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CHAPTER ONE

INTRODUCTION

1.1. Research Background

When the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was annexed to the Agreement Establishing the World Trade Organisation (WTO) in 1994, it set minimum standards for intellectual property (IP) protection, including protection of patent rights, that must be observed and enforced by all WTO Member States.¹ On the one hand, stringent Intellectual Property protection as seen innovation in the field of science where medical innovation has led to the creation of life saving vaccines which have reduced prevalence of diseases, ranging from polio to the human Papillomavirus, and invention of antiretroviral medicines which have greatly improved the lives of people living with the Human Immunodeficiency Virus (HIV).² On the other hand, the fulfilment of the obligations under TRIPS has generated a lot of controversy especially as they have been seen as the cause of reduced access to essential medicines in developing countries.

Although many factors normally influence access to medicines, patents rights and the obligation to protect them play a prominent role among these factors. A patent is an exclusive right usually granted to the owners of inventions. In the pharmaceutical industry, it is the right granted to the manufacturers of medicines excluding others from using or selling their medicines or processes that provide new ways of making medicinal products. By granting them these exclusive rights, patents create monopolies for the rights holders thereby putting them in a strong position to set prices. Such prices have made the new medicines too expensive for the target group in developing countries.³

Patents are, therefore, at the centre stage of the friction between the private interests and profit motives of pharmaceutical companies on the one hand and the public health and social impact concerns of governments, especially in developing countries including East Africa, on the other.

¹Sisule M.F. 'Access to Art and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations' (2007) p. 4.

² Report of the United Nation Secretary-General's High-Level Panel on Access to Medicines, 'Promoting Innovation and Access to Health Technology' (September 2016) p.7.

³Opati L.M, 'Intellectual Property Rights in Health – Impact on Access to Drugs' in Moni Wekesa and Ben Sihanya, (eds), Intellectual Property Rights in Kenya (Konrad Adenauer Stiftung, Nairobi 2009) p.13, 15.

To create the balance among these interests the WTO TRIPS Agreement has set norms, rules and standards that allow variation in the implementation of the TRIPS Agreement obligations, including limits on the exercise of intellectual property rights including patent rights.⁴ These norms are what have become to be known WTO-TRIPS Flexibilities.

These flexibilities aim to strike a balance between the exclusive rights conferred on the patent owners under Article 28 of TRIPS and the interests of consumers, competitors and the public at large as envisaged in the objectives of TRIPS under Article 7. These include: Compulsory licensing, parallel importing, voluntary licensing, and availability of new use pharmaceutical patents, Government use Licenses, Research Exemption, Early Working (Bolar Exception) and Test Data Protection. Their main purpose is to enable developing countries and east developed countries (LDCs), in particular, to tackle issues of societal importance such as access to essential medicines by their poor populations without restrictions usually imposed by the patents rights.

However, ‘these flexibilities have not been used to the full to improve access to essential medicines. The limited use and impact of the flexibilities in improving access can be explained partly by the technical and political challenges which developing countries including African countries face.’⁵ The Pressure usually exerted by the powerful pharmaceutical companies and their rich home countries is a big political threat to the effective utilisation of these flexibilities by the developing countries. This political threat is also aided, at the national levels, by weak institutions and incoherent legislations that do not define the scope and interpretation of these flexibilities, and at the regional levels lack of harmonization of patent laws and policies in the developing countries including East Africa Community Member States.

Many avenues and spaces have been created at the WTO system to enable developing countries to utilize the WTO-TRIPS flexibilities. Notably, the 2001 Doha Declaration resolved the issue of scope and interpretation of the TRIPS flexibilities. It accorded developing and least developed countries (LDCs) sufficient flexibility and discretion to ensure access to medicines in the interests of public health. In the declaration, the relationship

⁴Report of the United Nation Secretary-General’s High-Level Panel on Access to Medicines, ‘Promoting Innovation and Access to Health Technology’ (September 2016), p.6.

⁵Sisule M.F. ‘ Access to Art and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations’ (2007) p. 4.

between the TRIPS Agreement and public health (access to medicines) was expressed as follows in Paragraph 4:

‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’⁶

Additionally, Paragraph 6 of the Doha Declaration also gave direction on how to interpret the provisions of the TRIPS Agreement generally and specific clarifications on compulsory licenses and exhaustion of rights. Further, it recognised the challenges faced by members with insufficient or no manufacturing capacity in the pharmaceutical sector in using compulsory licenses and addressed the special case of LDCs. Article 31(f) TRIPS restricted the scope of a compulsory licence to the domestic market. Consequently, countries needing to import drugs under a compulsory licence could have difficulties in finding supplies.

The WTO General Council has made two important decisions to implement this paragraph. First, in August 2003 the General Council adopted Decision waiving certain obligations under Article 31 and establishing a mechanism to facilitate the import, by countries without manufacturing capacities, pharmaceutical products under compulsory licenses. The Decision, invariably referred to as the paragraph 6 Decision or 30 August 2003 Decision⁷ was adopted in the form of a waiver to TRIPS Articles 31(f) and (h) as an interim measure pending an agreement on a permanent solution. Subsequently, in November 2005, the General Council adopted a Protocol⁸ amending Article 31 of the TRIPS Agreement to incorporate the elements of the 30 August 2003 Decision into the text of the TRIPS Agreement.⁹ On LDCs, paragraph 7 of the Declaration provides that:-

⁶World Trade Organization, ‘Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health’ (2003), available at https://www.wto.org/english/tratop_e/implem_para6_e.htm (last accessed on 22/10/2016).

⁷World Trade Organization, ‘Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health’ (2003), available at https://www.wto.org/english/tratop_e/implem_para6_e.htm (last accessed on 22/10/2016).

⁸ General Council of WTO-TRIPS Agreement, ‘Amendment of the TRIPS Agreement, (2005) available at https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (last accessed on 22/10/2016).

⁹Sisule M.F. ‘Access to Art and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations’ (2007) p. 5.

‘We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.’

This waiver for the LDCs, which was initially set to expire on the 1st January 2016, was extended to January 2033 following a decision taken by the WTO’s Council for Trade-Related Aspects of Intellectual Property Rights on 6th November 2015.¹⁰ During this period, key provisions of the WTO’s intellectual property agreement, the TRIPS Agreement, will not apply to pharmaceutical products in LDCs. This means LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data until 2033.

This development at the WTO can be capitalized up on by the East Africa Community because of the existing regional policy which is pro-maximization of the WTO-TRIPS flexibilities in the EAC Member-states territories. Being a regional block consisting of four least developed countries (Burundi, Rwanda, Tanzania and Uganda) and one developing country (Kenya), the East Africa Community adopted a policy in February 2013 which aims to guide the EAC Partner States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilise the Public Health-related WTO-TRIPS Flexibilities.¹¹ This policy guide preceded the United Nation Secretary General’s High-Level Panel on Access to Medicines report which was released in September 2016. This report, in its assessment, acknowledged that National and Regional policy incoherence and troubling practices - such as uneven application of trade and health policy – have obstructed sovereign freedom of governments to promote public health. It urges the governments that:

‘... national laws should be drafted in a way that facilitates the prompt and expedient use of Compulsory Licenses or government use for non-commercial purposes of a patent, including criteria to determine the remuneration for the right holder. As the Doha Declaration notes,

¹⁰World Trade Organization, ‘WTO Members Agree to Extend Drug Patent Exemption for Poorest Members,’ (2015) available at https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm (accessed on 22/10/2016)

¹¹East Africa Community, ‘EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.

governments should retain the freedom to determine the grounds under which licenses are issued.’¹²

In spite of the above caution and the fact that the EAC Protocol on the Establishment of the East African Community Common Market provides for areas of cooperation in Intellectual Property¹³ including Patents, till now, IP rights in EAC Partner states are mainly governed by each Partner State’s legislation. Applications for IPRs protection are registered with the relevant IP offices in all member states, or, if applicable, with the African Regional Intellectual Property Organization (ARIPO) or Patent Cooperation Treaty (PCT) systems.

This Mini-Thesis explores the sub-regional effort of the East Africa Community, a home to four LDCs and one developing country, to maximise its utilisation of TRIPS flexibilities to facilitate importation and boost domestic manufacturing of essential and affordable medicines for its poor population.

1.2 Problem Statement

The problem this mini-thesis highlights is twofold: first, the East Africa Community (EAC) hesitation to fast-track the harmonisation process of its Member States’ legislations and establish mechanisms for regional cooperation in the field of Patent regulation is impeding the EAC ability to make full use of the public health flexibilities postulated in the Trade-Related Aspects of Intellectual Property Rights (TRIPS). For successful harmonization, establishment of a single patent office, among the member states of EAC is required.

Secondly, a broader reform of legislation and institutions that have direct and indirect effect on public health and access to medicines is essential to ensuring maximisation of the WTO-TRIPS flexibilities on public health within the EAC.

The East Africa Community policy on maximising its member States’ utilization of WTO-TRIPS flexibilities on access to public health (Essential Medicines) seems to be focussing on only reforming its Member States Intellectual Property Laws, particularly the patent laws such as Burundi’ Property Law No. 1/13 of 2009, Kenya’s Industrial Property Act, 2001, Rwanda’s Law on the Protection of Intellectual Property (2009), Tanzania’s Patents Act of 1987 (and Zanzibar’s Industrial Property Act No. 4 of 2008), and Uganda’s Industrial Property Act (2014). Effecting reforms in these laws alone will not suffice to optimise the

¹²Report of the United Nation Secretary-General’s High-Level Panel on Access to Medicines, ‘Promoting Innovation and Access to Health Technology’ (September 2016), p.23.

¹³EAC Protocol on the Establishment of the East African Community Common Market (2010), Article 43.

utilisation of public health-related TRIPS flexibilities. The legitimate trade interests codified in other legislations will always result in policy incoherence if these laws are not properly aligned with the national legislations and constitutional postulations.

As was noted by United Nation Secretary-General's High-Level Panel on Access to Medicines, incorporating public health-related flexibilities into national intellectual property law should cut across many government departments and ministries – trade and industry, economic development, science and technology, health, justice and foreign affairs, finance and national planning¹⁴ so as to strengthen the government coordination efforts in acting swiftly, but in a fair, predictable and implementable manner when it decides to use WTO-TRIPS flexibilities. Dreifuss observes that:

‘Policy incoherencies arise when legitimate economic, social and political interests and priorities are misaligned or in conflict with the right to health. On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives and the right to health.’¹⁵

1.3 Research objective and questions

The research aims to facilitate better understanding of the state of relevant intellectual property (IP) legislation in East Africa, the impacts or potential impacts on access to essential medicines and to lay a baseline for future analyses. The central question to this mini-thesis is: How has East Africa Community Member States approached the question of public health flexibilities in their legislations?

To comprehensively address this question, the following objectives will guide the answer: Why are Patents, especially in the pharmaceutical industry, and their protection necessary? What are WTO-TRIPS Flexibilities on access to public health and why are they justified? What gaps, if any, exist to ensure that the legislations in these countries are supportive of efforts to ensure increased access to essential medicines such? What solutions/reforms are

¹⁴Report of the United Nation Secretary-General's High-Level Panel on Access to Medicines, ‘Promoting Innovation and Access to Health Technology’ (September 2016), p. 24.

¹⁵UN SG's High-Level Panel on Access to Medicines ‘Calls for New Deal to Close the Gap between Health Innovation and Access,’ (2016) January 26, 2017, from <http://www.undp.org/content/undp/en/home/presscenter/pressreleases/2016/09/16/un-sg-s-high-level-panel-on-access-to-medicines-calls-for-new-deal-to-close-the-gap-between-health-innovation-and-access.html> (accessed on 20 December 2016).

required to strengthen the EAC, and its Member State's, legal and institutional framework to optimize the utilization of WTO-TRIPS Flexibilities on Public Health?

1.4 Significance of the problem

The relevance of this mini-thesis derives from the recent developments at the WTO following a decision taken by the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) on 6 November 2016, where the members agreed to extend drug patent exemption for poorest members.¹⁶ This development has seen Least-developed country (LDC) members of the WTO allowed to maintain maximum flexibility in their approach to patenting pharmaceutical products until at least 1st of January 2033. This means LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033.

As highlighted above, this research also derives its relevance from the release, in September 2016, of the *United Nations Secretary-General's High-Level Panel on Access to Medicines Report*, which addressed the policy incoherence between the rights of inventors, international human rights law, trade rules and public health where it impedes the innovation of and access to health technologies.

It is hoped that this study will positively inform and influence the students, researchers and practitioners with interest in the wider field of patent protection and access to essential medicines. It is also hoped will add to the scholarly literature on utilization of WTO-TRIPS flexibilities generally, and particularly from a regional perspective, and finds its usefulness among the policy makers dealing with the same issues.

1.5 Methodology

This study will mainly be premised on a desk-top research. It will be based on the reviews of both print and electronic materials. These include; Selected Constitutions and legislations, international legal instruments (WTO-TRIPS Agreement and related Declarations), Published books, journal articles, law reports (including reported and unreported judicial decisions) and newspaper articles.

¹⁶ Council for Trade-Related Aspects of Intellectual Property Rights, 'Extension of The Transition Period under Article 66.1 of the TRIP Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council for TRIPS of 6 November 2015 available at www.wto.org (accessed on 2/12/2016).

1.6 Chapter outline

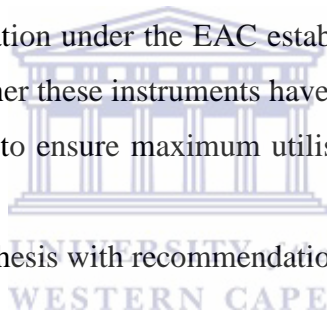
This research paper consists of six chapters. Chapter one is the introduction to the research paper. It consists of the background to the research, research objective/problem, research questions, significance of the problem, and the literature review of the topic under discussion, the methodology adopted by the research and an outline of chapters.

Chapter two discusses the conceptual framework of patent protection and justifications underpinning the patent system.

Chapter three reviews the international regime for patent protection and access to essential medicines. It also looks into the relationship between Patent protection under the WTO-TRIPS Agreement and the Flexibilities contained therein and their interpretations guided by the Doha Declarations of WTO-Flexibilities and access to public health.

Chapter four will review the legal and policy framework of the EAC on access to medicines. It also examines areas of cooperation under the EAC establishing Treaty, EAC Protocol and Policy on public health and whether these instruments have been incorporated under the EAC partner States patent legislations to ensure maximum utilisation of WTO-TRIPS flexibilities on public health.

Chapter five concludes the mini-thesis with recommendations.



