IP rights related to Medicine; Are IP rights an impediment for accessing essential medicines in Kenya.

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Declaration

I, AHLIYA MUSSA, do hereby declare that this research is my original work and that to the best of my knowledge and belief, it has not been previously, in its entirety or in part, been submitted to any other university for a degree or diploma. Other works cited or referred to are accordingly acknowledged.

Signed: .....

Date: .....

This dissertation has been submitted for examination with my approval as University Supervisor.

Signed:.....

Dr. Isaac Rutenberg

ABSTRACT

This research paper intends to demonstrate that essential medicines on patent do pose a barrier to access in terms of affordability. The research undertaken provides some empirical evidence on the prices of essential medicines that are on patent. The focus of this is to show how patented medicines when sold in generic forms often prove to be much cheaper than the original form of medicines. The research, then, delves into the various agreements and laws such as the TRIPS agreement and the Industrial Property Act that provide for flexibilities such as compulsory licensing. The research then discusses how Kenya needs to make its IP rights regime more transparent and the need for putting up measures to prevent situations of evergreening. In conclusion IP rights do pose a barrier to access for essential medicines since branded medicines are much more expensive then generic medicines.

LIST OF ABBREVIATIONS

TRIPS Agreement on trade related aspects of intellectual property rights

ARIPO The African Regional Intellectual Property Organization

WIPO World Intellectual Property Organization

MLEM Model list of Essential medicines (20th edition)

UDHR Universal Declaration of human rights

LIST OF CASES

Patricia Asero Ochieng and 2 others vs. Attorney General and Another

LEGAL AND INTERNATIONAL INSTRUMENTS

Constitution of Kenya

Industrial Property Act, 2001

The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1 January 1995, 1869 UNTS 299.

The African Regional Intellectual Property Organization (ARIPO) Protocol (Harare Protocol)

Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania

Convention establishing the World Intellectual Property Organisation

CHAPTER 1: INTRODUCTION

Background of the problem

Access to essential medicines in the developing countries is one of the most critical health issues faced. Many people living in developing countries face major challenges with regard to access to healthcare and essential medication. According to the World Health Organization "**essential medicines"** are defined as follows; **"Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility."**[1]

This paper intends to look at the effect that intellectual property rights (Patents) have on the prices of pharmaceutical medicines that are essential in Kenya, and it also intends to look at the effect of the TRIPS agreement (The Agreement on Trade-Related Aspects of Intellectual Property Rights).

The TRIPS agreement makes an effort to create flexibilities through; compulsory licenses and government use order which helps in addressing issues of high price medicines, lack of supply and emergency public health situations. Other flexibilities include parallel importing, voluntary licenses, the Bolar exception and the research, experimental use exception, availability of new use pharmaceutical patents.[2]

Furthermore, the paper intends to look at the pricing of essential medicines that have been patented to see the effects of the patents on essential medicines.

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[1] https://www.cugh.org/sites/default/files/106_WHO_Essential_Medicines_List_from_Idea_to_Implementation_FINAL.pdf on 04/01/2017.

[2] Article 31, The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1 January 1995, 1869 UNTS 299.

Statement of the Problem

Intellectual Property rights related to medicines; Are Intellectual property rights an impediment for accessing essential medicines in Kenya. This paper focuses on whether Patents impede access to essential medicines.

Hypothesis

Kenya is facing an access to essential medicine problem as many lives are lost due to inaccessible medicines. Kenya is part of the TRIPS agreement and other bilateral trade agreements with other countries which give patent protection to essential medicines hence triggering rise in prices of medicines.

Research questions

- What factors affect inaccessibility of essential medicines in Kenya? Are IP rights one of the factors?
- How multilateral trade agreements, bilateral trade agreements and domestic laws have affected the Intellectual Property Rights for access to essential medicines in Kenya.
- What is the way forward with regard to access to essential medicine in relation to Intellectual Property rights?

Justification

The question of access to medicine becomes a question of life and death in developing countries since many people in the developing countries to do not have access to medicine. One of the reasons is that the medicines are often very expensive, and few people can afford it. Many of the drugs being patented are by institutions such as universities, pharmaceutical companies.

"Many of the world's most important medicines and public health devices are wholly or partly developed in academic laboratories. Their accessibility to those living in poor nations is profoundly affected by the research, licensing and patenting decisions made by universities... . As members of these institutions of higher learning, we believe that universities have an opportunity and a responsibility to improve global access to public health goods—particularly those they have helped develop." [3]

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636619/ on 02/01/2017

One of the reasons that these prices are high is because of the incentives involved in research and development of these drugs; therefore this study seeks to show what has been implemented till date.

Another factor that affects access to medicine in developing countries is Patents. Patents tend to create monopolies for the drug production; hence these become very expensive for the low income society to access. IP rights have been put in place with the intention of economic advancement which in turn helps contribute to the enrichment of the society i.e. through research and innovations. This, however, has been more favourable to the pharmaceutical companies rather than the public (especially in developing countries).

Limitations

The first limitation of this dissertation is the vast literature with regard to the topic at hand. This is because the dissertation will not cover all the relevant literature written on the topic. Many developing countries face similar problems hence there are many case studies one could refer to but this dissertation will only look at one case study; Kenya.

The other major limiting factor would be time. This is because a lot of data can be collected however with the restraints of time the dissertation will not be able to look at all the essential medicines.

Definition of terms

MLEM: Model list of Essential medicines (20th edition): According to the World Health Organisation they are **"those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.**

The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility." [4]

Agreement on trade related aspects of intellectual property rights (TRIPS)

The TRIPS agreement which is an agreement on trade related intellectual property rights, was formed in the year 1994 but came into force in 1995 under the precursor body of the General Agreement on Tariffs and Trade (GATT) and it currently consists of 162 members. Prior to the TRIPS Agreement, the Paris Convention was the first major treaty governing intellectual property rights. Under this agreement, many countries had excluded medicines from patentability and of those that did grant patentability, it was mainly for processes rather than product patents. Under Article 28 of the TRIPS agreement, patentability extends to both process and product patents.

TRIPS was the only multilateral trade agreement that sought to protect the intellectual property rights worldwide. This was generally done by providing minimum standards for members to adhere to i.e. all member states to reform their national laws in order to comply with the TRIPS agreement.

Article 7 of the TRIPS Agreement sets out the objectives of the agreement which states

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[5]

Article 8 of the Agreement provides for the public health interest and states as follows:

"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."[6]

From these two Articles it could be inferred that the TRIPS agreement has taken into account both the protection of intellectual property rights and the public health aspect.

