.2.1 Kenya

1. Kenya should enact the Health Law Bill into law in order to realise the benefits of right to health including access to essential medicines for everyone as enshrined in the new Constitution article 43(1)(a). In particular, the legislation should empower the Cabinet Secretary for health to be able to apply for compulsory licensing and issue guidelines on parallel importation in order to promote access to essential medicines.
2. Kenya should ratify the Optional Protocol to the ICESCR in order to increase the protection of ESCRs including the right to health at the international level by facilitating individual communications.
3. Kenya should implement the *Patricia Asero* decision since it secures the right to health and specifically access to essential generic medicines in Kenya for persons living with HIV and AIDS. Specifically, the *Patricia Asero* decision would

be adequately implemented if the Kenyan anti-counterfeiting legislation would remove, from its application, patents. The implication of this move would be to remove generic medicines from the ambit of the war against counterfeit products.

4. Kenya should put in place a National Drug Policy that guarantees access to generic drugs since it is more affordable than branded medicines and therefore compliant with General Comment No 17.
5. Kenya should address its challenges relating to compulsory licensing. In particular it should amend its law in order to allow for limited imports and exports in line with the developments at the international level particularly in line with Paragraph 6 Decision of the TRIPS General Council of 30 August 2003.
6. Similarly, the challenges discussed in this study on parallel importation should be addressed. Of particular importance is the ambiguity in the Trademarks and Pharmacy and Poisons Act. Both laws are critical and should provide for provisions supporting the unlimited utilization of parallel importation. In addition, Kenya should put in place appropriate guidelines to facilitate parallel importation in the country.

5.2.2 South Africa

7. South Africa should ratify the ICESCR in order to benefit from international protection of ESCRs including the right to health. In addition, it should also ratify the Optional Protocol in order to allow for individual communications.
8. South Africa should continue its leadership in the region by providing more technical and financial support to AU in order to make it more robust in its

activities including the protection of right to health and access to essential medicines.

9. South Africa should maintain the supply of the *Nevirapine* medicine in order to prevent mother-to-child-transmissions (MTCT) in line with the *TAC* decision.
10. South Africa should continue pursuing the use of generic medicines as a cheaper alternative to branded medicines.
11. On compulsory licensing, the challenges as discussed under Chapter 3 should be addressed and in particular the law in South Africa should be reviewed to allow for a Tribunal process as opposed to a court process for compulsory licensing.
12. Similarly, parallel importation challenges as discussed under Chapter 4 should be addressed. In particular, South Africa should address the constitutional democracy challenges in order to promote more accountability and transparency in the system.

BIBLIOGRAPHY

Books

1. Adams & Adams (2012) *Practical guide to intellectual property in Africa* Pretoria University Law Press (PULP), Pretoria
2. Dugard, J (2011) *International law: A South African perspective* Juta Ltd, Western Cape
3. MacGillivray, RA (2010) *Parallel importation* The Cartwright Group Ltd, Ontario
4. Marett, P (1996) *Marett: Intellectual property law* Sweets and Maxwell, London
5. Mueller, JM (2003) *An introduction to patent law* Aspen Publishers, Missouri
6. Musungu, SF and Oh, C (2006) *The use of flexibilities in the TRIPS by developing countries: Can they promote access to medicines?* South Centre/ World Health Organisation, Geneva
7. Singer, JW (1993) *Property Law: Rules, policies and practices* Little, Brown and Company (Canada) Limited, Ontario