CHAPTER TWO

CONCEPTUAL AND THEORITICAL FRAMEWORK OF PATENT SYSTEM

2. Introduction

As introduced in chapter one, patents protection, particularly in the pharmaceutical industry, have for a long time been at the centre of a fierce debate. The exponents of stronger patent protection system argue that by granting temporary monopolies to innovators, the patent right protection inspire innovation and encourage investment.¹⁷ In the health sector, they argue, protecting the innovators and their inventions is a cornerstone in driving innovation in medical research by enabling researchers to have protection of their intellectual property and the possibility of capitalising on their inventions.¹⁸ Others argue the case for encouraging strong patent systems in developing countries, based on the potential benefits such protection might bring both in terms of focusing more research on tropical diseases and encouraging greater domestic and foreign investment in local research activities and encourage national scientists to invent new drugs and invest in their national economies, and improve the overall quality of health.¹⁹ To this school of thought, 'intellectual property protection has been, and will continue to be, an essential component of the innovation process that drives medical research.'²⁰

But the critics and advocates of access to medicines contend that there are social costs that the poorer societies bear because of the patent system.²¹ 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. In essence, when it comes to pharmaceuticals, it may be preventing valuable medicines from coming to market or making them unaffordable to the poor when they eventually reach the market.

¹⁷ Organisation for Economic Co-Operation and Development, 'Patents and Innovation: Trends and Policy Challenges,' (2004),p. 5.

¹⁸ Australia Law Reforms Commission, 'Economic benefits of the patent system,' (2004) ALRC Report 99 available at <http://www.alrc.gov.au/publications/report-99> (accessed on 8th February 2017).

¹⁹ Imam A., 'How Patent Protection Helps Developing Countries' (2005) 33 AIPLA Quarterly Journal 389.

²⁰ Australia Law Reforms Commission, 'Genes and Ingenuity: Gene patenting and human health' (2004) ALRC Report 99 available at <http://www.alrc.gov.au/publications/report-99> (accessed on 8th February 2017).

²¹ Mueller J.M 'An introduction to patent law.' (2003) p. 20-21.

Striking the balance between incentivising innovations and protecting innovators on the one hand and ensuring maximum public benefit from these innovations on the other, is a fundamental aim of the patent system established by the Trade Related-Aspects of Intellectual Property Agreement.²²

This chapter discusses the broader property law, especially patents and the right to health. These two areas are discussed below separately beginning with the basic concepts and theories associated with intellectual property (IP) law.

2.1 Conceptual Framework

The conceptual approach to patent system is adopted here to define the basic concepts associated with patent protection and public-health exceptions to patent protection. The aim here is to lay structural foundation of the public health flexibilities contained in the TRIPs Agreement that seek to strike a balance between patent protection and access to public health.

According to Singer, ‘property rights concern relations among people regarding control of valued resources. Property law gives owners the power to control things, and it does this by placing duties on non-owners.’²³ This law covers both the real and personal property law, with intellectual property law belong to the later.

Thus, before embarking on a journey toward explaining the relationship between intellectual property rights and access to essential medicines, it is important to lay down the conceptual framework first. Without proper way to conceptualise and adjudicate disputes on intellectual property rights by property right claimants and their socio-economic implications on the society in which such rights are granted, injustice will always occur. That is why this mini-thesis defines the following basic concepts, because they will be widely mentioned in the next chapters.

2.1.1 Defining intellectual property and patents

The TRIPS Agreement does not give a clear definition of intellectual property. However, the Convention Establishing the World Intellectual Property Organisation (1967) defines the Intellectual Property in terms of what it entails and what it doesn’t. Article 2 (viii) of the Convention postulates as follows:

²² Organisation for Economic Co-Operation and Development, ‘Patents and Innovation: Trends and Policy Challenges,’ (2004) p. 9.

²³ JW Singer ‘Property law: Rules, policies and practices,’ (1993), p.37.

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

Again this illustration falls short of giving a clear definition of Intellectual Property. But inference can be made from the above definition by positing that Intellectual Property denotes a creation of the mind. These include inventions, literary and artistic works, symbols, names and images which have both moral and commercial value.²⁴ The registration of this property by the state grants the creator an exclusive Intellectual Property Rights (IPRs), or a monopoly, to exploit and benefit from it within the territory of that state. Patents, alongside Copyrights and trademarks are forms, of Intellectual Property.

Simply put, patent is a document which describes an invention. ‘It is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.’²⁵ It confers an exclusive right to an inventor to prevent all others from using the invention, without license or authorization, for the duration of the patent in return for disclosure of the invention in a document known as the patent specification.²⁶ Patenting, therefore, essentially refers to exclusive rights over an invention which gives the owner control over it for a limited period of time and provides a legal monopoly on creations of the mind. These inventions can be either products or processes that offer a new way of doing something or gives a new technical answer to a problem.

2.1.2 Patentability criteria

As a general requirement by the TRIPs Agreement, the World Trade Organisation (WTO) members are mandatorily required to make available patents for inventions of products and processes in all fields of technology, including patents which is the mainstay of this mini-thesis, provided that such inventions are new, involves an inventive step and is capable of

²⁴ World Intellectual Property Organization, *What is Intellectual Property?* (2016) available at <http://www.wipo.int/about-ip/en/> (accessed on 14/12/2016).

²⁵ World Intellectual Property Organization, *What is Intellectual Patent?* (2016) available at <http://www.wipo.int/about-ip/en/> (accessed on 14/12/2016).

²⁶ Opati, L.M ‘Intellectual Property Rights in Health – Impact on Access to Drugs’ in Wekesa, M and Sihanya, B (ed.), *Intellectual Property Rights in Kenya* (2009) 13, 15.

being applied in a particular industry.²⁷ These are the patentability requirements enshrined in article 27 of the TRIPS Agreement. This mini-thesis notes that an assessment of these three conditions is fundamental since an invention that fulfils them has to be differentiated from a mere discovery, a natural process or a minor modification of an already existing product.

Another element that is not commonly talked of, but which is codified in article 29(1) of the TRIPS Agreement, is the requirement that a patent holder should ‘disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art’ and may be asked ‘to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where the priority is claimed, at the priority date of application’.

This element is very important for the generic industry and government(s) use of the provided flexibilities in case of emergencies that would need production of pharmaceutical products under a compulsory license regime or after the expiry of the patent, since it ensures full disclosure of the information needed.²⁸ It has been argued that this requirement is one of the cornerstones of the patent law because ‘patents can fulfil their social purpose only if Members ensure that the disclosure is really enabling and do not grant patents where this is not the case’.²⁹ The next section discusses, in details, the three patentability criteria of novelty, inventive-step and industrial use.

a. Novelty

The first patentability requirement of novelty requires that an invention has to be ‘new before the date of filing of a patent application.’³⁰ The underlying principle of novelty is that the invention or certain elements of the invention does not form part of the prior art or in public domain before the filing date of the patent application. The fact that TRIPs Agreement does

²⁷World Trade Organization-Trade Related-Aspects of Intellectual Property Agreement (1995) art. 27, Carlos M. Correa, ICTSD, WHO, UNCTAD ‘Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper’ (2006) available at: http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf [Guidelines 2006], pp. 3-4. Accessed on 25 July 2017.

²⁸ CIPR, Final Report of the Commission of Intellectual Property Rights: ‘Integrating Intellectual Property Rights and Development Policy’ (2002) CIPR [CIPR Report 2002], p. 14.

²⁹ H. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines (2008) OUP, p. 67.

³⁰ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 1.

not explain what prior art or public disclosure denotes, has left the concept to different interpretations by commentators and WTO members in their legislations.

In USA, the prior art denotes ‘the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention’³¹ In the European Union it is held to ‘comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.’³² The rationale for using these examples is simply that the US and EU support stronger protection of patents and thus their legislative provisions on novelty would be seen stricter- a feature good in the examination of patents (including pharmaceutical patents) in developing and least developed countries.

It must be noted that in some circumstance courts have held that a mere availability of the prior art of the invention does not deprive it of novelty. In *Prout vs. British Gas* (1992)³³, an employee of British Gas had an idea for a vandal proof bracket for fixing warning lamps to barriers placed around excavations in the highway. He submitted his idea to the company through the suggestion scheme. British Gas carried out field trials on the public highway but decided not to proceed with a patent application. The employee then applied for a patent in his own name (British Gas did not object to this). Sometime later, British Gas made use of the patent without permission. The employee sued the British Gas for an infringement. The latter argued that the patent was not valid as the invention was known at the time of filing of the patent application. The court held that the prior use was not sufficient to anticipate the patent. Something more than mere a trial in public was needed. The patent was declared valid and infringed by British Gas which was also liable for breach of confidence.

A clear contrast should therefore be made in relation to the absolute notion of novelty, i.e. inventions that are universally new in the whole world, compared to the relative novelty, where the invention is new within a restricted area.³⁴ This distinction is significant for pharmaceutical patents from the perspective of public health and access to medicines, since if a State applies the relative concept of novelty, and not the absolute, it will not be in a position

³¹ 35 U.S.C. Section 102.

³² The European Patent Convention (2007), art. 54(2).

³³ Routledge *intellectual property law* 6 ed. (2008) 27.

³⁴ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 3.

to decline patent applications for inventions that already exist in the public domain.³⁵

b. Inventive Step

After ascertaining the criterion of novelty of an invention, the next requirement of its inventive step automatically follows. This prerequisite is important in granting pharmaceutical patents.³⁶ It is met when ‘having regard to the state of the art, [the invention] is not obvious to a person skilled in the art’.³⁷ The European Patent office defines a person skilled in the arts to mean ‘a skilled practitioner in the relevant field, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date’³⁸ Its cornerstone is the non-obviousness of the invention and that is why the TRIPS, in the footnotes provided in Article 27(1), clarifies that the invention should ‘go beyond the normal progress of technology’ and not merely follow ‘plainly or logically from the prior art.’³⁹

Commentators like Carlos Correa have recommended setting a higher bar for determining an inventive step in the granting of pharmaceutical patents.⁴⁰ The rationale being that not only does ‘it creates strong patents and precludes the competition from infringing them, but it also prevents the inventor from making minor changes to the invention and thereby prolonging the patent duration (which leads to gaining profit from the so-called ‘evergreening’ patents).’⁴¹ The Author of this mini-thesis agrees with the above position, but adds that due to the life-threatening consequences normally brought about by the pharmaceutical patents in curtail

³⁵ WTO Secretariat ‘WHO-WIPO-WTO Technical Workshop on Patentability Criteria Geneva, 27 October 2015: The TRIPS Agreement and Patentability Criteria’ (2015) available at https://www.wto.org/english/tratop_e/trips_e/Roger_Kampf_trilatworkshop15_e.pdf (accessed on 7 August 2017).

³⁶ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p.28.

³⁷ EPO, ‘Guidelines for Examination in the European Patent Office’ (2010) available at: <https://www.epo.org/law-practice/legal-texts/guidelines/archive/guidelines-2010.html> (accessed on 25 July 2017).

³⁸ EPO, ‘Guidelines for Examination in the European Patent Office’ (2010) available at: <https://www.epo.org/law-practice/legal-texts/guidelines/archive/guidelines-2010.html> (accessed on 25 July 2017).

³⁹ World Trade Organization, ‘Agreement on Trade-Related Aspects of Intellectual Property’ (1994), p. 331.

⁴⁰ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 46.

⁴¹ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 46.

access to, and availability of, life-saving medicines in poorer countries, the invention must not merely be something new; it must represent a development over prior art.

c. Industrial application

The third patentability criterion is that of industrial applicability or usefulness of the invention. The rationale behind this requirement is that 'patent protection should not be available for abstract ideas or purely intellectual creations that cannot be put to any use.'⁴² The TRIPS Agreement, in the footnote to Article 27(1), mentioned above, stipulates that the term 'industrial applicability' equates to the term 'useful'. The term 'industrial' is used in a wide sense, and its interpretation varies from one country to another. In the EU, for instance, an invention is considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.⁴³

In a nutshell, particularly in the case of developing countries, adoption of a higher threshold of industrial applicability is recommended, since this will ensure that inventions, with no actual purpose and of have no industrial usefulness, are not patented.⁴⁴

Patented drug and generic drug

A Patented drug is a medicine protected by a patent and it can only be made, used, imported/exported or sold by the patent holder.⁴⁵ According to the World Health Organisation's Action Programme on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention.

A generic drug is a pharmaceutical product usually intended to be interchangeable with the original patented drug ("bioequivalent") because it does the same thing. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the patentee. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

⁴² Carlos M. Correa (ed.), 'A Guide to Pharmaceutical Patents, Vol. I' (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 46.

⁴³The European Patent Convention (2007), art. 57.

⁴⁴ Carlos M. Correa (ed.), 'A Guide to Pharmaceutical Patents, Vol. I' (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 108.

⁴⁵ Elliott R & Bonin M 'Patents, International Trade Law and Access to Essential Medicines' available at <https://www.researchgate.net> (accessed 20 July 2017).

Generic drugs should not be confused with counterfeit drugs. “Counterfeit goods are generally defined as goods involving slavish copying of trademarks.

According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging.”⁴⁶

Thus, pharmaceutical patent or drug patent is a patent for an invention in the chemical or pharmaceuticals industry. When a pharmaceutical company first develops a new drug to be used for a disease condition the drug is covered under patent protection, which means that only the pharmaceutical company that holds the patent is allowed to manufacture, market the drug and eventually make profit from it. They are not renewable and after the expiry, the patent can go into the public domain. Under Rwanda, Uganda and Kenyan laws, this period covers a maximum of twenty years after which the protection provided to the patent expires and hence can then be commercially utilized without the owner’s permission.⁴⁷

2.2 Theoretical Framework

The previous section set a conceptual foundation by defining the basic concepts that will be used in this mini-thesis. This section seeks to establish the theoretical framework. That said, it is prudent to note from this onset that this study is premised on the broader Intellectual Property Law, with focus on pharmaceutical patents and their interface with the right to health.

Theories of intellectual property have always been employed to conceptualize and inform the decisions often made to adjudicate conflicts that often arise between protecting intellectual property rights in the pharmaceutical industry and the right to health of the consumers of the patented pharmaceutical products. In the pool of many theories that are often used, this work focuses on the two: Natural right and utilitarian theories. This mini-thesis limits itself to these two theories because of the inherent limitation both in scope and words-count of this research. The rationale for selecting these theories is that both theories are often used, separately, to make a case for either strong patent protection or to strike a balance between

⁴⁶ World Health Organization, “Essential Medicines and Health Products,” available at www.who.int/medicines/regulations/ssffc/definitions/en/ (last access on 31/06/2017).

⁴⁷Institute of Economic Affairs, ‘The Status of Patenting in Kenya and its Implication for Development’ (2011) 7 Media Notes 1.

patent protection and other competing interests such as access to public health. More on this is set out below:

2.2.1 Natural rights theory

The natural right theory originally stems from the general justification of the right to property: both tangible and intangible property. It is premised on the creed that every man has an inalienable natural right to the creations of their minds, as such; the society has an obligation to enforce that right by protecting the man from any alienation of this right. Patent rights are highly valued in this theory; because once patents rights are destroyed then the destruction of other property rights ensues automatically.⁴⁸ On that account, the alienation or the use of ideas without unequivocal authorisation of the owner is regarded as pure theft.

Discussions on the natural rights argument generally refer to the principles of natural law as modified by John Locke's 'labour' theory of property rights, formulated in Chapter 5 of his famous book: *Second Treatise on Government* (1690). In a two-tiered proposition, Locke argues here that it is a fundamental law of nature (God's will) that Mankind be preserved, and that the man has a role of ensuring that this will is implemented.