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[4] https://www.cugh.org/sites/default/files/106_WHO_Essential_Medicines_List_from_Idea_to_Implementation_FINAL.pdf on 04/01/2017.

[5] Article 7, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

[6] Article 8, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

The TRIPS Agreement also includes some of the flexibilities in order to cater for the problem of access to medicines (including essential medicines). These flexibilities reduce the impact of patents i.e. they promote competition and therefore promote access to medicines.
Article 30 of the agreement provides for exceptions for patent rights. They do not, however, give particular exceptions to these patent rights.

"Members may 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 into account of the legitimate interests of third parties."[7]
Although here have been no set criteria of exceptions that every state must use; states have used the following as exceptions to rights related to patents; acts carried out for non-commercial purposes including experiments and scientific research that involve the invention; preparation of drugs by unit and on medical prescription in pharmacy dispensaries; tests carried out before the expiry of the patent to establish the bio-equivalence of generic drug; use of the invention by a third party that had used it bona fide before the date of application for the patent.[8]
When focusing on access to medicines, two exceptions are of importance, namely compulsory licensing and the Bolar exception,
Bolar exception is used for the manufacturing generic products, it allows for manufacturers to prepare production procedures before the patent expires. This reduces the time spent after the patent has expired.
Article 31 provides for Compulsory Licences and it states as follows:
"Other Use Without Authorization of the Right Holder...Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the [twelve] provisions shall be respected."[9]

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[7] Article 7, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*
[8] Opati L, *Intellectual Property Rights in Kenya,* Konrad Adenauer Stifung, Nairobi, 2009, 31

[9] Article 31, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

These are licenses that can be used as a tool in the context of access to medicines e.g. to reduce high prices of medicines, or when there are anti-competitive practices, or when patent holder doesn't supply the required medicines in the market to the population at large, in cases of public health emergency.[10]

Essentially these licences allow the government to interfere with the patent rights of the patent holder e.g. they can allow the manufacturing of generic medicines without the authorisation of the patent holder in the above mentioned circumstances. This can be done if certain conditions are met; they should reasonably compensate the patent holder and granting of a compulsory license should be for non-commercial purpose.[11]

Government Use Order relates to a situation where the government or its agent (a department, agency or person or a government ministry) exercises the right to exploit a patented invention without the authorization of the patent holder.[12] For government use, the prior consent of the patent holder or prior negotiations with the patent holder is not requirement but according to Article 31 adequate compensation must be paid.[13]

Intellectual Property rights

These are rights that are used to protect the creations of the mind. Some of these include; inventions, music, literature. Intellectual rights provide with exclusive rights to the right holders, so as to restrict access and use their property from third parties. According World Intellectual Property Organisation (WIPO) Convention defines intellectual rights as including rights relating to:

"Literary artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; 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." [14]

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[10] Opati, 'Intellectual Property Rights in Kenya', 24
[11] Opati, 'Intellectual Property Rights in Kenya', 24
[12] Opati, 'Intellectual Property Rights in Kenya', 24
[13] Opati, 'Intellectual Property Rights in Kenya', 24
[14] Article 2, *Convention establishing the World Intellectual Property Organisation*

This paper looks at how patents affect the public health sector in the context of access of essential medicines.

Patents are mainly intellectual property rights that cover inventions.[15] According to TRIPS there is no specific definition of an invention. According to the Industrial Property Act;

"invention" means a new and useful art (whether producing a physical effect or not), process, machine, manufacture or composition of matter which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.[16]

The term of a patent, when granted from the filing date can extend up to 20 years.[17]

According to Article 27 of the TRIPS agreement, for a patent to be granted it must meet the "patentability criteria". It states as follows ***"patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."***

It is important to note that the terms "inventive step" and "capable of industrial application" are synonymous to non-obvious and useful respectively.[18]

1. The invention must be "new", this entails that the invention must have been in the public domain or that the invention must not have been disclosed. If it is the case where the invention had already been in the public domain or knowledge, then the patent application would be rejected or that if the patent had already been granted it would be revoked as a consequence. Discoveries of natural minerals are also not regarded as inventions. In the year 1993, the University of Mississippi Medical Centre had been granted patent rights for "a new method of promoting healing of a wound by administering turmeric to a patient afflicted with a wound". It was later found that the use of turmeric had already been in use in India for centuries and thus the Council for Science and Technology of India successfully petitioned against the patent, contending that the invention was not new.[19]

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[15] Opati, 'Intellectual Property Rights in Kenya', 15
[16] Section 2, *Industrial Property Act,* 2001
[17] Article 33, *Agreement on trade related aspects of intellectual property rights*
[18] Article 27, *Agreement on trade related aspects of intellectual property rights*
[19] Opati, 'Intellectual Property Rights in Kenya', 16

2. The invention must involve "an inventive step", this entails that the invention must involve a development to prior art; it should include a "surprising effect" to the invention. It is also important that it should not be obvious to a person of ordinary skill in the field concerned.[20]
3. The invention must be "capable of industrial application", this essentially means that the invention should be useful in an industrial i.e. it should have an technical effect. Generally the WTO members differ as to what industrial application means e.g. under the US law the concept of 'utility', so an invention can be granted patent rights for developments that are not necessarily industrial products but rather they are operable and capable of satisfying some function of benefit to humanity.[21]

The African Regional Intellectual Property Organization (ARIPO)

This paper also focuses on how ARIPO protocol on patents has affected access to medicines. This is because Kenya is a member to this organization and hence it is affected by some of the activities carried out within ARIPO. One such example is the ARIPO Protocol on patents and industrial designs (i.e. "Harare Protocol"). Currently there are 18 parties to this protocol namely: Botswana, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Sudan, Swaziland, United Republic of Tanzania, Uganda, Zambia, Zimbabwe and Democratic Republic of Sao Tome and Príncipe.[22]

The ARIPO Secretariat is in charge of receiving and processing patent, utility models and industrial design applications as well as to grant patents, utility models and industrial design on behalf of its Contracting Parties. When a patent application is received at the ARIPO office it undergoes the examination process, and upon examination the patent is either granted or rejected. In the circumstance that the application is deserving of a patent then the Office would

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[20] Opati, 'Intellectual Property Rights in Kenya', 16
[21] Opati, 'Intellectual Property Rights in Kenya', 17
[22] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 14.

notify the applicant and each designated state.[23] Rule 18(4) of the Regulations to the Harare Protocol provides that the notification attaching the search and examination of the application shall be made public in each designated State. Once the notification has been received, the Contracting parties have six months to make a written communication to the ARIPO office objecting to the grant of the patent in its territory. The effect of such an objection by the Contracting State, would render the patent as ineffective in its territory. If the office does not receive an objection, consequently the ARIPO office "shall grant the patent, which shall have effect in those designated States which have not made the communication".[24]

Once granted, a patent is subject to provisions set out in the national patent law of each Contracting Party such as on compulsory licenses, forfeiture or use of the patented inventions in the public interest. [25]

This means that patents granted at ARIPO will have an impact in Kenya, hence it's important to take ARIPO granted patents into account since Kenya is a member of ARIPO.