Chapters in books

1. Biegon, J 'The inclusion of socio-economic rights in the 2010 Constitution: Conceptual and practical issues' in Biegon, J and Musila, GM *Judicial enforcement of socio-economic rights under the new Constitution: Challenges and Opportunities for Kenya* (2011) The Kenyan Section of the International Commission of Jurists
2. Biegon, J and Musila, G 'Socio-economic rights as one promise of a new constitutional era' in Biegon, J and Musila, G (eds) (2011) *Judicial enforcement of socio-economic rights under the new constitution: Challenges and opportunities for Kenya* The Kenyan Section of the International Commission of Jurists
3. Cotropia, CA 'Compulsory licensing under TRIPS and the Supreme Court of the United States Decision in *eBay v MercExchange*' in Takenaka, T (2008) *Patent law and theory: A handbook of contemporary research* Edward Elgar Publishing Inc.
4. Chandra, R 'The role of national laws in reconciling constitutional rights to health with TRIPS obligations: an examination of the *Glivec* patent case in India' in Pogge, T, Rimmer, M and Rubenstein, K (2010) *Incentives for global public health: Patent law and access to essential medicines* Cambridge University Press
5. Ley, B 'Patent rights and access to medicines: Are patents really the only barrier for good health care in developing countries?' in Sinjela, M (eds) (2007) *Human Rights and intellectual property rights: Tensions and convergences* Martinus Nijhoff Publishers
6. Liebenberg, S 'Adjudicating socio-economic rights under a transformative Constitution' in Langford, M (2008) *Social rights jurisprudence: Emerging trends in international and comparative law* Cambridge University Press
7. Mbazira C 'The judicial enforcement of the rights to the highest attainable standard of health under the Constitution of Kenya' in Biegon, J and Musila, GM *Judicial enforcement of socio-economic rights under the new Constitution: Challenges and Opportunities for Kenya* (2011) The Kenyan Section of the International Commission of Jurists
8. Opati, LM 'Intellectual property rights in health-Impact on access to drugs' in Wekesa, M and Sihanya, B (eds) (2009) *Intellectual property rights in Kenya* Konrad Adenauer Stiftung, SportsLink and Authors

9. Wekesa, M 'An overview of the intellectual property rights (IPRs) regime in Kenya in M Wekesa & B Sihanya (eds) (2009) *Intellectual property rights in Kenya* Konrad Adenauer Stiftung, SportsLink and Authors
10. Wong, T 'Intellectual property through the lens of human development' in Wong, T & Dutfield, G (eds) (2011) *Intellectual property and human development: Current trends and future scenarios* Cambridge University Press

Journal articles

1. Christiansen, EC 'Adjudicating non-justiciable rights: Socio-economic rights and the South African Constitutional Court' (2007) 38 *Col. Hum. Rts. L. Rev.* 321
2. Damstedt, BG 'Limiting Locke: A natural law justification for the fair use doctrine' (2003) 112 *The Yale Law Journal* 1179.
3. Dolmo, BC 'Examining global access to essential pharmaceuticals in the face of patent protection rights: The South African Example (2001) 137 *7 Buff. Hum. Rts. L. Rev.* 137.
4. Ford, SM 'Compulsory licensing provisions under the TRIPs Agreement: Balancing pills and patents' (2000) 15(4) *American International Law Review* 941.
5. Gathii, JT 'Rights, patents, markets and the global AIDS pandemic' (2002) 14 *Florida Journal of International Law* 261.
6. Gathii, JT 'The legal status of the Doha Declaration on TRIPs and Public Health under the Vienna Convention on the Law of Treaties' (2002) 15(2) *Havard Journal of Law & Technology* 295.
7. Gurry F 'The evolution of technology and markets and the management of intellectual property rights' (1996-1997) 72 *Chicago-Kent Law Review* 371.
8. He, J 'Developing countries pursuit of an intellectual property law balance under the WTO TRIPs Agreement' (2011) 10 *Chinese Journal of International Law* 830.
9. Helfer, LR 'Human rights and intellectual property: conflict or co-existence?' (2003) 5(1) *Minesota intellectual property review* 47.
10. Helfer, LR 'Towards a human rights framework for intellectual property' (2007) 40 *U.C. Davis Law Review* 973.
11. Hunt P and Khosla R 'The human right to medicines' (2008) 8 *Sur – International Journal on Human Rights* 99.
12. Rozek, R and Rainey, R 'Broad-based compulsory licensing of pharmaceutical technologies: Unsound public policy' (2001) 4 *Journal of World Intellectual Property* 469.
13. Spitzlinger, R 'On the idea of owning ideas: Applying Locke's labour appropriation theory to intellectual goods' (2011) 5 *Masaryk University Journal of Law and Technology* 282.
14. Yamin, A 'Not just a tragedy: Access to medications as a right under international law' (2006) 21 *B.U. Int'l L.J.* 370.
15. Yu, PK 'Reconceptualizing intellectual property interests in a human rights framework' (2007) 40 *U.C. Davis Law review* 1039
16. Vawda, YA 'Ensuring access through the Medicines and Related Substances Amendment Act 72 of 2008' (2009) *South African Law Journal* 667-668.
17. Widerquist, K 'Lockean theories of property: Justifications for unilateral appropriation' (2010) 2(1) *Public Reason* 3-22.