Secondly, Locke posits that the Earth and its vast resources, was created for all men to share; something he calls a 'common'. However, a man is only able to get his share of the property held in common, to the exclusion of others, once he has appropriated it. This comes from the understanding that every man or woman owns his/her body and what he/she produces with it. Therefore, when a person mixes the labour with the resources unowned or held in common, that person earns a valid property claim over that which is a product of their labour, because he has joined with it something which is his own. Thus, by adding something of his own to the natural resource, he excludes others from having a right to it.

However, this property claim is not absolute. It is tainted with caveats. For Locke "the same law of nature that does by this means give us property, does also bound that property too." First, for the appropriation to be justifiable, there must be 'enough, and as good left in common for others.' The second proviso is the non-waste condition which prohibits appropriator from exclusively taking, from the common, more than he can use.

⁴⁸Liivak Oskar, 'Rethinking the Concept of Exclusion in Patent Law' (2010) *The Georgetown Law Journal* [Vol. 98:1643]1657.

Norzick interprets this to mean that the 'acquisition of property through labour is legitimate if and only if other persons do not suffer thereby any net harm.'⁴⁹ What then qualifies to be a 'net harm'? According to Fisher, the "Net harm" would 'include such injuries as being left in a poor state than they would have been under a regime that did not permit the acquisition of property through labour or a constriction of the set of resources available for their use -- but does not include a diminution in their opportunities to acquire property rights in unowned resources by being the first to labour upon them.'⁵⁰

It then follows, from the foregoing, that the Lockean proviso is not violated by assigning a patent right to an inventor because, although limits will be put on other people's access to the invention by the issuance of the patent, such inventions would not have there, in the first place, without the skills of the inventor. In other words, consumers are helped, not hurt, by the grant of the patent.

Nozick contends, however, that fidelity to Locke's theory would mandate two limitations on the inventor's entitlements.⁵¹ First, subsequent modified inventions of the same subject matter should be allowed following the expiry of the patent and subsequent inventors must be permitted to make and sell it. Otherwise the assignment of the patent to the first inventor would leave them worse off. Second, for the same reason, patents should not last longer than, on average, it would have taken someone else to invent the same device had knowledge of the invention not disabled them from inventing it independently.

This line of thought on the importance of term limit in patents was seen in the WTO Panel report in *Canada — Patent Protection of Pharmaceutical Products*⁵² where the European Commission had brought a complaint against Canada, with the WTO dispute resolution mechanism, in respect of the alleged lack of protection of inventions by Canada in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation, in particular the Patent Act. The panel adjudicated by positing that:

‘...the so-called regulatory review exception provided for in Canada’s Patent Act (Section 55.2(1)) — the first aspect of the Patent Act challenged by the EC — was not inconsistent

⁴⁹Nozick, R, *Anarchy, State, and Utopia*, (1974) New York: Basic Books, pp. 178-82.

⁵⁰ Fisher W, 'Theories of Intellectual Property' (2001) available at <http://yimg.com> (accessed on 1 August 2017)

⁵¹Nozick, R *Anarchy, State, and Utopia*, (1974) New York: Basic Books, pp. 178-82.

⁵² Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, p. 2289.

with Article 27.1 of the TRIPS Agreement and was covered by the exception in Article 30 of the TRIPS Agreement and therefore not inconsistent with Article 28.1 of the TRIPS Agreement. Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires.”⁵³

It suffices to conclude from the foregoing that, once legitimately acquired, patent rights must be jealous guarded, protected and left to be enjoyed by the right holders. This argument is the pillar of the Natural right theory. However, this theory has been critiqued on multiple grounds as seen below.

The first criticism arises from the initial notion natural rights theory holds that the rights exist independent of any grant from the government. This is impractical in the context of the current patent system where every patent rights follows after assessment of the patentability criteria and subsequent grant of such rights from the relevant governing authorities. It is true some inventions worthy of patent protection accrue from individual modification of natural resources, including natural plants,⁵⁴ but an entitlement to them comes from the government grant of patent after prudent examination.

Secondly, it does not envisage the question of the term limit where the property right must lapse and passed to the public domain, a major component of the patent system as it current stands as enumerated in the WTO panel decision quoted above. Finally, natural right theory does not foresee a situation where the rights of the patent rights holder must be balance with the interests of the society, such us public heath rights.

2.2.2 Utilitarian theory

The utilitarian theory’s basic precept is that the patent laws are socially justified if they bring the greatest benefits to the greatest number of people. It is often associated to Jeremy Bentham’s argument that laws, in general, are justified when they bring greater satisfaction,

⁵³ Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, p. 2289.

⁵⁴ “According to Newman and Cragg 2012, the utility of natural products as sources of novel structures is still alive and well. Up to 50% the approved drugs during the last 30 years are from either directly or indirectly from natural products and in the area of cancer, over the time frame from around the 1940s to date, of the 175 small molecules 85 actually being either natural products or directly derived there from.” Excerpt from Veeresham C, ‘Natural products derived from plants as a source of drugs’ (2012) Journal of Advance Pharmaceutical Technology & Research 3(4): 200–201.

or profit, to the larger number of people. It has been popularly adopted to justify intellectual property rights.⁵⁵

The theory is conceptualized in two tiers. First part emphasizes the need to create a patent system that incentivizes inventions. The rationale here is that without ‘the copyright, patent and trade secret property protections, adequate incentives for the creation of a socially optimal output of intellectual products would not exist.’⁵⁶

It is therefore argued in this part that inventors invest heavily in research and development (R&D) of their inventions and thus should be allowed to recoup their investment and profit, to a certain extent, from their inventions. However, extent to which the inventors should influence the prices of patentable subjects in the market to recoup and benefit from their inventions must always be done through the watchful eyes of the government, so as the society is not deprived of patentable products due to their unaffordability.

Governments can also reduce the roles played by R&Ds in influencing such prices by establishing frameworks that give incentives to the inventors to lower the margin between the cost of invention and the profit that inventors need to make from them. This leads us to the second part of utilitarianism.

The second argument is premised on the notion that patents in themselves are incentives that encourage public disclosure. Without patents, important discoveries would remain undisclosed.⁵⁷ So long as there are no sanctions on copycats, inventors will not have motivations to continue inventing. This is what is commonly called the ‘public good problem. As Kieff argues the ‘treatment of patents as property rights provides incentives for the investment and ordering of private activities necessary for such a complex commercialization process while at the same time providing a workable framework for deciding which inventive activities merit government intervention in the first instance.’⁵⁸ The patent system solves this public good problem by granting term-limited (currently twenty years from the filing of a patent) monopolies to patentable products for inventors to sell and benefit from their inventions.

⁵⁵Hettinger, EC ‘Justifying intellectual property’ (1989) 18 *Philosophy and Public Affairs*, p.47.

⁵⁶Hettinger, EC ‘Justifying intellectual property’ (1989) 18 *Philosophy and Public Affairs*, p. 48.

⁵⁷ Davies D ‘The early history of the patent specification’ (1935) 50 *Law Quarterly Review* 86.

⁵⁸Scott FK ‘Property Rights and Property Rules for Commercializing Inventions’ (2001)85 *Minnesota Law Review* 697, 753.

It follows from the foregoing that availability of patents actually encourages inventions which in turn, if properly regulated, encourage disclosures for public goods. Unavailability of patents would create the public good problem as argued above, especially in the pharmaceutical industry, where new inventions and technological breakthrough in the field of medicines are critically needed. If patents are not available, investment in research and development of new inventions would be discouraged. Hettinger captures such scenario perfectly in the following lines;

‘If competitors could simply take one another’s inventions, there would be no incentive to spend the vast amount of time, energy and money necessary to develop these products.... It would be in each firm’s self-interest to let others develop products, and then mimic the results. No one would engage in original development...and consequently no new inventions would be developed.’⁵⁹

Sell agrees with Hettinger in her submission that ‘the rationale for intellectual property rights is that they provide incentives for the creation and dissemination of innovation. Without compensation made possible by intellectual property rights, public goods will be underprovided.’⁶⁰

The fundamental basis that patents should be available primarily for the good of the public and not primarily to profit the owner is the cornerstone of utilitarianism and is essential for any framework that seeks to utilize the WTO-TRIPS flexibilities.

2.3 Chapter Conclusion

This chapter has set out the conceptual and theoretical framework upon which the arguments presented by this research will be derived from. The conceptual framework set out at the beginning of the chapter will guide the investigation on how the five East Africa Community member states have defined key terms associated to patents and their versions of patentability criteria as codified in their respective national laws, and how they have contributed toward making access to essential medicines easier in that region. The theoretical framework provides a background understanding on how important principles of the current patent system came about and how the decisions are usually informed in disputes where patents rights are the subject matter. The next chapter will discuss the international, regional and

⁵⁹ EC Hettinger ‘Justifying intellectual property’ (1989) 18 Philosophy and Public Affairs, p. 48.

⁶⁰Sell, SK ‘TRIPS-Plus Free Trade Agreements and Access to Medicines’ (2007) 28 Liverpool Law Review 43.

national legal framework of patents with peculiar focus on TRIPS, Africa Regional Intellectual Property Organization.



CHAPTER THREE

INTERNATIONAL AND REGIONAL TREATIES

3.1 Introduction

The protection of intellectual property rights evolved from the state level before becoming an international concern. With regard to protection of IPRs at the domestic level, it has been noted that ‘Intellectual property rights (IPRs) have a history going back many centuries. The first patent law for the protection of inventions was passed in Venice in 1474 during the Renaissance to overcome what was widely considered to be a period of technological stagnation and intellectual darkness due to the influence of barbarism and religion.’⁶¹

This statute, which sought to encourage technological advancement by issuing private grants and importation licenses, established a foundation for the world’s first patent system. Its preamble contained a utilitarian purpose that encourages innovation and grants inventors exclusive patent rights on the condition that their inventions proved to be useful, novel, industrially applicable and that they would be disclosed in exchange for right of monopoly, with geographical and time limit. It also had provisions on rights enforcement and remedy for their infringement.⁶²

Another early patent law was the English Statute of Monopolies of 1624.⁶³ This law remained in force until 1977 when the British started to implement the European Convention.⁶⁴ But it was the United States’ that replicated the Venice standards by allowing applications to be registered when they meet the test of novelty and usefulness.⁶⁵

These early statutes would decades later influence the creation of the current international IPR regime. Starting with the 1873 Vienna Congress, there was a series of meetings to create an international IPR regime. This culminated in the signing the Paris Convention of 1883. One of its objectives was:

⁶¹ Krebs R.E Groundbreaking Scientific Experiments, Inventions, and Discoveries of the Middle Ages and the Renaissance(2004) p.190.

⁶² Nard C.A & Morris A.P ‘Constitutionalizing Patents: From Venice to Philadelphia’ (2006) Faculty Publications. Paper 587, p.234-235.

⁶³ Bentham J ‘An introduction to the Principles of Morals and Legislation (edited by JH Burns & HLA Hart, (1970), p.30-32.

⁶⁴ Wekesa M ‘An Overview of the Intellectual Property Rights (IPRs) Regime in Kenya’ in Wekesa, M & Sihanya, B (eds), *Intellectual Property Rights in Kenya* (2009), P. 1,3.

⁶⁵ As above.

‘the creation of a union which, without encroaching on the municipal law of the contracting countries, would lay down a number of general principles securing the interests of industrial property in the interior of a country as well as abroad.’⁶⁶

The Paris convention marked the first attempt at harmonization and internationalisation of patents. This chapter is divided into two sections: The first section discusses the existing international patent regimes. The discussion here will be based on: The 1883 Paris Convention of the International Union for the Protection of Industrial Property, Patent Cooperation Treaty (1978), The 1994 Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Doha Declaration. The second section discusses the Lusaka Agreement which established Africa Regional Intellectual Property Organization (ARIPO).

These treaties were chosen because they both covered the substantive and procedural and administration of patents and use of patents to influence access to essential medicines – the mainstay of this mini-thesis.

3.2 The 1883 Paris Convention of the International Union for the Protection of Industrial Property

The Paris Convention, signed in Paris in 1883, created the first major international step in ensuring creators of intellectual work had protections in other countries; the Paris Convention applies to industrial property in the widest sense. It includes patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications and the repression of unfair competition.⁶⁷ It was one of the very first intellectual property treaties. This convention was designed to protect the industrial property of member states without losing the important principle of claiming a right to priority. This is one of the most important aspects of the international patent regime and makes it possible for a patent applicant to claim a priority right in one country based on an initial patent application filed in another country.⁶⁸

The substantive provisions of the Convention fall into three main categories these are: national treatment, right of priority, common rules.

⁶⁶ Vohra D. et al ‘Intellectual Property Glossary’ (2011). 18.

⁶⁷ Newman A. Howard, ‘Patent Cooperation Treaty (PCT) Protection: When Your IP Target Country is not in The Group of 152’ available at <http://www.newmanlawoffices.com/single-post/2017/03/09/PATENT-COOPERATION-TREATY-PCT-PROTECTION-WHEN-YOUR-IP-TARGET-COUNTRY-IS-NOT-IN-THE-GROUP-OF-152> (accessed on 26 July 2017) please put the accessed date in ()

⁶⁸ Institute of Economic Affairs, ‘The Status of Patenting in Kenya and its Implication for Development’ (2011) 7 Media Notes 2.

The ambit of the national treatment provisions contained in Article 2 of the convention postulated that, with regard to protection of the industrial property, a contracting party must accord, to the nationals of other contracting states, the same protection it gives its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.⁶⁹

The Paris Convention, however, does not include a definition of a patent, and left it up to the Member states to define their own versions of patent in their respective national legislations.⁷⁰ Regarding pharmaceutical patents, the most relevant provisions of the Convention are the Article 5(A(2&4)), which deals with compulsory licenses, and Article 10*bis* which provides for the protection against unfair competition.

Article 5(A(2)) made it a sovereign right for every member state to make domestic laws and policies that allow grant of compulsory licences to prevent patent owners from abusing their exclusive rights generated by patent, such as failure to put those rights into use, including failure to supply the market with patented products and refusal to grant a license for the use of their patent rights on reasonable terms or setting unreasonable high prices for the patented products when they actually reach the market..

The Paris Convention also provides for the right of priority in the case of patents, marks and industrial designs. The Convention priority right, also called Paris Convention priority right or Union priority right, was also established by Article 4 of the Paris Convention, and is regarded as one of the cornerstones of the Paris Convention.⁷¹ This right means that, on the basis of a regular first application filed in one of the Contracting States, the applicant may, within a certain period of time (12 months for patents and utility models), apply for protection in any of the other Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application.⁷²

⁶⁹ World Intellectual Property Organization, 'Summaries of Conventions, Treaties and Agreements Administered by WIPO' available at http://www.wipo.int/edocs/pubdocs/en/intproperty/442/wipo_pub_442.pdf (accessed on 24 July 2017).

⁷⁰Bodenhausen G. H. C., *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised in Stockholm in 1967* (1968) BIRPI, p. 25.

⁷¹ European Patent Office "Decision T 15/01 (Mystery Swine Disease/SDLO) of 17 June 2004 of Board of Appeal 3.3.01 of the European Patent Office (EP) 2004 available at <http://www.epo.org/law-practice/case-law-appeals/recent/t010015ep1.html> (accessed on 24 July 2017).