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[23] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 17.

[24] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 17.

[25] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 17.

Chapter summary

Chapter 1: This chapter includes the background of the topic, the justification, the limitations and the relevant statutes and treaties that guide Intellectual Property rights within Kenya.

Chapter 2: Theoretical framework.

The main theories include Human rights and Human dignity, the Social contract theory (John Locke), Prospects theory and the theory on Reward on services rendered.

Chapter 3: Case study

This chapter explains the research questions in depth and also provides a case study on the Anti-Counterfeit Act of 2008; lastly it also provides the literature review for the dissertation.

Chapter 4: Findings;

This mainly project the statistics of the patented medicines in the Model list of Essential Medicines, the health statistics within the Kenyan population and give an overview of how the pharmaceutical situation is in Kenya.

Chapter 5: Research questions:

It answers the research questions as explained in chapter 3.

This chapter also analyses different multilateral agreements such as TRIPS, ARIPO and it also looks at the Industrial Property Act of Kenya. Lastly it gives its conclusion and recommendations with regard to the topic.

CHAPTER 2: THEORETICAL FRAMEWORK

The theories included in this chapter are; Human dignity and Human rights, the Social contract theory (John Locke), Prospects theory and the theory on Reward on services rendered.

Human dignity and Human rights

Access to essential medicine can be related to the right to health, which is a fundamental human right. There are other rights that are related to this right, and these include; the right to development, and the right to dignity. According to human rights, the right to health is connected to the principles of non-discrimination, equality, accountability, transparency and participation.[26]

Hence this study is based on the theoretical framework of human rights, which provides that access to medicine is crucial to the life of a human being.

According to Article 1 of The Universal Declaration of Human Rights (UDHR) "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."[27] This means that every human is equal and every human being has an intrinsic human dignity. The German philosopher Immanuel Kant held a view that all human beings have an intrinsic worth (dignity) and that all human beings are above from all creation. This is because human beings are rational beings i.e. they are free agents to make their own decisions, setting their own goals and guiding their conduct by reason. Thus it is imperative that all human beings must be respected for their intrinsic human dignity; hence the right to access medicine is one such right that is imperative for the dignity of every human being. This is because access to medicines for a human being helps in the flourishing of that person's life and therefore respecting the person's human dignity.

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[26] http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx on 04/02/2017.
[27] Article 1 *Universal Declaration of Human Rights.*

Article 27 of the UDHR states that "everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."[28] This means that the UDHR has provided for the protection of Intellectual property rights. Intellectual property rights are also imperative for the protection of property, a strike of balance between the protection of human dignity and the protection of property is crucial. This paper looks at the access to medicine issue which is related to the dignity of a human being and the effect of intellectual property rights of those medicines.

The Social Contract Theory (John Locke)

This theory was articulated in the book *Two Treatises in Government.* In this theory John Locke believes that a man was born in the state of nature which entails a state of perfection whereby a man is free to make decisions without the interference of others. He stated that we all belonged equally to God and therefore we must never harm each other. Another aspect of his theory includes the protection of property; which is essential for the civil authority to protect which then brings about the idea of 'the social contract'. The executive arm of the government is responsible for every person's property and well-being. He also states in the effect that the property owned by people should be limited; so that one should not take more than what one needs or can use.[29] This is related to the topic because it is the State's duty to protect the interests of its citizens, whether they are the property owners (Patent owners) or whether they are the public (who need access to essential medicine). It is, therefore, the State's responsibility to strike a balance between these two groups of people, especially with regard to access of essential medicines. This could be done by State interference (through laws) that allow for access to such medicines.

John Locke believed that property rights were linked to labour of a person. This means if a person had expended his or her labour on the property, then the property belonged to that person.[30]

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[28] Article 27, *Universal Declaration of Human Rights*

[29] http://www.iep.utm.edu/soc-cont/ on 30/08/2017

[30] Ndlovu L, ' Access to medicines under the world trade organisation TRIPS agreement: A comparative study of select SADC countries', Thesis for doctor of laws, University of South Africa, May 2014, 32.

This applies to intellectual property rights because intellectual property is seen as labour expended hence the Patent owners of the essential medicines have a right to the medicines. This, however, does not entail that the State has no responsibility towards the protection of its citizens from the lethal diseases. Hence it is an obligation upon the State to balance the rights of these patent owners of the

Criticism of this theory is that Property rights are seen as the only reward mechanism available for the labourer (Patent owner). This, however, is not always the case because other reward mechanisms include awards, fees, gratitude, acknowledgment, praise, security, power, status, and public financial support.[31] Also if efforts of the labourer are disproportionate to the property rights granted, then granting of such rights would be ineffective. When looking at efforts 3 points are taken into consideration. These include; (I) how hard someone tries to achieve a result, (2) the amount of risk voluntarily incurred in seeking this result, and (3) the degree to which moral considerations played a role in choosing the result intended. The harder one tries, the more one is willing to sacrifice, and the worthier the goal, the greater the property rights.[32]

Prospects Theory

According to this theory Patents provide an incentive for the inventor. It provides with legal security to promote venture capital, search for market opportunities, make investments and promote research and development. This theory justifies that patent owners of medicines should be given exclusive rights to their inventions so as to promote investments and research The criticism of this theory is that it bars competition because it does not allow for researchers to work on the same research. For example the Wright brothers who were the inventors of the modern airplane used their patent to impede the efforts of other inventors such as Curtis. A representative of Curtis had to remark that, 'a man has to have ten years in law school before he has had a chance of becoming an aviator'.[33]

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[31] Hettinger E, 'Justifying Intellectual Property' Volume 18 *Philosophy and Public Affairs* (1989), at 41

[32] Hettinger E, 'Justifying Intellectual Property' 42

[33] Ndlovu L, ' Access to medicines under the world trade organisation TRIPS agreement: A comparative study of select SADC countries', Thesis for doctor of laws, University of South Africa, May 2014, 36.