Papers and reports

1. Baker, B 'Processes and issues for improving access to medicines: Willingness and ability to utilise TRIPS flexibilities in non-producing countries' (2004) 19, http://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf (accessed on 2 July 2012).
2. COMESA *Sector strategy for access to medicines in COMESA* (2011).
3. Correa, MC 'Implication of the Doha Declaration on the TRIPS Agreement and Public Health' (2002) 18, <http://www.who.int/medicinedocs/en/d/Js2301e/> (accessed 2 July 2012).
4. Correa, MC 'The TRIPS Agreement and developing countries' (undated) 450, <http://web.cenet.org.cn/upfile/109807.pdf> (accessed 20 May 2013).
5. Dimitrijevic, V 'Customary law as an instrument for the protection of human rights' (ISPI working paper 7, 2006) 8, http://www.ispionline.it/it/documents/wp_7_2006.pdf (accessed 16 May 2013).
6. Erbenznik, K 'Does Lockean proviso commit us to global redistribution' (undated) 6, http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=19&ved=0CHEQFjAIOAo&url=http%3A%2F%2Fconfaculty.gmu.edu%2Fpboettke%2Fworkshop%2Farchives%2Ffall06%2FPaper%2520Version%2520-%2520Lockean%2520Proviso.doc&ei=3OvnUbndE-To4QTrn4HwBg&usg=AFQjCNGSlgyZBUHake-2xrmuS_u90tO7w&sig2=ejQi8rqMCMbBBhXK97qj5g&bvm=bv.49478099.d.bGE (accessed 18 July 2013).
7. Guide for the application and granting of compulsory licenses and authorization of government use of pharmaceutical patents, WHO, 2009. WHO/PH1/2009-1.
8. Kenya National Commission on Human Rights (KNCHR) & Kenya UPR Stakeholders Coalition 'Universal Periodic Review (UPR) annual progress report 22nd September 2010-21st September 2011: An assessment by stakeholders of government's performance in implementation of UPR recommendations' (September 2011).
9. Lewis-Lettington, R & Munyi, P 'Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study' (2004) 7, http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf (accessed on 3 July 2012).
10. Musungu, SF & Oh, C 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' (2005), 'http://digitalcollections.sit.edu/cgi/viewcontent.cgi?article=1856&context=isp_collection (accessed on 2 July 2012).
11. Report of the Commission on Intellectual Property Rights 'Integrating Intellectual Property Rights and Development Policy' (2002) 39, http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf (accessed 2 July 2012).
12. 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (2009) 17. UN Doc No.: A/HRC/11/12, <http://www2.ohchr.org/english/issues/health/right/> (accessed 2 July 2012).
13. Sihanya, B 'Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya' (2011), http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm (Accessed 3 August 2011).