⁷² World Intellectual Property Organization, 'Summaries of Conventions, Treaties and Agreements Administered by WIPO' available at http://www.wipo.int/edocs/pubdocs/en/intproperty/442/wipo_pub_442.pdf (accessed on 24 July 2017).

The Convention also established certain common rules that must be observed by all the contracting parties in relation to patents: The most potent one was the rule that made patents granted in different countries on the same invention independent of each other. This does not mean that the fact that a patent has been granted or refused in one country, it should be equally granted or refused in another contracting state.⁷³

Besides its opening up of the international space for patents regulation, the Paris Convention was marred with scepticism. The developed countries were not satisfied with the fact that developing countries were not willing to sign the Convention and thus would not make domestic legislations to ensure adequate protection of the industrial property.⁷⁴ The resulting push and pull between the developed and developing countries in 1988, resulted in 49 member states excluding pharmaceutical patents from patentability, while 10 states excluded pharmaceutical processes.⁷⁵ These developments led to an increase in the voices calling for an improved multilateral system that will ensure strong protection for intellectual property rights, including patents. The next in line was Patent Treaty Corporation Agreement in 1970.

3.3 Patent Cooperation Treaty

The Patent Cooperation Treaty (referred to as PCT in this work) was concluded in 1970 and came into existence in 1978, and now has 133 countries as contracting signatories. All the East Africa Community member states, except Burundi, are contracting parties to the PCT. Kenya became the first member of EAC to deposit its instruments of accession to the Director-General of World Intellectual Property Organization (widely referred to as WIPO) on 8th March 1994.⁷⁶ The United Republic of Tanzania deposited its instrument of accession to the PCT on June 14, 1999 and it became bound by the treaty on the 14th of September 1999.⁷⁷ On 31 May 2011 Rwanda deposited its instrument of accession of the PCT; it became a contracting state on 31 August 2011.

⁷³ World Intellectual Property Organization, 'Summaries of Conventions, Treaties and Agreements Administered by WIPO' available at http://www.wipo.int/edocs/pubdocs/en/intproperty/442/wipo_pub_442.pdf (accessed on 24 July 2017).

⁷⁴ H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2008) OUP, p. 36 and 38.

⁷⁵ H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2008) OUP, p. 39-40.

⁷⁶ WIPO, 'PCT Notification No. 90 Patent Cooperation Treaty (PCT): Accession by the Republic of Kenya' available at http://www.wipo.int/treaties/en/notifications/pct/treaty_pct_90.html (accessed on 24 July 2017).

⁷⁷ WIPO, 'Patent Cooperation Treaty (PCT): Accession by the United Republic of Tanzania Brings to 103 the Number of Contracting States of the PCT' available at http://www.wipo.int/pressroom/en/prdocs/1999/wipo_upd_1999_65.html (accessed on 24 July 2017).

Any resident or national of a contracting state of the PCT may file an international application under the PCT that specifies the office which should conduct the search. The PCT application serves as an application filed in each designated contracting state. However, in order to obtain patent protection in a particular state, a patent needs to be granted by that state to the claimed invention contained in the international application. The advantage of a PCT application is that fewer searches need be conducted and the process is therefore less expensive. Thus, although application and search are to some extent standardised across offices, grants are not. In fact, 87 per cent of the PCT applications go to one of three patent offices for search: those in the United States, Europe, and Japan.⁷⁸ Most of the other systems rely on these offices for the search process and follow them in a number of other areas. Therefore, much of what follows focuses on these three major systems.

3.4 The Trade-Related-Aspects of Intellectual Property Agreement (1994)

When the WTO Agreement was signed in 1994 as a multilateral trade treaty in 1994, the TRIPS Agreement was also attached to it as annex 1C and the signing parties to the WTO automatically became parties to the TRIPS. The TRIPS covers all of the main areas of IPRs.⁷⁹ It is said to represent ‘theoretically, one form of incentive for innovation in developed and developing countries.’⁸⁰ For the first time, the TRIPS Agreement established a nexus between Intellectual Property and Trade and the impact of the former over the later.⁸¹ It departs from the IP related provisions in the Paris Convention setting up a multilateral mechanism for dispute settlement between States Parties on matters related to IP. At the same time, it recognised ‘the special needs of the least developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations’.⁸²

The purpose of the Agreement is well articulated in Articles 7 and 8. Article 7 calls for a need to strike a balance between the interests of the rights holders and the users of technological knowledge ‘in a manner conducive to social and economic welfare.’ As Hestermeyer posits,

⁷⁸ As above.

⁷⁹ L. Bentley and B. Sherman, *Intellectual Property Law* (3rd Edition, 2009), OUP, p. 7.

⁸⁰ CIPIH, ‘Public Health, Innovation and Intellectual Property Rights’ (2006) WHO, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> [CIPIH Report 2006], p. 83.

⁸¹ TRIPS Agreement, art.27.

⁸² TRIPS Agreement, Preamble.

‘accessibility of medicine is one of the interests of society that have to be brought into balance with the TRIPS’⁸³ He uses Article 8 of the TRIPS to justify his stance.

Article 8 gives Members a policy space to take legislative measures for the protection of public health and promotion of socio-economic and technological development. These legislative measures may be required by the State to ‘prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.’⁸⁴

The adoption of the TRIPS was of great importance for pharmaceutical patents, because it created uniformity in legislation in the sector. The pre-TRIPS literature shows that patent protection for pharmaceuticals was not provided for in more than 50 countries, and the patent duration was much shorter than 20 years.⁸⁵

Although TRIPs might be seen as a victory accord to the right holders in the pharmaceutical industry, since their rights are well enshrined in Article 27 such as the ‘right of the patent owner to prevent unauthorised persons from using the patented process and making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process, it also acknowledged the rights of the users of these rights in the pharmaceutical industry. It provides for some flexibilities, the most important (and most disputed) of which, in relation to public health and access to essential medicines, is compulsory licensing provided for in Article 31.’⁸⁶

The TRIPS Agreement also contained some transitional provisions to allow developing countries and least developed countries to delay the implementation of the IP protection for products in areas of technology, e.g. pharmaceutical products.⁸⁷ This period expired in 2005

⁸³Hestermeyer, H. *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2008) OUP, p. 51.

⁸⁴Hestermeyer, H. *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2008) OUP, p. 51.

⁸⁵ Carlos M. Correa, ICTSD, WHO, UNCTAD ‘Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper’ (2006) available at: http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf [Guidelines 2006], p. Vii

⁸⁶ Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 117.

⁸⁷ TRIPS Agreement, Art. 65.

for the developing countries, while the initial deadline of 1st July 2013 that was given to the least developed countries was extended to 1st January 2033.⁸⁸

The next section discusses the Doha Declaration which reaffirmed flexibility of TRIPS member states in circumventing patent rights for promotion of public health and better access to essential medicines.

3.5 The Doha Declaration

After the enactment of the TRIPS Agreement, it became apparent that implementation of the Agreement's intellectual property standards is having a considerable impact on access to medicines and public health. While the developed countries had already embarked on enacting legislations that maximise protection of IP rights without creating room for their flexibility in the situations that needs improvement of public health in the developing and least developed countries, the developing countries (that were TRIPS compliant) on the other hand were making their legislations in the manner that promotes access to public health, particularly emphasizing on the maximum use of compulsory licenses and parallel import regimes set out in article 31 of the TRIPS.

These parallel developments brought about a conflict between the rich developed countries and poor developing countries. At the behest of the influential pharmaceutical lobby developed nations would threaten sanctions on countries that attempted to take advantage of parallel importing or compulsory licensing. For example in 1997, the United States notoriously threatened trade sanctions against South Africa unless they repealed a section of the Medicines and Related Substances Control Amendment Act which allowed compulsory licensing and parallel importing, despite it being TRIPS compliant.⁸⁹

To avert further conflicts on the need to protect IP rights and public health, the WTO at a Ministerial Conferences held in a Qatari capital of Doha November 14, 2001 adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).⁹⁰ This

⁸⁸ World Trade Organization, WTO members agree to extend drug patent exemption for poorest members' (2015) available at https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm(accessed on 28 July 2017).

⁸⁹ International Intellectual Property Institute. Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa. World Intellectual Property Organization; 2000 available at. http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf(accessed on 28 July 2017).

⁹⁰ WTO, 'Declaration on the TRIPS Agreement on Public Health', WT/MIN(01)/DEC/2, 20 November 2001, [Doha Declaration] available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed on 28 July 2017).

declaration sought to address three important issues that had arisen from the interpretation of pharmaceutical-patents-related provisions of the TRIPS.

First, it sets the records straight on the issue of whether the member states can interpret the TRIPS agreement in a manner that favoured the advancement of public health. Paragraph 4 confirmed the Agreement's compatibility with public health and the right of member nations to interpret the agreement with the aim of improving public health crises.

Secondly, the Doha Declaration sought to allay concerns of external pressure that was being exerted on the developing countries by the developed counterparts to omit measures in the legislations (though TRIPS compliant) that encourage the use of TRIPS flexibilities for public health purposes. In paragraph 5 (d), it was clarified that member nations have the right to engage in parallel importing without interference from external actors.

The third concern related to the practical applicability of the parallel import and compulsory regimes set up by the TRIPS, particularly whether compulsory licensing is permissible is used to supply the market in the authorising country.⁹¹ Article 31(f) of the TRIPS dealing with 'other use without authorisation of the right holder'⁹² stipulates that manufacture of a patented product under article 31 shall be 'predominantly for the domestic market of the member authorising such use' with the result that members without sufficient manufacturing capacity could not make use of this flexibility without flouting this provision of the TRIPS Agreement. The difficulty with this situation is that developing nations rarely have the infrastructure required to support a stable pharmaceutical industry. That is why Paragraph 6 of the Doha Declaration came in handy in addressing this as below:

'We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.'

The council did not meet the 2002 deadline; however, it would later come up with the solution on 30th August 2003⁹³ recommending that all least developed countries² that are

⁹¹Junaid S, 'Scrutinized: The TRIPS Agreement and Public Health' 2006 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323529/#b8-mjm0902p152> (accessed on 27 July 2017).

⁹² A note on article 31 provides that "other use" refers to use other than that allowed under article 30 which deals to exceptions to rights conferred.

⁹³ World Trade Organization. TRIPS Council. Decision of 30 August 2003; 2003. Available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed on 28 July 2017).

WTO members will be exempted from the requirement of themselves producing patented drugs under compulsory license. And those countries that fall outside the least developed country category can issue a compulsory license (if the drug is patented in its jurisdiction) for the supply of a developing country if that country's public health situation falls under certain criteria such as: Evidence of a public health concern; Evidence that the importer's pharmaceutical industry is non-existent or inadequate; and proof that the drug will be used only for public, non-commercial purposes.⁹⁴

For the above proposition to have a legal status, paragraph 11 recommended an amendment be made to the TRIPS Agreement. The Decision suggested a 'Protocol Amending the TRIPS Agreement', which stipulated that the Agreement would be changed through Article 31bis following Article 31, and an Annex to the TRIPS following Article 73.⁹⁵ Although this decision seemed like a viable solution to the problem, the amendment of the TRIPS, in a typical fashion of push-and-pull-style of negotiating WTO Agreements, took more than ten years to enter into force. On 23 January 2017, the WTO Secretariat announced the entering into force of the first ever amendment to the Agreement on the Trade-Related Aspects of Intellectual Property (TRIPS), and the first for any WTO Accord, consisting on new Article 31 bis related to compulsory licenses for the export of pharmaceutical products.⁹⁶ This secured for developing countries a legal pathway to access affordable medicines under WTO rules.

Regardless of the above positive development, only one country has made use of the Doha declaration's paragraph 6 system. This country is Rwanda, a member of the EAC. In July 2007 Rwanda notified the TRIPS Council of its intention to use the Paragraph 6 system to import anti-retroviral combination drug for HIV/AIDS from Canada, and in October 2007 Canada also notified its intention to use the system to meet Rwanda's request.⁹⁷

As seen above, the PCT and Paris convention have similarities and differences. On similarities: Like the Paris Convention, the Patent Cooperation Treaty (PCT) is an

⁹⁴Junaid S, 'Scrutinized: The TRIPS Agreement and Public Health' 2006 available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323529/#b8-mjm0902p152> (accessed on 27 July 2017).

⁹⁵ WTO, 'Amendment of the TRIPS Agreement', WT/L/641, 8 December 2005 [2005 Amendment]

⁹⁶ World Trade Organization, WTO IP rules amended to ease poor countries' access to affordable medicines, (2017) available at https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm (accessed on 28 July 2017).

⁹⁷ Council for TRIPS, 'Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Canada', WTO Doc. IP/N/10/CAN/1, 8 October 2007.

international treaty. Secondly like the Paris Convention, it allows the filing of a single application in the applicant's home country while preserving rights in other countries.

The difference is that the PCT is expressly equivalent to filing a patent application in each designated PCT country. The PCT procedure also includes an International Search Report, which may assist the applicant in determining what prior art the application might face before the individual national patent offices. An optional international examination procedure allows the presentation of further amendments and arguments, just like examination in front of the national patent offices. The relationship between the aforementioned two international treaties and the TRIPS is inherent in the standards of IPR protection and flexibilities contained in either Paris Convention or Patent Cooperation Treaty. The TRIPS standards, concerning availability, scope and use of IPRs, are reproduced literally from articles 1 to 12 and 19 of the Paris Convention.⁹⁸ Additionally, TRIPS refers to the above convention in its enforcement and acquisition of IPRs requirements.⁹⁹

3.6 The Lusaka Agreement Establishing Africa Regional Intellectual Property Organisation (1982)

The conception of Africa Regional Intellectual Property Organisation (ARIPO) dates back to a Regional Seminar on patents and copyright for English - speaking African countries held in Nairobi, Kenya, in the early seventies. It was at this seminar that the idea for the establishment of ARIPO was midwived. It was thereafter established in 1973 - through the help of the United Nations Economic Commission for Africa (UNECA) and the World Intellectual Property Organisation (WIPO) - following a request by English-speaking countries for assistance in pooling their resources together in industrial property matters by establishing a regional organisation.¹⁰⁰

Following a number of meetings at ECA headquarters in Addis Ababa and WIPO in Geneva, a draft Agreement on the Creation of the Industrial Property Organisation for English-

⁹⁸ See Articles 9 to 40 TRIPS with regard to Copyright and Related Rights, Trademarks, Geographical Indications, Industrial Designs, Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-Competitiveness Practices in Contractual Licences.