Theory on reward for services rendered

This theory was largely propounded by Adam Smith. In his view, inventors must be rewarded for their inventions by the society because they have contributed to the society. Hence recognition and the protection of IP rights is necessary for the inventor and this has to be granted by the society. One of the criticisms of this theory is that whether the inventor should be rewarded for his effort or for the usefulness of their invention to the society, and what happens in the case of accidental inventions – how is the inventor supposed to be rewarded?[34]

[34] Ndlovu L, ' Access to medicines under the world trade organisation TRIPS agreement: A comparative study of select SADC countries', Thesis for doctor of laws, University of South Africa, May 2014, 35.

CHAPTER 3

This Chapter expounds on the research questions posed in Chapter 1, it also provides a case study of The Anti-Counterfeit Act of 2008 and whether it was constitutional. Finally, the chapter provides a literature review of the dissertation.

RESEARCH QUESTIONS

As for the first research question; what factors affect inaccessibility of essential medicines in Kenya? Are IP rights one of them? This question generally looks into the different factors that have an effect on the accessibility of essential medicines to the general the public. Accessibility in this context refers to the price ranges of the various essential medicines. It also entails availability and affordability of safe medicines at the public and private health care facilities throughout the country. One of the main issues that hinder such accessibility of essential medicines is the deep poverty levels within the country. The aim of this question is to compare whether patents of essential medicines are affecting the price ranges of these medicines hence affecting accessibility of these medicines to the wider public.

As for the second question; how multilateral trade agreements, bilateral trade agreements and domestic laws have affected the IP rights for drugs in Kenya as at 2017. This research question explores into the TRIPS agreement (Agreement on trade related aspects of intellectual property rights); which is a multilateral trade agreement that Kenya is a party to. Hence it will delve into the different principles espoused in the TRIPS agreement. It will also delve into provisions related to patents such as the safeguard mechanisms in practice from the TRIPS and Doha Declaration and public health. Lastly this research question shall also probe into the domestic laws of Kenya such as the Industrial Property Act of Kenya 2001 which include some of the mechanisms in the TRIPS agreement. It will further expound on some of these mechanisms such as licensing mechanisms and parallel importation with regard to Kenya.

The last research question on what is the way forward with regards to the easy access to medicine in relation to the Intellectual Property rights; this will be tackled in the last chapter of the dissertation. It involves recommendations and the conclusion of the dissertation.

CASE STUDY; Patricia Asero Ochieng and 2 others vs. Attorney General and Another (Petition No. 409 of 2009 in the High Court of Kenya) – The case on the Anti-Counterfeit Act of 2008.

In this case three petitioners, who were living with HIV, petitioned the court that section 2 of the Anti- Counterfeit Act of 2008, which defines counterfeiting, was confusing the term counterfeit medicine with generic medicine. The petitioners who were living with HIV were heavily relying on generic medicines, and this Act sought to criminalise the manufacture, sale and distribution of generic medicines in Kenya. Hence, it posed as a barrier to the accessibility of affordable generic medicines in the country.[35] They argued that this Act was in contravention to Article 43 of the 2010 Constitution of Kenya which states that "every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care."[36]

Section 2 of The Anti-Counterfeit Act of 2008 defined counterfeiting as **"according to the Act, means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya in respect of protected goods-**

(a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;

(b) the manufacture, production or making, whether in Kenya, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his license;

(c) the manufacturing, producing or making of copies, in Kenya, in violation of an author's rights or related rights;"[37]

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[35] *Patricia Asero Ochieng and 2 others v Attorney General and Another* [2009]
[36] Article 43, *Constitution of Kenya* (2010)
[37] Section 2, *The Anti-Counterfeit Act* (Act No. 13 of 2008)

For the purposes of this case study, generic medicines are those medicines that are similar to the original medicine. They are those medicines that are genuine because they contain the requisite active ingredients hence are of good quality. They may only differ in appearance or flavour.[38] Generic drugs are less expensive than the original drugs because the manufacturers did not have to incur the cost related to research (which was already incurred by the original manufacturer). Generic goods in Kenya have had a positive impact with regard to access; HIV, Malaria and TB treatment prices have reduced by 80% since 2001.[39]

The broad definition used for counterfeiting proves to be very problematic for the production of generic goods. According to Article 51 of the TRIPS agreement counterfeiting relates to counterfeit trade mark goods and pirated copy right goods and not generic medicines. Counterfeit trademark goods refer to goods, **"including packaging, bearing without authorization a trademark which is identical to the trademark validly registered [in Kenya] in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in Kenya;".**[40] While Pirated copyright goods refer to goods **"which are copies made without the consent of the right holder or persons duly authorized by the right holder in Kenya and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right in Kenya."**[41]

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[38] http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017

[39] http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017

[40] http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017

[41] http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017

The second issue of the Anti- Counterfeit Act was the criminalization of manufacturing, production and packaging of similar goods. Section 32 of the Act provides for the offences of counterfeiting, whereas under the TRIPS agreement there is no obligation upon Kenya to criminalize such disputes because these disputes are of a civil nature and not a criminal nature. [42]

The third contention of the Act is that under Section 25 inspectors of the Board (provided under the Act), are given excessive powers to seize suspected counterfeit goods. This poses as a threat to generic medicines since they could be regarded as counterfeit products hence impeding access to such medicines. Also these inspectors do not have the requisite expertise to determine the quality of the generic medicines (whereas quality is a key factor in determination of counterfeit medicines).[43]

Fourthly, the Act does not give a specified period of time within which the seized goods are to be held. Hence, the expiry of the seized goods (medicines) could amount to a major problem and thus creating a hindrance for the access to medicine and a timely treatment.[44]

Lastly, the Act in Section 34 allows for the government to detain goods that are to be transported to other countries. This poses as a challenge because now many other countries will be affected by the government interference on generic medicines, therefore, threatening access to medicines.[45]

The above mentioned challenges of Anti Counterfeit Act could have serious consequences for accessing affordable medicines (including essential medicines) throughout the region. The High Court ruled for the petitioners and declared Sections 2, 32 and 34 of the Act as unconstitutional. It was to this effect that Judge Mumbi Ngugi stated that "the Act is vague and could undermine access to affordable generic medicines since it failed to clearly distinguish between counterfeit and generic medicines."

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[42]http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017
[43]http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017
[44]http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017
[45]http://kelinkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf on 19/09/2017

LITERATURE REVIEW

With regard to literature on IP rights and access to medicine in Kenya, Dr Ben Sihanya, Prof Moni Wekesa and Linda Opati have published a book namely "Intellectual Property Rights in Kenya". She has dedicated a chapter in the book on how IP rights have affected the access to medicines in developing countries; it expounds on the TRIPS agreement and how it has been implemented and whether Kenya has been flexible in the implementing access to medicines.

At first it looks at the definition of patents and the justifications for it in the pharmaceutical company. This includes the furthering of economic objectives and enrichment to society, by promoting the domestic industries and international trade.[46]

It then looks at the issue of research and development as a justification and whether it is a valid justification since the costs for research and development are quite low compared to how much the pharmaceuticals earn due to the patents.[47]

The chapter takes a look into the international community pre-TRIPS; and observes that there was non-uniformity in the granting of patents; this means that there were few countries that granted pharmaceuticals patents whilst other countries refused to grant patents to pharmaceutical companies. The chapter then delves at the post-TRIPS period whereby The World Trade Organization (WTO) was given the responsibility to be a multilateral governing body dealing with the rules of trade between countries with regards to pharmaceutical patents.[48]

It also comments on the Doha declaration as a means to explain the flexibilities mentioned in the TRIPS agreement about public health; compulsory licenses, parallel importation and exhaustion of IP rights, voluntary licensing, availability of new use pharmaceutical patents, government use licenses, research exemption, early working (bolar exception) and test data protection.[49]

As for compulsory licenses, the TRIPS agreement allows for countries to manufacture generic goods without the consent of the patent holder but with certain conditions such as failed negotiations with patent holder and adequate remuneration.[50] The Doha Declaration mentions that the countries can choose the grounds upon which compulsory licenses are granted.

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[46] Opati, 'Intellectual Property Rights in Kenya', 19.
[47] Opati, 'Intellectual Property Rights in Kenya', 19.
[48] Opati, 'Intellectual Property Rights in Kenya', 19.
[49] Opati, 'Intellectual Property Rights in Kenya', 24.
[50] Opati, 'Intellectual Property Rights in Kenya', 24.

Parallel importation and exhaustion of IP rights involve a patent holder losing his/her rights due to the release of the product (through importation) into the commercial market, by another generic company.[51] The Doha Declaration states in the effect that the country should provide for specific legislation for this to occur. Voluntary licenses mean the patent holder can choose to give licenses to another company to use its patented rights in return for a royalty fee.[52] Availability of new use pharmaceutical patents or ever greening refers to the patentability of new uses of the product after the patent has expired.[53] TRIPS has provided that patents only be granted to products or processes which are new, involve an inventive step and are industrially applicable. Hence countries should refrain from granting patents on the basis of new uses in relation to medicines. Bolar exceptions are when generic manufacturers are allowed to prepare production and regulatory procedures before the expiration of patents.[54]

The chapter also looks into the implementation of TRIPS in Kenya as at 2009; For instance the Industrial Property Act of 2001 which includes TRIPS compatible mechanisms for access to medicines such as exhaustion of intellectual property rights.

[51] Opati, 'Intellectual Property Rights in Kenya', 28.
[52] Opati, 'Intellectual Property Rights in Kenya', 29.
[53] Opati, 'Intellectual Property Rights in Kenya', 32.
[54] Opati, 'Intellectual Property Rights in Kenya', 19.

CHAPTER 4: FINDINGS

Methodology

This chapter mainly includes empirical data that sought to compare price differences between generic essential medicines on patent and original essential medicines on patent.

Due to constraints of time, the data gathered is not exhaustive thus these findings aim at providing the broad underlying spectrum of prices of some essential medicines. The medicines chosen are from the MLEM 20th edition and they are assumed to be on patent according to a WIPO Research carried out by Reed F Beall form the University of Ottawa.

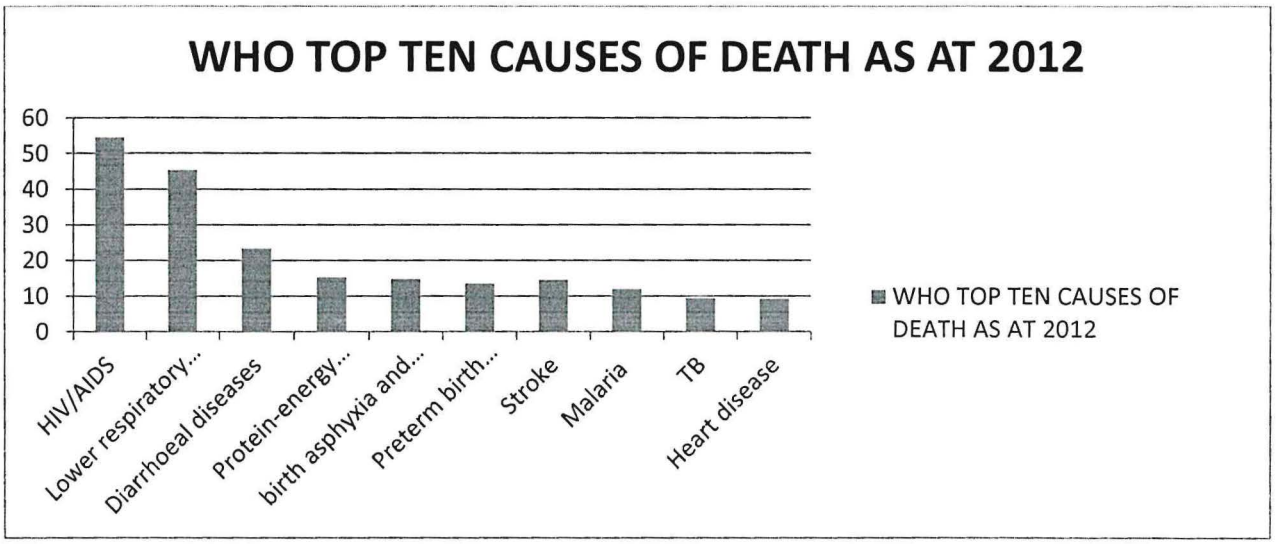
Interviews were also conducted with pharmacists, scholars of access to medicine within the Kenyan region, and some of data gathered was from key organisations (such as the World Health Organisation, ARIPO and research papers) that provide important data relating to the subject.

Kenya's Pharmaceutical Statistics as per the Pharmaceutical Policy in the East African Community[55]

Kenya is the largest and most developed pharmaceutical manufacturing sector in EAC region. Its branded and generic market share is 44% and 56%, respectively. The market share of locally produced pharmaceuticals is currently at 28%, of which 35-45% of the locally produced medicines are exported to neighbouring countries. There is a 15% marginal preference scheme for local products by government tenders. The local production meets 30% of the national demand of pharmaceuticals. There is generally a negative market perception of local manufacturers. The local production is predominantly generic and raw materials mostly imported

[55] Mashingia J,' Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania', 18.

World Health Organization Statistics:



Top 20 Patent Pharmaceutical Applicants in ARIPO Between 1/1/2003 and 31/12/2013

1. Boehringer Ingelhiem International GMBH	**11. Iceutica Pty. Ltd**
2. Pfizer Inc.	**12. Pfizer Limited**
3. Pfizer Products INC.	**13. Warner-Lambert Company LLC**
4. Les Laboratoires Servier	**14. Bayer Intellectual Property GMBH**
5. Gilead Sciences INC	**15. Novartis AG**
6. Tibotec Pharmaceuticals Ltd	**16. Euro-Celtique S.A.**
7. Cipla Limited	**17. Intermune Inc.**
8. Takeda Pharmaceutical Company Limited	**18. Ranbaxy Laboratories Limited**
9. Panacea Biotec Limited	**19. Centre National de la Recherche Scientifique**
10. Janssen Pharmaceutica N.V.	**20. Medivir AB**

Price of Essential Medicines:

These medicines were picked from the MLEM 20th edition. . According to a WIPO Research carried out by Reed F Beall form the University of Ottawa, these medicines are on patent within the developing countries.[56] Kindly note that the medicines might not be on patent within Kenya, as there exists generic medicines in the market. The aim of this price comparison is to juxtapose generic prices and original prices.

Artemether + lumfrantine	**Chemist 1**	**Chemist 2**
Use	MALARIA	
Availability	Yes	Yes
Dosage	8 tablets for 3 days	
Price (Ksh) – Original	80 (Coartem)	400
Price (Ksh) – Generic	60	200

Omeprazole	**Chemist 1**	**Chemist 2**
Use	GASTROESOPHAGEAL REFLUX	
Availabilty	Yes	Yes
Dosage	Relative to the disease	
Price (Ksh) – Original	43 (per tablet)	120(per capsule)
Price (Ksh) – Generic	16 (per tablet)	5 (per tablet)

CHEMIST 1 – FAIZ PHARAMCY (Located in Mombasa CBD)

CHEMIST 2- STRATHMORE MEDICAL CLINIC (Located in Nairobi, at the University)

[56] Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access, World Intellectual Property Organization.

Essential Medicines on Patent within ARIPO:

ABACAVIR (ABC): (HIV/AIDS)

This is a drug that is in the Model list for essential medicines (20th edition). It is generally recommended for infants and children as an ARV treatment. The basic patent had expired in 2010, secondary patents related to hemisulfate salt, pediatric composition were filed and granted by the ARIPO to GSK. GSK has already started to enforce its patent in many countries. The medicines patent pool had announced a licence agreement of ABC covering 118 countries, which include the ARIPO region. Since Kenya is part of the ARIPO region, it could therefore affect the Kenyan population hence precluding generic producers from manufacturing this drug.[57]

DIDANOSINE: (HIV/AIDS)

It is a drug that is recommended for HIV/AIDS. The enteric coated capsules are included in WHO's Model List of Essential Medicines. Since this product is patent free in India, hence generic versions have been launched. As for the ARIPO region affordable importation of generic versions from India would be blocked (MSF, 2013) due to patents on the product. In June 2011, BMS signed an immunity-from-suit agreement with Mylan enabling the generic company to manufacture and sell ddI in sub-Saharan Africa (MSF, 2013).[58]

RITONAVIR AND LOPINAVIR:

Kaletra; a combination of two antiretroviral agents ritonavir and lopinavir (included in the MLEM), its patent had set to expire in 2014 and 2016 respectively. Abott has filed a number secondary patents which bar entry of generic versions in certain markets up until 2028 i.e. . 12

[57] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 27.

[58] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 28.

years after the basic compound patent expires and 39 years after the first patent for ritonavir was filed (I-MAK, 2012).[59]

ANALYSIS ON DATA GATHERED

Given that the Gross National Income of the Kenyan population is USD 1380 per capita (that amounts to approximately Ksh. 12,000 per month), according to the 2016 World Bank statistics. It is evident that the average Kenyan has a very limited purchasing power especially with regard to healthcare and given that diseases are widespread such as HIV/AIDS and Malaria, a real change needs to occur in both the legal and government sector.

It is quite evident from the findings above that the original medicines are way more costly than the generic medicines. Even though these findings are restricted to just two chemists, it does indicate, however, that there is a price disparity between the original medicine and the generic. Hence emphasising on the point that generic medicines (especially for essential medicines) are more economically accessible to the population at large. Therefore Kenyan IP laws need to place an emphasis on guaranteeing the access to generic medicines (including essential medicines). As for the issue of evergreening as seen in the case of Abacavir, Ritonavir and Lopinavir, the criteria for patentability needs to be stricter in order to preclude secondary patents from being granted. This is because secondary patents would restrict access to essential medicines, in this case ARV medicines, which are crucial to the public at large due to the deaths that occur as a result of HIV.

[59] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 28.

Interview

Paul Omondi Ogendi

December 2017

The interview conducted was with regard to essential medicines and how patents have affected the access of such medicines.

Mr Paul Omondi has a specialisation in intellectual property rights with regard to access to medicines. His thesis was based on access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa. He contends that access to essential medicines is a human rights issue that needs addressing. There are two schools of thought the debate of access. One school argues that there are other factors that affect access to essential medicines and that intellectual property rights do not pose as a serious threat to access. Whereas the other group argues, that intellectual property rights do pose to be a serious threat especially when one looks at the current condition of the healthcare sector and the expensive medicines that are common to find within the pharmaceutical industry.

Amir Attaran a scholar who has written on the topic argues that the pharmaceutical industry is not negatively impacted by intellectual property rights. Holger Hestermeyer, however, in his book on human rights and the WTO: The case of patents and access to medicines provides a comprehensive study on the conflict between human rights law and patent law and the need for the integration between the two.

CHAPTER 5: RESEARCH QUESTIONS

What factors affect inaccessibility of essential medicines in Kenya?

For the purposes of this paper access can be defined as affordability and availability of essential medicines by the Kenyan populace.

Article 12 of the International Covenant of Economic Social and Cultural Rights (ICESCR), provides for the right for everyone to enjoy the highest attainable standard of physical and mental health and it also provides that "the steps to be taken by state parties present to the covenant to achieve the full realization of this right shall include necessary for ....prevention, treatment and control of epidemic, endemic, occupational and other diseases" and " the creation of conditions which would assure to all medical service and medical attention in the event of sickness." [60]

It is important to note that according to General Comment No. 14 of the "Right to the highest attainable standard of health", access to health (which includes access to essential medicines) was defined using three elements

1) Physical accessibility: This means that the population should have physical access (i.e. within reach) to the health goods and services.

2) Economic accessibility: This means that the health goods and services should be affordable.

3) Information accessibility: This is related to the right to seek, receive and impart any data regarding health related issues e.g. treatment and pricing.

Therefore it could be inferred from this definition of access, (in this case access to essential medicines) can be categorised to physical, economic and information access. This paper will mainly focus on the physical and economic i.e. availability and affordability.

Given the statistics regarding the health situation in developing countries it is important to point out the circumstances that contribute to this unfortunate situation. Access to medicines plays a major in the public health sector. Some of these factors include; the high levels of poverty in the developing countries, the poor governance on the part of the government, inadequate infrastructure and obsolete legal frameworks that need to be reformed.

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[60] Article 12, *International Covenant of Economic Social and Cultural Rights,* 16 December 1966, 993 UNTS 3.

This paper looks at whether intellectual property rights play a role in restricting or blocking the access to essential medicines in Kenya, in terms of physical and economic access

As to the question of whether patents are a barrier to the access of essential medicines, it is important to note that patents can eliminate competition on the products that are patented and this leads to the high prices of the medicines during the period of the patent. This coupled with the increasing need of the essential medicines can defeat the aim of access to essential medicines. Hence it is imperative that granting of such intellectual property rights should be restricted. Many times pharmaceutical companies apply for multiple patents for a single a pharmaceutical compound (e.g. patents over new forms, derivatives, uses, combinations, formulations and even dosages) – a practice commonly known as "evergreening", therefore keeping the medicine free from competition and enabling high pricing.[61]

Patents have also been at friction between private interests and public interests. Pharmaceutical companies argue that they need patent protection in order to cater for their research and development costs, whereas the public has to face the high costs of medicines as a consequence of such patents. It has been argued, however, that the costs involved for research and development of new medicines are relatively low.[62]

How multilateral trade agreements, bilateral trade agreements and domestic laws have affected the Intellectual Property Rights for access to essential medicines in Kenya.

This paper focuses on the TRIPS agreement, ARIPO, the Industrial Property Act of Kenya and the Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, and Tanzania.

[61] Opati, 'Intellectual Property Rights in Kenya', 16
[62] Opati, 'Intellectual Property Rights in Kenya', 22

TRIPS

Compulsory licensing is arguably the most effective flexibility within the TRIPS agreement. It allows for the government to permit companies the use, manufacture,,sell,or import a product under patent provided that certain conditions are met.[63]

The Doha Declaration on Public Health and the TRIPS Agreement (Doha Declaration) which provides for the use of compulsory licenses states in the effect, that members have the 'freedom to determine the grounds for the granting of compulsory licences.' These grounds could include; public health, public interest or national emergency situations (although this list is not exhaustive).

Some of the conditions stipulated under Article 31 of TRIPS agreement include;

1. That the granting of compulsory licences should be considered on individual merits.
2. Article 31(b) provides that the patent owner must be promptly informed, and give an express authorization on reasonable commercial terms. This however does not apply to situations of 'national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.
3. Compulsory licences that are granted are of limited scope and duration, taking into account the 'purpose for which it was granted'. This means that the purpose and duration of the compulsory licence must be clearly defined.
4. Once a compulsory licence has been granted it should be non-exclusive i.e. it should be available for everyone to use or exploit.
5. Compulsory licenses are non- assignable by any other enterprises unless it receives a grant from the State or enjoys similar goodwill.
6. The compulsory licence should take into account the commercial interests of the patent owner and hence use it strictly for domestic consumption. In 2003 a decision was rendered at the World Trade Organization (WTO) TRIPS Agreement General Council, which allows least developed countries (countries with insufficient manufacturing capacity) for limited exportation and importation of pharmaceutical products.
7. Compulsory licence expires once the conditions that led to it have ceased to exist.

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[63] Article 7, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

8. Adequate remuneration must also be given to the patent owner although the need to correct anti-competitive practices need to be considered while remunerating the owner.
9. The granting of the compulsory licence can be challenged in a court of law or 'other independent review by a distinct higher authority'. This includes challenges on the remuneration. The Dispute Settlement Body of the WTO, however, has not been able to set a precedent for concluding whether they are legal under the TRIPS Agreement. A case to be noted is when the USA had disputed its legality under the TRIPS agreement when South Africa had authorized the Minister of Health to be able to issue compulsory licenses for pharmaceuticals.[64]Another case in point is when the USA had disputed the granting of compulsory licenses by India of a cancer drug called Nexavar. Last year the case was finally settled by the Patent controller of India, by granting the country's first compulsory licence.[65] The judgement provided that the patent owner, Bayer, had not met the reasonable requirement of the public i.e. it did not satisfy the needs of the Indian populace and the drug was also expensive for the public. A spokesperson from Bayer responded to this by noting that their intellectual property rights had been infringed in India.

It can be concluded that the flexibility of compulsory licences within the TRIPS agreement is very complex and it is unclear whether these compulsory licences are used adequately within countries that need it most. As sited from the case above it seems that there is a struggle between certain stakeholders whether or not to grant these compulsory licenses.

Industrial Property Act, Kenya

Section 58 of the Industrial Property Act (IPA) provides for the limitations of rights. It provides for as follows "...The rights under the patent shall be limited by the provisions on compulsory licences for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions....".[66] This provision sets the foundation

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[64]Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 44.

[65]http://www.thehindubusinessline.com/companies/Indias-first-compulsory-licence-granted-to-Natco-for-Bayers-cancer-drug/article20408026.ece at 04-02-2018

[66] Section 58, *Industrial Property Act,* 2001

for the flexibility of compulsory licensing. It can be inferred that patent laws can be infringed in cases of 'public interest', which could include the access to essential medicines.

Sections 72 to 78 generally provide for the laws governing compulsory licensing. The grounds, provided in sections 72 and 73, for granting a compulsory license include "supply on reasonable terms" and "interdependence of patents". The supply on reasonable terms entails that if four years after the filing of a patent or three years after a patent has been granted there are no supplies in the market on reasonable terms without any justification another person may apply for a compulsory license in Kenya.[67] Other preconditions for obtaining a compulsory license are set out in Section 74 e.g. the person requesting the license must prove that he was 'unable to obtain the license on reasonable commercial terms', although this does not for national emergencies.