14. Southern and Eastern Africa Trade, Information and Negotiation Institute (SEATINI) in the Regional Network for Equity in Health in East and Southern Africa (EQUINET) 'Implementation of the TRIPS Flexibilities by East and Southern African Countries: Status of Patent Law Reforms by 2010' (2010) 15, <http://www.equinetafrica.org/bibl/docs/Diss80TRIPSupdate2010.pdf> (accessed 3 July 2012).
15. WHO/HAI project on medicines prices and availability 'External reference pricing' (Review series on pharmaceutical pricing policies and interventions working paper 1, 2011) 19, <http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf> (accessed 20 May 2013).
16. WHO/HAI project on medicines prices and availability 'Sales taxes on medicines' (Review series on pharmaceutical pricing policies and interventions working paper 5, 2011) 17, <http://www.haiweb.org/medicineprices/05062011/Taxes%20final%20May2011.pdf> (accessed 20 May 2013).

Theses & Dissertations

1. Nyaga, JIM 'Implementing parallel importation and licensing mechanisms to increase access to medicines in Kenya' unpublished LLM thesis Stanford Program in International Legal Studies, Stanford University, (2009).
2. Ogendi, PO 'Safeguarding access to essential generic medicines in Kenya's Anti-Counterfeit Act: Implementing *P.A.O & 2 Others v AG* decision' unpublished LLM (Human Rights and Democratisation in Africa) thesis, University of Lagos (2012).
3. Sacco, SF 'A comparative study of the implementation in Zimbabwe and South Africa of the international law rules that allow compulsory licensing and parallel importation for HIV/AIDS drugs' unpublished LLM (Human Rights and Democratisation in Africa) thesis, American University in Cairo, (2004).

Hard and soft laws

International

1. Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The legal texts: The results of the Uruguay round of multilateral trade negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
2. Convention on the Elimination of All Forms of Discrimination Against Women, 18 December 1979, United Nations, Treaty Series, vol. 1249, p. 13, available at: <http://www.unhcr.org/refworld/docid/3ae6b3970.html> (accessed 6 July 2012).
3. Convention on the Rights of the Child, 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3, available at: <http://www.unhcr.org/refworld/docid/3ae6b38f0.html> (accessed 6 July 2012).
4. Declaration on the TRIPS Agreement and Public Health, (Ministerial Conference Fourth Session Doha, 9-14 November 2001, Decision No: WT/MIN(01)/DEC/W/2, 14 November 2001).
5. East African Community 'Regional intellectual property policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation' (2013) 8. Available with the author on file.

6. General Comment No 3 (1990), UN DOC. E/1991/23, <http://www.unhcr.org/refworld/pdfid/4538838e10.pdf> (accessed 3 July 2012).
7. 'General Comment No 14: The right to the highest attainable standard of health' (2000) 17. UN DOC. E/C.12/2000/4, <http://www.unhcr.org/refworld/pdfid/4538838d0.pdf> (accessed 2 July 2012).
8. General Comment No 17 (2006) para 35, UN DOC. E/C.12/GC/17, <http://www.unhcr.org/refworld/category,LEGAL,CESCR,,441543594,0.html> (Accessed 3 July 2012).
9. International Covenant on Economic, Social and Cultural Rights, adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966. Available at: <http://www2.ohchr.org/english/law/cescr.htm> (accessed 3 July 2012).
10. Resolution on access to medicines in the context of the right to health, UN Doc A/HRC/23/L.10/Rev.1, http://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/23/L.10/rev.1 (accessed 16 July 2013).
11. Universal Declaration of Human Rights, 10 December 1948, 217 A (III), <http://www.unhcr.org/refworld/docid/3ae6b3712c.html> (accessed 6 July 2012).