⁹⁹ Trade Related-Aspects of Intellectual Property (1994), Art. 41-62

¹⁰⁰ African Regional Intellectual Property Organization, 'About ARIPO' available at <http://www.aripo.org/index.php/aboutaripo> (accessed on 27 July 2017).

speaking Africa (ESARIPO) was prepared. This agreement, now known as the Lusaka Agreement, was adopted in Lusaka, Zambia on 9 December 1976.¹⁰¹

The Lusaka Agreement gave birth to the African Regional Intellectual Property Organisation in its Article IV. The Agreement established objectives of the Organisation in Article III which laid a foundation for the Organisation's reason d'être, i.e., development of further legal instruments that should elaborate operational details of the work of the Organisation within the ambit of those objectives.¹⁰² The 1982 Harare Protocol on Patents and Industrial Designs became one of these legal instruments within the framework of the African Regional Intellectual Property Organisation (ARIPO) to deal with the substantive issues of patents, industrial designs and utility models,¹⁰³ while the Banjul Protocol was designated to cover marks (Trademarks and service marks).¹⁰⁴ This study, for obvious reasons, focuses of the Harare Protocol on patents.

The ARIPO, based in Harare, Zimbabwe is empowered by the Harare Protocol on Patents and Industrial Designs to grant patents and to register utility models and industrial designs on behalf of contracting states. The Protocol empowers the ARIPO Office to receive and process patent and industrial design applications on behalf of states party to the Protocol.¹⁰⁵

The following countries are some of the 19 contracting states to the protocol: Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, São Tomé and Príncipe, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

Under the Protocol an applicant for the grant of a patent or the registration of an industrial design can, by filing only one application, designate any of the contracting states in which he or she wishes his/her invention or industrial design to be accorded protection. The Protocol requires the filing of the application to be made with either one of the contracting states or directly with the ARIPO Office.¹⁰⁶

¹⁰¹ African Regional Intellectual Property Organization, 'About ARIPO' available at <http://www.aripo.org/index.php/aboutaripo> (accessed on 27 July 2017).

¹⁰² African Regional Intellectual Property Organization, 'The ARIPO Protocols' available at <http://www.aripo.org/index.php/about-aripo/legal-framework> (accessed 23 July 2017).

¹⁰³ This substantive area was added by a 2001 amendment to the Protocol.

¹⁰⁴ Kongolo T "The African Intellectual Property Organizations: The necessity of adopting one uniform system for all Africa" (2000) 3(5) Journal of World Intellectual Property 717.

¹⁰⁵ African Regional Intellectual Property Organization, 'The ARIPO Protocols' available at <http://www.aripo.org/index.php/about-aripo/legal-framework> (accessed 23 July 2017).

¹⁰⁶ African Regional Intellectual Property Organization, 'The ARIPO Protocols'

In Kenya, for instance, the Kenya Industrial Property Institute (KIPI) acts as a receiving office where a regional application is filed with it by a national or a resident of Kenya. A regional application filed with the Institute as the receiving office under the Protocol should be in triplicate; be in English; and be accompanied by the transmittal fee.¹⁰⁷

A patent, in respect of which Kenya is a designated state, granted by ARIPO by virtue of the ARIPO Protocol has the same effect in Kenya as a patent granted under the Industrial Properties Act except where the Managing Director communicates to ARIPO, in respect of the application thereof, a decision in accordance with the provisions of the Protocol that if a patent is granted by ARIPO, that patent shall have no effect in Kenya.

It therefore follows from the foregoing discussion that a patent granted by the ARIPO office shall, in each designated State, have the same effect as one registered, granted or otherwise having effect under the national law of the applicable designated country.¹⁰⁸ However, there is a requirement, under section 3(10) of the Harare protocol that a grant of the patent must conform with the applicable domestic law, hence, a patent granted by the ARIPO shall in each designated State be subject to the provisions of the applicable domestic law on compulsory licences, forfeiture or the use of patented inventions in the public interest. The implication is that domestic IP patent office retains substantive autonomy notwithstanding the operation of a supranational regional registry.

3.8 Chapter Conclusion

Chapter three has highlighted both the international and regional frameworks, and instruments, for patent protection. The TRIPS, Doha Declaration and ARIPO's Harare Protocol on patents and industrial designs have been considered at length. More discussion shall be done on them to the extent of their relevance in the next chapter, which delves into the EAC legal framework on patent and access to public health. It has been argued in this chapter that TRIPs, from the beginning, set strict mechanism for patent rights protection.

The Doha declaration, whose legal status was affirmed in January 2017 and which was made part and parcel of the TRIPs by that affirmation, came in to balance between the rights of the patent owners and that of those in dire need of effective public health provision. The access

<http://www.aripo.org/index.php/about-aripo/legal-framework> (accessed 23 July 2017).

¹⁰⁷ Kenya Industrial Property Institute, 'Regional Patents (ARIPO)'

<http://www.kipi.go.ke/index.php/regionalpatents-aripo> (accessed 23 July 2017).

¹⁰⁸ Section 2 of the Harare Protocol on Patents and Industrial Designs.

to essential medicines situation in EAC and its individual member states is wanting and that is where the next chapter commences its assessment.



CHAPTER FOUR

EAC SUB-REGIONAL AND NATIONAL FRAMEWORKS ON PATENTS

4.1 Introduction

This chapter focuses on discussing each applicable patent law in each of the EAC partner states and EAC regional legal framework that encourage cooperation in the IP and health sectors among the EAC partner states. To achieve this, a review of each EAC partner state's patent legislation shall be made to the extent of how they seek to optimise the utilisation of the TRIPS flexibilities on access to medicines; the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation shall be used as a guide in discussing the regional framework. Finally, the challenges facing these nations in their individual and collective efforts to implement TRIPS flexibilities for public health purposes shall be underlined. This will subsequently inform the potential solutions and recommend actions this study will make in Chapter five.

4.2 Spheres of cooperation between the EAC partner states on intellectual property

As mentioned in the last chapters, EAC is a regional intergovernmental organisation consisting of 6 partner states of: Burundi, Kenya, Rwanda, South Sudan, Uganda, and United Republic of Tanzania.¹⁰⁹ The current EAC was re-established in 2000 following its initial collapse in 1977.¹¹⁰ Its establishing legal instrument is the EAC Treaty (the Treaty), particularly Article 2 of the Treaty creates the EAC regional block. It was signed on 30 November 1999 and entered into force on 7 July 2000 after its ratification by the founding three Partner States - Kenya, Tanzania and Uganda. The Republic of Rwanda and the Republic of Burundi later joined the community on 18 June 2007 after successfully submitting their acceding instruments and became full Members with effect from 1 July 2007.¹¹¹ The Republic of South Sudan acceded to the Treaty on 15 April 2016 and become a full Member on 15 August 2016. Five Member states of the EAC are members of the WTO save for the Republic of South Sudan, which gained independence in 2011 and is yet to join, and be bounded by rules set under, the multilateral trading system.

¹⁰⁹East Africa Community 'Overview of EAC' (2017) available at <http://www.eac.int/about/overview> (accessed on 11 August 2017).

¹¹⁰ East Africa Community 'History of the EAC' (2017) available at <http://www.eac.int/about/EAC-history> (accessed on 11 August 2017).

¹¹¹East Africa Community 'History of the EAC' (2017)available at <http://www.eac.int/about/EAC-history> (accessed on 11 August 2017).

The core objective of the resuscitated EAC is to ‘develop policies and programmes aimed at widening and deepening cooperation among partner states in political, economic and social affairs for their mutual benefits.’ To this end the EAC countries established a Customs Union in 2005, a Common Market in 2010, subsequently a Monetary Union protocol in 2013 which laid groundwork for the establishment of the permanent Monetary Union within 10 years. The ultimate goal of the EAC is to establish a political union.¹¹²

To strengthen its political, economic and social integration in the Intellectual Property Sector, the EAC partner states committed themselves in the Common Market Protocol to ‘cooperate in the promotion and protection of intellectual property rights.’¹¹³ Article 43(2b) peculiarly mentions patents as one of the IP area that the members need to administratively collaborate in promoting and protecting¹¹⁴ for effective functioning of the common market and attainment of the mutual benefits. In the health sector, the partner states undertake, in Article 118 of the establishing Treaty, to:

‘take joint action towards the prevention and control of communicable and non-communicable diseases and to control pandemics and epidemics of communicable and vector-borne diseases such as HIV-AIDS, cholera, malaria, hepatitis and yellow fever that might endanger the health and welfare of the residents of the Partner States, and to co-operate in facilitating mass immunization and other public health community campaigns.’¹¹⁵

This is where the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation comes in 2013. It provides a legal framework to guide the EAC Partner States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilise the Public Health-related WTO-TRIPS Flexibilities. It is therefore incumbent for individual partner state’s legislatures to make these adjustments. The following section highlights the existing patent laws in each of the EAC member states and how they have incorporated TRIPS-flexibilities.

¹¹² Treaty Establishing East Africa Community, 1999 (2000), Article 5 available at http://www.eac.int/sites/default/files/docs/treaty_eac_amended-2006_1999.pdf (accessed on 11 August 2017)

¹¹³ East African Community Protocol on the Establishment of the East African Community Common Market (2010), Article 5(3) & 43.

¹¹⁴ East African Community Protocol on the Establishment of the East African Community Common Market (2010), Article 43(2b).

¹¹⁵ EAC ‘The Treaty for the Establishment of the East African Community’ (1999), Article 118(a).

4.3 Overview of the EAC Policy Statement on the Maximum Utilisation of WTO-TRIPS Flexibilities on Public Health

There are in-built flexibilities in the TRIPS Agreement that developing and least developed countries can use to remedy the negative effects of pharmaceutical patents. This mini-thesis will limit itself to those flexibilities identified by the EAC Policy and Protocol¹¹⁶ that needs to be maximised by the EAC member States. These include: Transition period on pharmaceutical products and processes; patentability criteria; materials excluded from patentability; research exception; research exceptions; marketing approval (Bolar) exception; test data protection; disclosure requirements; administrative opposition procedures; compulsory licensing; parallel imports and exhaustion of patent rights; and anti-competitive behaviour and patent abuse. The following is their overview:

a. Transition period on pharmaceutical products and processes

Transition period refers to the duration under which the LDCs are exempted to apply and enforce patent protection obligations, enshrined in the TRIPS Agreement, on pharmaceutical products and/or processes and clinical test data protection.¹¹⁷ At the onset of the promulgation of TRIPS in 1994, the LDCs were given until 1st January 2006 to comply with the TRIPS minimum standard obligations of patent (including pharmaceutical patents) protection, this period was extended in 2002 to 1st January 2016¹¹⁸ and again in January 2017 to 1st January 2043. The rationale of this transition period and its triple extension is premised on the ‘special needs and requirements of least developed country members, their economic, financial and administrative constraints, and their need for flexibilities to create a viable technology base.’¹¹⁹

Above provision notwithstanding, Article 70(8) of the TRIPS Agreement requires the implementation of a ‘mailbox’ obligation for any Member that ‘does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products. The ‘mailbox’ obligation basically stipulates that Members

¹¹⁶EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013).

¹¹⁷Lalitha L ‘Doha Declaration and Public Health Issues’ (2008) 13 Journal of Intellectual Property Rights, p. 401.

¹¹⁸ WTO ‘Responding to least developed countries’ special needs in intellectual property’ (2013) available at https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (accessed on 18 August 2017).

¹¹⁹Trade Related-Aspects of Intellectual Property Agreement, art.66(1).

should accept patent applications for examination during the transition period and grant a patent to the successful applications upon the expiry of the transitional period.¹²⁰

In the event the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, article 70(9) instructs that it had to — subject to certain conditions set by the government — provide the patent applicant an exclusive marketing right for the product for five years, or until a decision on a product patent was taken, whichever was shorter.

The EAC policy statement on the transition period instructively provides that ‘all EAC LDC Partner States with a ‘mailbox’ provision in their national (draft) patent laws can abolish this provision. Additionally, EAC Partner States’ patent laws can provide for a possible extension of the transition period, as may be agreed upon by the Council for TRIPS.¹²¹ Its justification is premised on the need to ‘protect generic pharmaceutical producers who have, during the transition period, used products that may enjoy patent protection after 2016, and mitigate the adverse effects of such a ‘mailbox’ rule on generic production.’¹²²

b. Patentability Criteria

A discussion on Patentability criteria under the WTO-TRIPS Agreement has been presented in chapter two. Article 27 of the TRIPS Agreement stipulates that ‘patents shall be made available to all inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.’ It was also noted in Chapter two that TRIPS does precisely define the three patentability criteria. This lack of precision in defining the criteria for patentability gives advantage to the member state to adopt their independent definitions of ‘novelty’, inventive step and industrial application. The question is in how best they make use of this flexibility.

As one of the TRIPS-flexibilities available to the developing and least developed countries, the EAC policy encourages its partner states to apply a strict application of the three patentability criteria in their patent laws and patent examination guidelines to enable them to maintain a broad policy domain in order to benefit public health purposes.

¹²⁰Ho C.M ‘Access to medicines in the global economy: International Agreements on Patents and Related Rights,’ (2011), p.85.

¹²¹The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.12.

¹²²The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.12.

On the ‘Novelty’ criterion, the policy advocates for the use of ‘wide prior art’ definitions which entails everything in the public domain, ‘whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public.’¹²³ The rationale, as Roin notes, is premised on the fact that ‘... if an invention is not new, then it is presumed that the public already has access to it, and thus that there is no reason to issue a patent for it.’¹²⁴

The EAC policy requires that the invention has to be non obvious to a person ‘highly’ skilled in the art. The standard of the ‘highly skilled person in the art’ envisages involvement of more than one expert to examine the invention before it’s accepted for patent. This would imply that an early examination done by one expert can be subjected to further examination by a more highly skilled expert than the first one. This is a departure from the European Patent Office (EPO) jurisprudence which requires an invention be determined by ‘a person skilled in the art’ of the inventive step test.¹²⁵

However, The EAC policy relies on the United State Patent and Trademark Office (USPTO) guidelines EPO threshold for determining ‘industrial applicability’ of an invention. It implores on its members to limit the patentability of research tools only to those for which a specific use has been identified.¹²⁶ This strict industrial application tests is to ensure inadmissibility of applications for the research tools which may be used for a variety of different uses.

c. Materials Excluded from Patentability

As a general requirement, article 27(1) of TRIPS instructs WTO members to make available patents for all inventions, whether products or processes, in all fields of technology (including medicines) without any discrimination as to place of invention, field of technology, import or local production. However, article 27(3) of the TRIPs Agreement provides that Member States may exclude from patentability certain inventions. These include: ‘Diagnostic, therapeutic and surgical methods for the treatment of humans or animals; Plants and animals other than micro-organisms, and essentially biological processes

¹²³The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.12.

¹²⁴Roin N. ‘Unpatentable Drugs and the Standards of Patentability’ (2009) 87 Texas Law Review 518.

¹²⁵Convention on the Grant of European Patents (European Patent Convention) (2016) art.56.

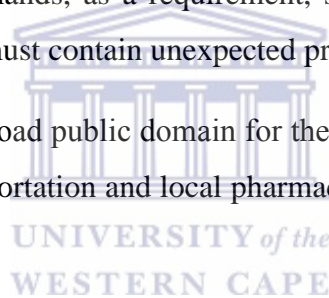
¹²⁶The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.13.

for the production of plants or animals other than non-biological and microbiological processes.¹²⁷

The EAC policy proceeds, in imploring member states to incorporate these exclusions in their national legislations, from the understanding that the TRIPs Agreement does not give definition of the term ‘invention.’ Thus, thus the policy opines that the EAC member states have the flexibility to define the term in their respective legislations, and in doing so, exclude, from the definition, natural substances, new uses and product derivatives.

The justification for the foregoing is grounded on, one, curbing the ‘evergreening’ of patents-where new patents are given for discovery of a new use of already patented substances. Secondly, the exclusion of derivatives of medical products and processes from patentability is to avoid ‘slight and insignificant variations of originally patented pharmaceutical substances from restricting the public access. To achieve this, the policy recommends use of the Indian and USA approaches which demands, as a requirement, significantly enhanced therapeutic efficacy and that the inventions must contain unexpected properties respectively.

The objective is to ‘maintain a broad public domain for the promotion of access to affordable health products through both importation and local pharmaceutical production of high quality generic medicines.’¹²⁸



d. Research Exception

This flexibility is derived from the proviso contained in article 30 of the TRIPs Agreement which provides that:

‘members to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’¹²⁹

The above provision thus allows WTO Members to carve out research exceptions to patent rights that meet the so-called “three-step test”, i.e. that the exception: (1) is limited; (2) does not unreasonably conflict with normal exploitation; and (3) does not unreasonably prejudice the legitimate interests of the patent holder. To strike this balance, the EAC policy

¹²⁷ As above.

¹²⁸ As above, p.14.

¹²⁹ Trade Related-Aspects of Intellectual Property Agreement (1995), art.30.

acknowledges a clear research exception permitting the use of patented inventions as a means to this end.

The EAC Policy underscores this exception and emphasizes that ‘a strong research base is fundamental to the competitiveness of the EAC region vis-à-vis other markets and for the promotion of social welfare in the region, it is important that the right balance is struck between the system of patent rights and the opportunity to conduct research.’ It therefore implores on the partner states to provide for a research exception authorising local scientists and researchers to use patented substances for both scientific and commercial research ‘on’ a patented substance in order to gain new knowledge about the substance itself. The predominant purpose of this commercial research is strictly for the improvement of the patented substances, as opposed to mere reverse engineering and copying of the patented invention.¹³⁰

Furthermore, the policy recommends inclusion of clauses that provide researchers with a right to claim a non-exclusive licence for the use of such research tools against payment of reasonable compensation.

e. Marketing Approval (Bolar) Exception

The EAC policy identifies marketing approval or Bolar exception as another flexibility that can be justified under article 30 of the TRIPs agreement. The policy recommends changes in the partner states’ patent legislations to enable early market entry of generic pharmaceutical products as soon as the term of the patent expires. To achieve this, these legislations must incorporate clauses that, one, authorise the use of patented substances by interested parties for marketing approvals by national and foreign medicines regulatory, and two, clarify the scope of the marketing approval/Bolar exception to the effect that generic producers may use patented substances for acts ‘reasonably related’ to the development and submission of information required for marketing approvals.¹³¹

It appears from the foregoing that generic medicines producers could be allowed to file their application for market approval of competing pharmaceutical products, that is, clinical trials and other preparatory activities on or with a patented pharmaceutical product, prior to the expiry of the patent term.

¹³⁰The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.15.

¹³¹The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.15.

f. Test Data Protection

Test data being referred to here is the information pharmaceutical producer present, as a condition for obtaining marketing approval, to the Medicines Regulatory Authorities (MRAs) regarding safety, effectiveness and quality that is generated in the preclinical and clinical testing of a medicine. With some limitations, article 39(3) of the TRIPs Agreement requires governments to protect against unfair commercial use of confidential test data submitted in the process of securing regulatory and marketing approval of new pharmaceutical products and agricultural chemical products. The limitation in this provision is the fact that TRIPs is silent on constitutes ‘unfair commercial use’. It is therefore incumbent on the members to determine the test for unfair commercial use.

The EAC policy interpretation of article 39(3) above suggests that the ‘provision only requires protection of undisclosed test data originated from new chemical entities which require considerable effort to generate.’ Thus, it calls on the EAC partner states (including the LDCs after the expiry of the transition period) to adopt the misappropriation approach which implement a regime of test data protection that allows MRAs to rely on the originators’ test data for the approval of generic medicines. This approach is aimed at boosting local generic production compared to the compensation liability approach. As the policy observes:

‘...a compensatory liability approach would also authorise MRAs to rely on originator test data provided. However, the generic competitor, in exchange, would have to pay compensation to the data originator, and this might exceed the local generic producers’ financial capabilities.’¹³²

The importance of the misappropriation approach is premised on the reality that in some circumstances EAC Partner States could, jointly or individually, become obliged, either under limitation of a free trade agreement or in response to overwhelming bargaining power, to adopt a regime of data exclusivity prohibiting MRAs reliance on originators’ test data for the approval of generic medicines. In the face of these situations, they will have an option to mitigate the potentially harmful effects of such a system on local generic producers and medicine availability, by, authorising MRAs to approve generic medicines for marketing on the basis of the originator data in cases where national health concerns prevail, for instance, in cases of compulsory licensing.

¹³² As above.

Finally, the policy advises the partner states from establishing, in their patent legislations, a linkage between patent protection and marketing authorisation, since this linkage would prevent MRAs from granting marketing approval for generic medicines before the lapse of the respective patent. The objective of all the foregoing is to avoid unnecessary costly and lengthy clinical trials of generic pharmaceutical products.

g. Disclosure Requirements

The EAC policy on disclosure requirements is contained at policy statement No. 7. It seeks to promote technological learning and follow-on innovations by local innovators in EAC. To achieve this, the partner states are implored to enact legislations that ‘require patent applicants to disclose all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the respective EAC Partner State.’¹³³ Additionally, these applicants could be required to provide information concerning their corresponding foreign applications and grants, and be obliged to disclose the International Non-proprietary Name (INN) of a pharmaceutical substance or an active pharmaceutical ingredient as soon as the INN is available.

The rationale for the foregoing disclosure requirement is premised on, one, the need to ensure the effective operation of the patent system, and secondly, to achieve this effectiveness, the disclosures of patented inventions need to be: sufficient, complete, thorough and precise in order to enable those skilled in the art to practise the invention based on the information disclosed sufficiently definite to give the public notice of what constitutes an infringement; identify the best mode of practising the invention known to the inventor when they file a patent application.¹³⁴

h. Administrative Opposition Procedures

The Policy proposes an amendment of EAC partner states’ patent legislations to widen the scope of pre-grant and post-grant administrative opposition procedures.¹³⁵ The rationale being that with the continues expansion of patent rights into new areas of technology, patent examiners unfamiliar with prior art may lack the expertise to assess the patentability criteria of an invention. To mitigate this, national legislations ought to ‘provide mechanisms to challenge and revoke the validity of a patent where closer scrutiny reveals that the

¹³³The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013), p.17.

¹³⁴ As above (note 23).

¹³⁵ See note 23 above, p.17.

patentability criteria may not be met.¹³⁶ To meet this end the permission of competent third parties, within a certain span of time, to oppose patent applications before national patent offices and ARIPO (except for Rwanda and Burundi, which are not ARIPO Members) becomes paramount. This is to ensure that patents are only granted to inventions that meet the three patentability criteria and to avoid time- and cost-intensive post-grant litigation.

i. Compulsory Licensing

Compulsory license is a document or an authorisation given by the government, or an authority exercising the government powers (such as judicial orders), that allows any person or body corporate to produce the generic patented product or process without consent of the person or institution that owns/registered the patent.¹³⁷ It is usually granted after the failed attempts to persuade the patent owner to voluntarily allow third parties to exploit the patent.¹³⁸ The Paris Convention, as previously noted, based the grant of compulsory licence on failure to work or insufficient working of the patented invention.¹³⁹

In the public health domain, it is used by governments as a policy tool to address, inter alia, high prices of medicines, anti-competitive practices by pharmaceutical companies, failure by pharmaceutical patent holders to sufficiently supply the market with needed medicines, and in addressing emergency public health situations.

The TRIPs Agreement, in Article 31, leaves Members the freedom to determine grounds for granting compulsory licences, provided that the conditions and procedures imposed by Article 31 are met, and taking into account the other provisions of TRIPs. These include the need to grant such licences on merit of each application, evidence of the prior request for and failure by pharmaceutical patent holders to give voluntary license, and non-exclusivity of the licence. Additionally, the scope and duration of such use without the patent holder's authorization must be limited to the authorised purposes. It must be noted that re-assigning the compulsory licence to other third parties is expressly prohibited under this article. And

¹³⁶ As above.

¹³⁷World Trade Organization, Compulsory licensing of pharmaceuticals and TRIPs, available at https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (accessed on 14 August 2017).

¹³⁸Musungu F. Sisule, Villanueva Susan &Blasetti Roxana, Utilizing Trips Flexibilities For Public Health Protection through South-South Regional Frameworks, (2004), p.11 available at <http://www.eldis.org/document/A17810> (accessed on 14 August 2017).

¹³⁹WIPO, Summary of the Paris Convention for the Protection of Industrial Property (1883), available at http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (accessed on 16 August 2017).

the authorisation of such use must be predominantly for the supply of the domestic market of the Member authorising such use.¹⁴⁰

Article 31 TRIPs does not specifically pursue grounds based on which compulsory licences can be issued, but rather conditions and procedures that must be respected when issuing them. Some grounds are however expressly mentioned in Article 31 (emergency and extreme urgency, public non-commercial use by government or third parties, dependent patents and anti-competitive practices) though without limiting the Member's possibility to grant compulsory licences on other grounds. Other possible grounds could be deduced from other TRIPs provisions, such as for instance Article 8.2 allowing Members to take measures necessary to protect, inter alia, public health and nutrition or to prevent abuses, provided that such measures are consistent with the Agreement.

It therefore follows from the foregoing that Article 31 of the TRIPs Agreement leaves Members some discretion in granting compulsory licences, provided that the conditions and procedures imposed by Article 31 are met, and taking into account the other provisions of TRIPs.

The EAC Policy¹⁴¹ makes specific recommendations to the partner states that seek to optimize the use of compulsory licence regime. These include broadening the grounds upon which compulsory license can be issued, for instance 'to remedy anti-competitive behaviour or other forms of abusive exercise of exclusive patent rights'¹⁴²; taking advantage of the decision of WTO General Council of August 30, 2003 [Paragraph 6 Decision) by making provisions authorising the export of up to 100% of their pharmaceutical production to countries lacking sufficient pharmaceutical capacities; reducing the time (to maximum 90 days) for prior negotiations with the patent right holder for voluntary licensing before an application for compulsory licences may be filed and waiver of such prior negotiations in situations national emergency, other situations of extreme urgency, public non-commercial use (government use) and to remedy anti-competitive behaviour of the patent right holder.

Additionally, the policy also calls for the limitation of the role judiciary plays in compulsory license in two ways; first it instructs the partner states to exclude injunctive relief as a remedy

¹⁴⁰Tejan-Cole A., *Flexibilities in The Trips Agreement And Its Impact On National Intellectual Property Policy*, (2009) p. 28.

¹⁴¹The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, P. 19.

¹⁴² As above.

available under independent review of government use licences, and secondly, confer the authority to grant any kind of compulsory licences to administrative entities (instead of courts).

j. Parallel Imports and Exhaustion of Patent Rights

In patent, parallel imports (PI), also called grey-market imports, refer to goods produced originally under patent protection, placed into circulation in one market, and then imported into a second market without the authorisation of the local owner of the intellectual property right. WIPO defines it as ‘import of goods outside the distribution channels contractually negotiated by the manufacturer.’¹⁴³ The conceptual underpinning of parallel imports is based on the understanding that the patent holder has been adequately remunerated through the first sale of the product and his further monopoly over the resale of the product would unreasonably stifle fair trade and would breach the rules of competition.¹⁴⁴ Once the patent right holder has circulated his products in one market and has been commensurately remunerated, he is said to have exhausted his rights over that product. Thus, ‘exhaustion’, sometimes referred to as the ‘first sale doctrine’, is one of the limits of the IP rights.

Article 6 of the TRIPS Agreement, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, provides that Members are free to choose their own regime of exhaustion of IP rights. But that is dependent on ‘whether the country of importation, for reasons of law or policy, applies the concept of national, regional or international exhaustion.’¹⁴⁵

The national exhaustion disallows the patent holder to further control the commercial exploitation of goods put on the domestic market himself or with his authorisation. However, the patent holder can still rely on the right of importation to oppose the import of original goods marketed abroad. The regional and International exhaustion put limits on the patent holder’s right once the product has been sold by the patent owner or with his consent within the region and in any part of the world respectively.

¹⁴³ WIPO, International Exhaustion and Parallel Importation, available at http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (accessed on 17 August 2017).

¹⁴⁴ Musungu F. Sisule, Villanueva Susan & Blasetti Roxana, Utilizing Trips Flexibilities For Public Health Protection through South-South Regional Frameworks, (2004), p. 13 available at <http://www.eldis.org/document/A17810> (accessed on 14 August 2017).

¹⁴⁵ WIPO, International Exhaustion and Parallel Importation, available at http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (accessed on 17 August 2017).

The EAC Policy statement, In order to promote access to medicines and medical devices, calls on the partner states to ‘adopt a regime of international exhaustion authorising the import, by third parties, of originator products including medicines and active pharmaceutical ingredients for local production from countries where these products are sold at lower prices than in the home country.’¹⁴⁶

k. Anti-Competitive Behaviour and Patent Abuse

Emboldened by article 8.2 of the TRIPs Agreement which postulates that ‘appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology,’ the EAC policy urges the member states to design policy framework that prevents such abuses.¹⁴⁷ The objective of this recommendation is to ensure creation of a pro-competitive environment in order to promote transfer of technology for the development of local pharmaceutical production capacity.¹⁴⁸

In a nutshell, the implementation of the recommendations postulated above is left to individual member states to take its own path of implementation of the East African Community Regional Intellectual Property Policy on the Utilisation of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.

4.4 National Laws before and after EAC Policy

In East Africa Community, the main barrier to public access to essential medicines is two faceted: while availability of medicines is poor in government health facilities, they are on average 3-5 times more expensive in the private sector, where the majority of people cannot afford them. A number of factors have been given for this catastrophe, with intellectual property protection, particularly patents, being a major contributor.

As previously noted in this chapter, each member state of the WTO has the sovereignty to make domestic patent laws within their territories that are TRIPS compliant. Thus, all the five, WTO, member states of the EAC have separate patent law regimes in their domestic

¹⁴⁶The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, p. 18.

¹⁴⁷The EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, p. 20.

¹⁴⁸ As above, p.21.

laws. This section discusses the features of these regimes, per country, and how they have incorporated public flexibilities as set out in the TRIPS Agreement and which have been recommended by the EAC Policy.

a. Kenya

Kenya is the only EAC partner state that is a developing country. It is a signatory to the TRIPs agreement but, unlike its EAC counterparts, does not enjoy the flexibility of excluding pharmaceutical patents protection. Patents are governed by Industrial Property Act no 3 of 2001 (IPA) and Industrial Property Regulations, 2002. The constitution mandates the state to support, promote and protect the intellectual property rights of the people of Kenya.¹⁴⁹

Patent protection of patentable subject matter is available through a national filing, in appropriate circumstances claiming priority, or an ARIPO application designating Kenya, or an international application under PCT designating Kenya. However, sections 21 of the Industrial Property Act, explicitly excludes some innovations from being patented. The ones related to public health include: Discoveries or findings that are products or processes of nature where mankind has not participated in their creation (including animals, plants and micro-organisms) and scientific and mathematical methods and theories; methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; except products, in particular substances or compositions, for use in any of those methods.

The Act puts limits on patent rights in circumstances of parallel importation¹⁵⁰ to the extent that such rights do 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. This is the basis for parallel importing exemption. This seems to refer to those of invention not discovered/innovated within Kenya, and do not have a registered patent in Kenya. Section 58(2) of the IPA also provides that the rights under a 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. The implication of this clause is that it establishes an international exhaustion regime for patent rights and therefore permits parallel imports.

Further, Regulation 37 of the Industrial Property Regulations of 2002 provides that 'limitation on the rights under a patent in Section 58.2 of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the

¹⁴⁹ Constitution of Kenya (2010), art. 40(5).

¹⁵⁰ Industrial Property Act no 3 of 2001, sec. 58.

market.’ This suggests that Kenya permits parallel importation of products produced under compulsory licenses, too. Generic drugs produced under compulsory licenses are also ‘legitimately’ put on the market. This provision has been challenged before in Kenya but it continues to be in force to the benefit of improving access to affordable medicines in Kenya.

The IPA provides for compulsory licensing of third parties to produce patented items in cases of public interest, in particular health,¹⁵¹ to remedy patent right abuses or anti-competitive behaviour,¹⁵² or to enable the use of dependent patents for the promotion of technological development.¹⁵³ Recourse to compulsory licensing occurs also when the government of Kenya perceives that patent holders have not satisfied the market demand for a given product by supplying sufficient quantities at prices that broad sectors of the public can afford.¹⁵⁴ Section 80(9) and Section 75(2) (b) expressly state that the compulsory license may only be granted for the exploitation primarily for the supply of the country’s market.¹⁵⁵

Besides other procedural requirements, such as non-exclusivity and limitation in scope and duration of compulsory licenses, the applicant for a compulsory license in Kenya has to compensate the patentee adequately¹⁵⁶ and must generally have unsuccessfully attempted to negotiate a voluntary license within a ‘reasonable period of time.’¹⁵⁷ Moreover, section 80(1) (b) of the IPA appears to generally exclude the payment of remuneration in case of grant of compulsory licence due to anti-competitive conduct. Sections 74(2) and 80(2) waive the prior negotiations requirement in cases of national emergency or other extreme urgency.

b. Rwanda

The law governing patents in Rwanda is Law no 31 of 2009 on the Protection of Intellectual Property. Rwanda, being a signatory to the Paris Convention, the PCT, ARIPO (Harare Protocol) and the WTO/TRIPS, avails patent protection through national filing or via an ARIPO application delegating Rwanda as the patent office. That notwithstanding, it is important to note that Rwanda has not yet implemented the Harare Protocol and the provisions of the PCT in its national laws.¹⁵⁸

¹⁵¹Industrial Property Act no 3 of 2001, sec. 80(1)(a).

¹⁵²Industrial Property Act no 3 of 2001, sec. 80(1)(b).

¹⁵³Industrial Property Act no 3 of 2001, sec. 73(1).

¹⁵⁴Industrial Property Act no 3 of 2001, sec. 72 .

¹⁵⁵Industrial Property Act no 3 of 2001.

¹⁵⁶Industrial Property Act no 3 of 2001, sec. 80(4) and 75(2)(e).

¹⁵⁷Industrial Property Act no 3 of 2001, sec. 74(1)(a) and 80(2).

¹⁵⁸Adams and Adams ‘Practical Guide to Intellectual Property in Africa’ (2012), p.439.

However, it appears that valid patent protection could be obtainable by filing via ARIPO or PCT, based on a specific provision of its patent law which postulates that any international intellectual property treaty which the country is a party, shall apply. And in case of the conflict with aforementioned legislation, the provisions of the said law prevail. It should be noted further that, Rwanda, as a LDC and in conformity with the TRIPs dictates discussed above, exempts from patent protection pharmaceutical products.

Rwanda has made available in its patent law the flexibilities that promote public health. Like Burundi and Kenya, discussed in the foregoing, Rwanda provides for contractual licenses¹⁵⁹ and non-contractual licenses¹⁶⁰ that gives a third party the right to exploit patent rights of the patent owner. Whereas contractual license equates to the voluntary license where the patent owner, out of his or her own volition, assigns the patent right to the third party, the non-contractual licenses consist of the compulsory license and the 'right to use license', where the government have absolute authority for its grant on grounds of no use of patent, anti-competitive behaviour and public health concerns.¹⁶¹ That law also provides for post-grant opposition and circumstances for successful invalidation of the patent.¹⁶²

In conclusion and as earlier alluded to, Rwanda does not grant pharmaceutical patents courtesy of the waiver it enjoys under the TRIPs Agreement. The provisions on TRIPs-compliant flexibilities will only aid its public-health policies once that waiver lapses. Additionally, as discussed in the previous chapters, Rwanda has been at the forefront of maximising the utilisation of TRIPs flexibilities, particularly compulsory license and parallel import, to improve public health.

Tanzania

The United Republic of Tanzania (commonly referred to as Tanzania), made up of Tanzania-mainland and Islandic region of Zanzibar, have two sets of patent laws. Their union is cemented in Article 4 of the Union of Tanganyika and Zanzibar Act, 1964.

The Union maintain two separate patent regimes. The governing patent legislation in Tanzania-mainland is Patent (Registration) Act of 1995 and the accompanying Patent Regulations of 1995. On the other hand, the relevant patent law in Zanzibar is the Industrial Property Act number 4 of 2008. The explanation of for these two regimes is found in the

¹⁵⁹Law no 31 of 2009 on the Protection of Intellectual Property in Rwanda, art. 44.

¹⁶⁰Law no 31 of 2009 on the Protection of Intellectual Property in Rwanda, art. 46 & 47.

¹⁶¹Law no 31 of 2009 on the Protection of Intellectual Property in Rwanda, sec.7.

¹⁶²Law no 31 of 2009 on the Protection of Intellectual Property in Rwanda, sec.8.

establishing article 4 of the aforementioned Union's Act which gives the two regions of the Union independent legislative jurisdictions.

Tanzania has also ratified Patent Cooperation Treaty (PCT) 1970, Paris Convention 1883–1967, Agreement on Trade Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the WTO 1994) and the Harare Protocol within the framework of African Region Industrial Property Organization. The patent provisions enshrined in the aforementioned international and regional instruments are binding on Tanzania.

The Patents protected under Tanzania-mainland Patent Act are patents of inventions 'other than a discovery, scientific theory, mathematical method, aesthetic creation, computer program or presentation of information) meeting specified requirements relating to novelty, utility and inventiveness.'¹⁶³ This Act does not provide for a transitional period flexibility given to the LDCs under the TRIPs to exclude protection of pharmaceutical products and processes. However, section 13 of the same Act gives a vague temporary exclusion of the pharmaceuticals from patentability. It postulates that:

'Inventions which concern certain kinds of products, or processes for the manufacture of such products, may, by statutory instrument be extended for further periods, each such period not exceeding ten years.'¹⁶⁴

A more explicit exclusion is only found in section 3(1) of the Tanzania-Zanzibar Industrial property Act which exempts from patent protection '...pharmaceutical products and processes until January 1, 2016 or the expiry of such later period of extension agreed upon by the World Trade Organization Council for TRIPs.'¹⁶⁵ The importance of this provision including the possible extension of the transitional period means that pharmaceutical patents remain excluded in Zanzibar until 2043 and possibly beyond that period if and when extended by the WTO council for TRIPs.

Another striking difference between the two legislations is also found in the duration it allows for patentable inventions. While Zanzibar's legislation allows patent protection for a duration

¹⁶³Patent (Registration) Act of 1995, sect. 7.

¹⁶⁴Patent (Registration) Act of 1995, sect. 13.

¹⁶⁵Industrial Property Act number 4 of 2008, sec. 3 (1)(x).

of 20 years, Tanzania-mainland's law grants patent protection for a period of 10 years, with an option to extend for further two terms of 5 years.¹⁶⁶

Both laws set out the provisions for compulsory licences and recognizes that it could be issued for the purpose of promoting public health and on other various grounds including: non-use, unreasonable use of the inventions for the Tanzania market demands, patented products being imported into Tanzania, and subverting the working of the invention and refusal of the patent owner to grant voluntary licences on reasonable terms.¹⁶⁷

The government may also issue compulsory licences when it deems such a move would be vital to the economic growth of the country.¹⁶⁸ Additionally, the government through its institutions or designated third party can rely on the grounds of public interest, public health or national security to exploit an invention without necessarily procuring the consent of the patent owner. The aggrieved owner has a right to take judicial appeal to challenging this administrative decision and courts can only review, overturn or uphold the amount of the remuneration fixed by the govern to be paid to the owner of the patent but not the decision to exploit the invention.¹⁶⁹

Although Tanzania does not explicitly provide for the parallel import flexibility, the notification to import or export drugs is always linked to the conditions set above through compulsory licence to the extent that justification for granting compulsory licences is premised on the fact that the patent owner is unfairly and substantially prejudicing the export of the patented invention from Tanzania.¹⁷⁰

c. Uganda

The applicable patent legislation in Uganda is the Industrial Property Act 2014. It makes provision for the LDC transition periods that excludes from protection 'pharmaceutical products and test data until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade

¹⁶⁶Industrial Property Act number 4 of 2008, sec. 24; Patent (Registration) Act of 1995, sect.39.

¹⁶⁷Patent (Registration) Act of 1995, sect.55; Industrial Property Act number 4 of 2008, sec. 14.

¹⁶⁸Patent (Registration) Act of 1995, sect.54.

¹⁶⁹Patent (Registration) Act of 1995, sect. 62.

¹⁷⁰Patent (Registration) Act of 1995, sect.52.

Organization.¹⁷¹ This is the departure from the pre-2014 Act which did not exempt pharmaceutical patents in Uganda.¹⁷²

The Act also provides for Bolar exception in an expansive sense by granting exception the grounds of scientific research and commercial purpose.¹⁷³ This is essential to public health as it ensure early market entry of generic pharmaceutical products. Another exception to exclusive patent rights that aims to promote public health and access to medicines is the use of the patented invention in relation to the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription.

The parallel import provisions are also made available to manufacture and export to another country a patented healthcare invention where the export of the invention addresses a health need identified by the other country. This provision is justified and grantable where: the product is either not patented in the third country or where the compulsory licence has been granted in the third country and the production for export of the invention is intended only for the market of the that country.

Voluntary licences are allowed in Uganda on terms similar to that discussed in the Tanzania legislation above.¹⁷⁴ The grant of compulsory licences upon the application by a third party is restricted to issuance on the grounds that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.¹⁷⁵ However, more expansive grounds are provided to justify exploitation of patented inventions by the Government or by third parties authorised by the Government. These include: public interest, in particular, national security, nutrition, health, environmental conservation, national emergency or the development of other vital sectors of the national economy requires, and anti-competitive behaviours of the patent owner.¹⁷⁶ A patent holder is not entitled to any compensation under this provision.

A person aggrieved by the decision of the government in relation the grant of compulsory licence can take redress in the courts for judicial review. Unlike the situation in Tanzania, where courts cannot overturn the decision of the government to issue compulsory licence on

¹⁷¹Industrial Property Act 2014, sec. 8.

¹⁷²Cap 216, The Patent Act, 1993.

¹⁷³Industrial Property Act 2014, sec. 8.

¹⁷⁴Industrial Property Act 2014, part X.

¹⁷⁵Industrial Property Act 2014, sec. 58.

¹⁷⁶Industrial Property Act 2014, sec. 66 (1).

the above grounds, courts in Uganda are not restricted in determination of the judicial review suits in collation to government exploitation of patents.¹⁷⁷

d. Burundi

Burundi is an East African country of 27,834 km², with a population of about 10.5 million inhabitants. The urban population, according to the World Bank collection of development indicators, is about 12% while the population living in rural areas is about 88% by 2016. Life expectancy at birth in the year 2016 is estimated around 56.3.¹⁷⁸ Being a country slowly recovering from years of violent conflict, the World Bank in 2014 put poverty headcount ratio at national poverty lines of 64.6% of the population.¹⁷⁹

Burundi's health system presents low capacity in most areas in a country where tropical diseases and HIV/Aids remain a major threat to public health.¹⁸⁰ The national medicines regulatory authority is hugely under-resourced, resulting in poor monitoring of the quality of medicines and other needed health products. Even when the medicines are available they are too expensive for the majority of the population.

Although the Government of Burundi has been undertaking the development of a series of policies and reforms since 2004¹⁸¹ to improve access to essential medicines, little attention was put on the role patents play in blocking access to medicines as evidenced by the fact in the Patents Act of 1964 and Patent Regulations of 1965, as amended by Decree No. 1/170 of 1968, patents were granted, without examination, for all inventions for a term of 20 years. And there were no provisions for compulsory licenses. This limited the government capacity to adopt intervening policies that would promote public health.

This position changed in 2009 when Law no 1/13 of 2009 relating to Industrial Property in Burundi was enacted and become the governing patent law in Burundi, repealing all the previous legislations. It puts in place a comprehensive system of protection of patent, utility models, industrial designs, trademarks, geographical indications.

¹⁷⁷Industrial Property Act 2014, sec. 66 (1)(b).

¹⁷⁸ World Bank 'World Bank WDI and Macro Poverty Outlook for Burundi' (2017) available at <http://pubdocs.worldbank.org/en/708231492188151479/mpo-bdi.pdf> (accessed on 2 September 2017).

¹⁷⁹ As above.

¹⁸⁰Centers for Diseases Control and Prevention 'Global Health-Burundi,' (2017) available at <https://www.cdc.gov/globalhealth/countries/burundi/default.htm> (accessed on 2 September 2017).

¹⁸¹ World Health Organization 'Improving Health System Efficiency: Burundi Performance based financing of priority health services,' (2015), p.6.

Patent protection is available by way of a national filing as long as they meet patentability criteria.¹⁸² Inventions are protected through a formalized system of filing an application for patent or utility models. The term of patent protection for any invention is 20 years as from the date of filing.¹⁸³

It is worth noting that although Burundi is a member of TRIPs and Paris Convention and is thus obligated by the dictates of the said international treaties, it is not a member of the Patent Convention Treaty (PCT) so that applications cannot be filed in Burundi via PCT. However, the law does provide that the industrial property Director must take into consideration an international search report and an international preliminary report issued under PCT.¹⁸⁴

As a LDC, Burundi has taken advantage of the transition period to exclude protection of pharmaceutical products and processes up until January 1, 2016.¹⁸⁵ However, the provision is yet to be amended to extend this period, to 1 January 2043 in line with the WTO extension of the transitional period to LDCs on pharmaceutical patents as discussed in chapter one. The same article also excludes from patent protection methods of surgical or therapeutic treatment of the human or animal body as well as diagnostic methods; natural substances, even if purified, synthesised or otherwise isolated in another manner; and known substances for which a new use has been discovered.

Furthermore, the legislation allows for pre-grant opposition within 90 days following the publication of the patent application for any interested person to file a notice of opposition, in which the person must indicate the patent application concerned as well as the arguments and evidence put forward by the opposing party to prevent the grant of the patent.¹⁸⁶

The law also allows a patent holder to, by contract, assign to a natural person or legal entity a voluntary license enabling him/it to exploit the patented invention.¹⁸⁷ A compulsory licence regime is also available and this kind of licence may be granted by the government, at the request of any person or public prosecution's office, in cases of public interest (including public health), non working or of anticompetitive exploitation.¹⁸⁸

¹⁸²Law no 1/13 of 2009, art. 3.

¹⁸³ Law no 1/13 of 2009, art. 62.

¹⁸⁴ As above in note 46.

¹⁸⁵Law no 1/13 of 2009, article 17.

¹⁸⁶Law no 1/13 of 2009, art. 48.

¹⁸⁷ Law no 1/13 of 2009, art. 69.

¹⁸⁸ As above.

A judicial grant of compulsory license is also available where any interested party may request the Commercial Court to grant a compulsory licence. This grant is generally premised on public interest, abuse of patent rights and anti-competitive behaviour, refusal of the patent holder to grant licenses on reasonable commercial conditions and terms, failure to meet reasonable conditions of demand for the protected product in sufficient quality and quantity.¹⁸⁹ A patent holder is at all times entitled to a reasonable compensation once a compulsory licence has been successfully issued by the government.

Exploitation of the invention by the State or the third party authorised by the state to which the compulsory license is granted is primarily aimed at supplying the market in Burundi. The law provides exception to the foregoing on the basis of paragraph 6 of the Doha declaration discussed in chapter three, where the compulsory license concerns a patent relating to a pharmaceutical product or a manufacturing process for a pharmaceutical product, for the export of patented products or products manufactured by means of the patented process in a foreign territory or country with non-existent or insufficient manufacturing capacities.¹⁹⁰

e. South Sudan

The Republic of South Sudan became a full member of EAC on the 5th September 2016 with equal rights, obligations and privileges after depositing the instruments of ratification on the accession to the establishment of the East Africa Community.¹⁹¹ South Sudan has not yet enacted a patent legislation of its own. After gaining independence in 2011, following decades of civil war, South Sudan maintained all the laws and institutions that existed prior to independence. Article 98 of the transitional constitution provides that

‘...all current Laws of Southern Sudan shall remain in force and all current institutions shall continue to perform their functions and duties, unless new actions are taken in accordance with the provisions of this Constitution.’

Prior to independence the applicable patent law in the then Southern Sudan – a semi-autonomous region within the Republic of the Sudan, was the Sudanese Patent Law no. 58 of 1971. With lack of subsequent repeal of the above legislation, it remains the governing legislation on patents in South Sudan.

¹⁸⁹ Law no 1/13 of 2009, art. 78.

¹⁹⁰ Law no 1/13 of 2009, art. 88.

¹⁹¹ EAC ‘Republic of South Sudan deposits Instruments of Ratification on the accession of the Treaty for the establishment of the East African Community to the Secretary General’ (2016) available at <http://www.eac.int/news-and-media/press-releases/20160905/republic-south-sudan-deposits-instruments-ratification-accession-treaty-establishment-east-african> (accessed on 27 September 2017).

Sudan being a member of the Paris Convention, ARIPO (Harare Protocol), and the PCT, provides for patent protection through national filing or through ARIPO where Sudan is a designated State. The Act is yet to be amended to cater for patent application via PCT. Any invention which is new, involves an inventive step and is capable of industrial application deemed to be patentable¹⁹² for a duration of 20 years.¹⁹³ These include pharmaceutical products and processes and any invention constituting an improvement upon a patented invention. This implies that public health concerns are not covered under this Act. This could be informed by the fact that Sudan, and by extension South Sudan, is not a member of World Trade Organization and thus does not benefit from the fruits of the WTO-TRIPs flexibility on the transitional period to exempt pharmaceutical patents.

The law allows application by private persons for a grant of a transferrable¹⁹⁴ and non-exclusive compulsory licence on grounds of non-use of the patent and refusal by the patent holder to grant licenses on reasonable terms. Although the law does not provide for the circumstances, such as national emergencies and public health concerns, under which compulsory license could be issued, this non-definitive approach opens avenues for the use of compulsory license to respond to public health concerns.

With that said, in practice, South Sudan has not considered the use of this legal framework to provide for patent protection in general and particularly pharmaceutical patent protection or lack of it. The government, through the business registry, situated at the Ministry of Justice, does not receive patent applications. It only adopts a trade marks deposit system to protect trademarks.

Among the six EAC member states, Kenya, in spite of it having been listed as a developing country thus exempted from the transitional period, seems to be having a comprehensive patent law that seek to balance between the patent rights and right to public health. Uganda, Tanzania and Rwanda legislations have been undergoing surgical review to incorporate that recommendations made by the EAC protocol (discussed above) to maximise the utilisation of the in-built TRIPs flexibilities on access to essential medicines. Burundi's and South Sudan's development of TRIPs and EAC protocol compliant legislations is being slowed down by civil and military unrests and lack of prioritization from the governments grappling with financial problems and institutional incapacities.

¹⁹²Patent Law no. 58 of 1971, sec. 3.

¹⁹³Patent Law no. 58 of 1971, sec. 25.

¹⁹⁴Patent Law no. 58 of 1971, sec. 39.

4.5 Chapter Conclusion,

As seen from above, chapter four has discussed the EAC legal framework on patent laws, starting with the spheres of cooperation between the EAC partner states on intellectual property, to give a better understanding of how the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation was derived. The gist of this policy is to guide EAC member States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilize the public health related WTO-TRIPS Flexibilities.

It gives a roadmap for optimisation of the population's access to health and other health related products. It also provides the lowest common denominator of intellectual property legislation that can be approximated across the EAC partner states. Some of the legislation and policy positions taken by the EAC largely show that the regional block seeks to benefit from enforcement of IPR through pursuing compliance with TRIPS.

However, in this pursuit, EAC should thus seek to stick to its development priorities and utilize the TRIPS flexibilities to the advantage of the block as against blind obedience to the inclinations for strict compliance without paying attention to the development priorities and goals of the region and critical challenges that must be fixed for the benefit of the East African people. It is from this understanding that chapter five concludes and makes recommendations contained therein.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

5.1 Conclusion

This chapter relies on the arguments and discussions presented in the previous chapters. Chapter one has introduced a somewhat familiar tension that often arise between patent protection and access to essential medicines. To this end, it has been emphasised that at the centre stage of this friction are the private interests and profit motives of pharmaceutical companies, that own patents, on the one hand and the public health and social impact concerns of governments, especially in developing and least developed countries.¹⁹⁵

Chapter two, besides setting out the conceptual framework of patent protection¹⁹⁶, also took a theoretical approach to explain justification of patent protection, relying on the two theories of natural rights and utilitarianism. While it was observed that natural rights theory seeks to justify the need maintain strong patent protection mechanism¹⁹⁷, it was the utilitarian approach to patent protection that was settled up on by this mini-thesis. Reason being that it is premised on the understanding that patents should be available primarily for the good of the public and not to only profit the patent holders, and that patent laws are socially justified if they bring greatest benefits to the greatest number of people.¹⁹⁸ This is essential for any framework that seeks to utilize the WTO-TRIPs flexibilities

Chapter three has delved into the existing international patent protection regime, tracing the emergence of international patent framework from a municipal approach where patents protection existed only within the issuing states without extending abroad.¹⁹⁹ At the heart of this development was the Venice Patent Statute of 1474 which sought to encourage technological advancement by issuing private grants and importation licenses, effectively extending patent protection to patents granted abroad as long as their inventions proved to be useful, novel, industrially applicable and that they would be disclosed in exchange for right of monopoly. The enactment of the 1883 Paris Convention of the International Union for the Protection of Industrial Property established the first move toward internationalization of the patents system by coming up with the principle of right to priority which made it possible for

¹⁹⁵ See Section 1.1.

¹⁹⁶ See section 2.

¹⁹⁷ See section 2.2.1.

¹⁹⁸ See section 2.2.2.

¹⁹⁹ See section 3.1.

a patent applicant to claim a priority right in one country based on an initial patent application filed in another country.²⁰⁰ It also enshrined the doctrine of national treatment that prohibits discrimination between imported and domestically produced goods with respect to internal taxation or other government regulation. These principles were later replicated in the Patent Cooperation Treaty and the Trade Related-Aspects of Intellectual Property.²⁰¹

Also discussed in chapter three was the Doha Declaration which sought to address three important issues that had arisen from the interpretation of pharmaceutical-patents-related provisions of the TRIPS. First it affirmed the members' right to interpret the TRIPS Agreement in a manner that favours the national priorities, particularly in the area of access to public health. Secondly, it reaffirmed the right of developing and least developing countries to engage in parallel importation and issuance of compulsory licenses of pharmaceuticals without interference from external state or non-state actors.²⁰²

Chapter four explored the use of TRIPS flexibilities in East Africa Community and how each member state of the community has incorporated the said flexibilities in their respective patent legislations. It was observed that the EAC member states seek to utilize these flexibilities by approximating their patent legislations in line with the recommendations of the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.²⁰³

A review of these patent legislations proved that the EAC member states have incorporated the TRIPS flexibilities.²⁰⁴ In spite of this incorporation only Rwanda²⁰⁵, as discussed, in the chapter therein the EAC has ever utilised only the flexibility of parallel importation in 2007 to import HIV/AIDS drugs from Canada.

This lack of use could be attributed to many constraints including: financial incapacities; inadequate domestic research and manufacturing capacities in the pharmaceutical sector to allow inter-state importation of pharmaceutical products within the EAC; insufficient infrastructural and technical capacities for medicines regulation; difficulties in putting into place efficient pharmaceutical management and procurement systems; and external pressures

²⁰⁰ See section 3.1

²⁰¹ See Section 3.4.

²⁰² See section 3.5.

²⁰³ See section 4.3.

²⁰⁴ See section 4.4.

²⁰⁵ See section 4.4b.

arising from bilateral treaties with developed countries that advance the interest of their pharmaceutical companies and the expense of the accessibility of pharmaceutical products by the poor EAC citizenry. It is from this background that this mini-thesis makes the following recommendations to maximize the use of TRIPs flexibilities in a manner that improves access to public health in the EAC.

5.2 Recommendations

To begin with, this mini-thesis recommends the establishment of an EAC patent office in within the framework of the EAC common market protocol and article 118 of the EAC establishing Treaty, that calls for a joint corporation in the area of IP, to not only enhance the regional cooperation in effectively promoting and protecting intellectual property rights but also mobilize their collective scarce financial and human resources to maximize the utilization of TRIPs flexibilities on public health. This is not a call to abandon respective national patent offices, but a call to have a body operating within a limited scope of coordinating the implementation of the regional policies on patents envisioned in article 118 of the EAC treaty. Secondly, provide the needed expertise, when called upon by national patent offices, in areas of patent application examination. And thirdly temporarily act as a patent office for a member state that has not yet established a patent office or whose patent office has halted operations due to financial or human resource incapacities.

This office would act as a central pillar of an institutionalized approach, within the EAC, to promote research and innovation in the pharmaceutical sector and, particularly, as a focal point for political coordination, information exchange, research and training of stakeholders, and regular training of national policy makers to aid the faster and efficient incorporation of the policy approaches prescribed by the EAC Policy and Protocol on the use of TRIPs flexibilities for public health promotion and protection.

Secondly, EAC partner states that have not yet incorporated the policy statements, of the ‘EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPs Flexibilities and the Approximation of National Intellectual Property Legislation’, should fast-track changes in their national legislations.

Thirdly, EAC partner States should incorporate strict patentability criteria for, and examination of, pharmaceutical patent applications processed within their territories, and develop clear frameworks on proper and effective implementation of patentability criteria in

relation to pharmaceutical patents. This would limit proliferation of patents in the pharmaceutical sector by not granting patents applications that do not meet such standards

In the same vein, pre-grand and post-grand opposition procedures with regards to pharmaceutical patents should be made available and need to be operationalised, made easier and inexpensive to access by citizens, civil societies and public health advocates. One way of doing this is ensuring transparency mechanisms exist. These mechanisms include regular and timely publication of the complete information related to patents application and patents granted.

This information should be made available in both English and other the languages understood by most, if not all, people within the EAC. In spite of Kiswahili being the mostly spoken language in the EAC community, EAC policies and protocols, and all national published patent legislations (except for Burundi and Rwanda which use both English, French and Kinyarwanda respectively²⁰⁶), are published only in English. Article 119 of the EAC Treaty, provides for the development and promotion of indigenous languages especially Kiswahili as a lingua franca of the region, it is imperative that States publish Kiswahili versions of their patent legislations and policies to ensure expansive accessibility of information related patents in order to effectively administer them.

There is also a need to improve pharmaceutical manufacturing capacity within the EAC. As noted in chapter three²⁰⁷, in absence of pharmaceutical manufacturing capacities implementation of paragraph 6(i) of the WTO 30 August 2003 Decision becomes difficult. Although the said decision allowed parallel importation of essential medicines from the countries with the manufacturing capacities, there is still an urgent need for the EAC States to improve domestic manufacturing capabilities to avoid over-reliance on foreign and developed countries. This will need a political goodwill from the apex of EAC leadership, commitment of sufficient financial resources to research in pharmaceutical sector to boost production.

²⁰⁶Rwanda's patent legislation 'Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property' is available in both French and Kinyarwanda under the following titles respectively: The French versions is 'Loi n° 31/2009 du 26/10/2009 portant protection de la propriétéintellectuelle.' And the Kinyarwanda version is 'Itegeko N° 31/2009 ryokuwa 26/10/2009 rigamijekuregeraumutungobwite mu BY'UBWENGE.' Both publications are available at the WIPO website: <http://www.wipo.int/wipolex/en/details.jsp?id=5249> (accessed on 27 September 2017).

On the other hand, Burundi's patent legislation 'Law No. 1/13 of July 28, 2009, on Industrial Property in Burundi' is available in French version as Loi n° 1/13 du 28 juillet 2009 relative à la propriétéindustrielle au Burundi' and is also available at the WIPO website: <http://www.wipo.int/wipolex/en/details.jsp?id=8324> (accessed on 27 September 2017).

²⁰⁷ See section 3.5

Institutionalized cooperation on the issuance and recognition of compulsory system at the EAC is also needed to boost effectiveness and usefulness of every compulsory license granted by individual member State in cases of public health needs.

Besides the issue of patents and the none use of the public health flexibilities impeding access to essential medicines in the EAC, the effects of poverty and political instability, particularly in Burundi²⁰⁸ and South Sudan²⁰⁹, have featured in the discussion in chapter four as contributing factors to the inaccessibility of essential medicines. This calamity should be captured under the compulsory license regimes and proper mechanisms should be put into place for the deployment of health experts and procurement of medicines during emergencies must be as rapid and streamlined as possible



²⁰⁸ See section 4.4e.

²⁰⁹ See section 4.4f.

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