In Kenya the compulsory licensing process is handled by the Industrial Property Tribunal. It is argued that the processes involved within the courts in developing countries are often burdensome and costly. Therefore it is unlikely that the local pharmaceutical companies would try and obtain compulsory licences for essential medicines because they would be unwilling to cater for the costs and resources accompanied. [68]

In 2007, Kenya's parliament rejected a proposal to revoke the government's power to issue compulsory licences. This has not been the first time that such a proposal was made. If the government had lost its powers to issue compulsory licences, it would not be allowed to permit the use and manufacture of generic medicines, without the permission from pharmaceutical companies.[69]

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[67] Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 45

[68] Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 45

[69] https://www.ip-watch.org/2007/09/14/kenyan-parliament-rejects-bid-to-remove-governements-compulsory-licensing-option/ at 25/01/2018

One of the main legal challenges of compulsory licenses is that the TRIPS agreement is ambiguous with regard to the 'reasonable' paid to the patent holder; this is very confusing since there are not set criteria for determining the compensation. This can then result to legal battles whether the compensation was adequate or in Kenya's case, equitable. Therefore, making it undesirable for local manufacturers from obtaining them.[70]

ARIPO

Kenya is one of the developing countries within the ARIPO Region. Despite this fact, the Harare Protocol does not provide for exemptions for the Least Developed Countries from the processing of patent filings for pharmaceuticals (LDCs are given a transition period (but the Harare Protocol does not provide for this). This brings about a barrier to access of essential medicines because they provide the opportunity for essential medicines to be patented. Uganda and Rwanda have incorporated in their national laws the pharmaceutical product transition period. This is imperative for the access to essential medicine to the public because such legislation gives essential medicines an exemption from patent protection.[71]

Another major issue with the Harare Protocol is the patentability criteria. It is argued that ARIPO's patentability criterion is too lax hence providing a broad range of pharmaceutical products to be patented including essential medicines. This includes secondary patents which extend the patent protection to forms of new chemical entity such as new formulations, combinations, dosages and uses. These secondary patents have been strategically used to "evergreen" patents by pharmaceutical companies hence extending their patent monopoly and bringing an undue delay for the entry of generic industry. This, consequently, adversely affects the affordability of essential medicines. It would therefore be important that ARIPO adopt a rigorous patentability criterion that would preclude the situation of 'evergreening' or secondary patents.

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[70] Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 44.

[71] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 24.

Specific rules should be adopted with regard to the examination and grant of pharmaceutical patents. This will then prevent a situation where essential medicines are subject to prolonged patent protections.[72]

Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania

The East African Community (EAC) is mainly governed by the East African Community Treaty. This policy was intended to improve access to medicines through regulatory harmonization in the East African Community. This policy focuses on action in three areas, namely, access, quality, and rational use.[73]

Article 118 of the Treaty provides for the governing of health, joint action towards the control and prevention of communicable and no-communicable diseases, harmonization of health policies and regulations and promoting the exchange of information in order to achieve quality health within the Community and cooperation in development of pharmaceutical products.

Within the East African Community, all countries have their National Medicines Policy (NMP), these policies were formed using the WHO recommendations, some of these recommended components include;[74]

Supply: local production, procurement mechanisms, distribution and storage, disposal of unwanted or expired medicines;

Rational use: STGs, Medicines Information, rational medicine use for training, education, promotion;

Affordability: taxes or tariffs on essential medicines, pricing, use of generics, TRIPs mechanisms;

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[72] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 23.

[73]Mashingia J,' Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania', 13.

[74] Mashingia J,' Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania', 20.

Legislative and regulatory framework: Drug Regulatory Authorities, good governance for medicines, legislation and regulation, medicines registration and licensing, quality assurance (inspection and enforcement), regulation of prescription and distribution.

It is important to note that these policies are intended to promote access to essential medicines within the East African region by urging member states to use the TRIPS flexibilities exhaustively.[75]

All the member states have provided for implementation for their policies through legislation, but the problem is that the legislation is often out-dated and therefore not relevant in its time and context.[76]

[75] Mashingia J,' Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania', 21.
[76] Mashingia J,' Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania', 21.

CONCLUSION

What is the way forward with regard to access to essential medicines in relation to Intellectual Property rights?

The Kenyan Constitution provides for Economic and social rights under Article 43, which provides for the highest attainable standards of health care services. This right, however, has not been realized because of the major diseases such as HIV/AIDS pandemic widespread within the country and the exorbitant prices or the lack of availability of the essential medicines within the country. It is true that there are many factors that have contributed to this situation, such as lack of infrastructure, poor governance, corruption and high poverty levels. Intellectual property rights, however, are also a contributing factor which has impacted the accessibility of essential medicines. An example is the Patricia Asero case which confirmed the right to health enshrined in the Constitution and it also, by extension, included the right to access essential medicines. This was done by rendering Anti counterfeit Act unconstitutional as it sought to prohibit the access to affordable generic medicines. Therefore, there needs to be a more robust and practical legal framework put in place that would aid in the accessibility of essential medicines.

RECOMMENDATIONS

Kenya needs to establish a transparency mechanism that enables the information relating to patented medicines to be freely available to the public, e.g. making it available in their websites with sufficient information that relates to the patent. Kenya Industrial Property Institute, therefore, needs to make public its databases, giving adequate patent information.[77]

Kenya's patentability criteria should be rigorous enough to prevent situations of evergreening or secondary patents that prolong the patent period of medicines as noted below:

"The EAC states shall provide for and apply a strict novelty requirement through considering a wide concept of prior art, including everything disclosed to the public 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 accessed by the general public; (b) shall provide that the non-obviousness of an invention

[77] Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 48.

shall be determined on the basis of a person who is highly skilled in the art; (c) shall strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use was identified."[78]

Kenya should include in its National Medicine policy the guarantee of generic medicines, since generic medicines are relatively cheaper than branded medicines. This is clearly demonstrated in the findings above.[79]

As for compulsory licenses, Kenya could change the law with regard to granting a compulsory licence only for the domestic market (Section 75 2(b)). This is in order to allow for limited imports and exports in which are provided for Paragraph 6 Decision of the TRIPS General Council of 30 August 2003.[80]

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[78]Sangeeta S, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines' South Centre Research Paper 56, November 2014, 48.

[79] Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 72.

[80] Omondi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM Thesis, University of Nairobi, 2013, 72.

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