Regional

12. African Charter on Human and Peoples' Rights adopted on 27 June 1981, CAB/LEG/67/3 rev. Available at http://www.africa-union.org/official_documents/treaties_%20conventions_%20protocols/banjul%20charter.pdf (accessed 3 July 2012).
13. Africa Union Resolution on Public Health and Needed Medicines, adopted in 2008. (ACHPR/Res. 141 (XXXIII) 08), <http://www.chr.up.ac.za/index.php/ahrru-news.html> (accessed 3 July 2012).
14. Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa, 11 July 2003, available at: <http://www.unhcr.org/refworld/docid/3f4b139d4.html> [accessed 6 July 2012].
15. Protocol to the African Charter on the Rights and Welfare of the Child adopted in Addis Ababa, Ethiopia July 1990, OAU Doc. CAB/LEG/24.9/49 (1990), entered into force 29 November 1999, www.africa-union.org/root/au/Documents/Treaties/Text/A.%20C.%20ON%20THE%20RIGHT%20AND%20WELF%20OF%20CHILD.pdf (accessed 21 August 2012).

National

16. Anti-Counterfeit Act, Act No 13 of 2008 (Kenya).
17. Constitution of Kenya (2010).
18. Constitution of South Africa (1996).
19. Health Law Bill, 2012 (Kenya).
20. HIV and AIDS Prevention and Control Act, Act No 14 of 2006 (Kenya).
21. Industrial Property Act, Act No. 3 of 2001 (Kenya).
22. Medicines and Related Substances Control Act, Act No. 101 of 1965 (South Africa).
23. National Drug Policy, 1994 (Kenya).
24. National Drug Policy of 1996 (South Africa).
25. National Health Act, 61 of 2003 (South Africa).
26. Patent Act, 1987 (South Africa).
27. Pharmacy and Poisons Act, Cap 44 Laws of Kenya.

28. Trade Act, 1974 (United States).
29. Trademark Act, Cap 506 Laws of Kenya.

Cases

1. *International Pen and other (on behalf of Saro-Wiwa) v Nigeria* (2000) AHRLR 212 (ACHPR 1998).
2. *Lords Healthcare Limited v Salama Pharmaceuticals Limited*, High Court of Kenya, Nairobi (Milimani Commercial Courts) Civil Suit No. 334 of 2007
3. *Minister for Health and Others v Treatment Action Campaign and others* 2002 5 SA 721 (CC).
4. *Patricia Asero Ochieng and Others v Attorney General* Petition No. 409 of 2009.

Website sources

1. 'Compulsory licensing', *World Trade Organisation* http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm (accessed 19 November 2012).
2. 'India says "no" to policy that would block access to affordable medicines' *MSF Access Campaign* 22 June 2011, <http://www.msfacecess.org/about-us/media-room/press-releases/india-says-no-policy-would-block-access-affordable-medicines> (accessed 2 July 2012).
3. 'Parallel importation', <http://www.drugterm.com/country/world.htm> (accessed on 22/10/2011 at 6:19pm).
4. 'UNAIDS report on the Global AIDS Epidemic' (2010), http://www.unaids.org/documents/20101123_globalreport_em.pdf (accessed 2 July 2012).

Newspapers sources

1. 'Foreign policy will favour Africa' *The Standard* 16 July 2013.
2. 'Kenya: ARVs to cost 30 percent less as WHO clears manufacturer' *The Star* 2 November 2011
3. 'Pediatrics AIDS War Threatened by Waning Funds' *The Standard* 6 September 2011 7.

Emails

1. Email interview with B Baker, 11 October 2012.
2. Email interview with B Baker, 20 May 2013.

Cases

1. *Beecham Group v. International Products Ltd*
2. *Lords Health Care Limited v Salama Pharmaceutical Limited* [2008]eKLR
3. *Minister for Health and Others v Treatment Action Campaign and others* 2002 5 SA 721 (CC)
4. *Patricia Asero Ochieng and Others v Attorney General* [2012] eKLR
5. *Social Economic Rights Centre (SERAC) and Another v Nigeria* (2001) AHLR 60 ACHPR 2001.
6. *Thiagraj Soobramoney v Minister of Health, KwaZulu-Natal* 1998 (1) SA 765 (CC)
7. *Government of Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC)