

**AN ANALYSIS OF THE EFFECT OF PATENTS ON THE  
RIGHT TO HEALTH IN DEVELOPING COUNTRIES: A  
CASE STUDY OF ZAMBIA**

**AN ANALYSIS OF THE EFFECT OF PATENTS ON THE RIGHT TO HEALTH IN  
DEVELOPING COUNTRIES: A CASE STUDY OF ZAMBIA**

By

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A dissertation submitted to the University of Zambia in partial fulfilment of the requirement  
for the award of the degree of Bachelor of Laws (LLB)

MARCH

2010

THE UNIVERSITY OF ZAMBIA

SCHOOL OF LAW

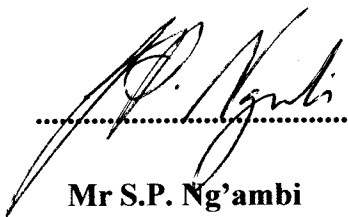
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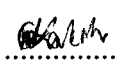


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## **DEDICATION**

To my late grandmother, Mrs Christine Bwalya Siame, who touched the lives of many with her love and kindness. May Her Soul Rest In Eternal Peace.

## **ACKNOWLEDGMENTS**

First and foremost, I would like to thank the Lord for his goodness and kindness that has seen me all the days of my life.

I would also like to express my deepest appreciation to my supervisor and lecturer, Mr Sangwani Ng'ambi who continually assessed my work and whose contributions aided me to its completion. Thank you for your encouragement, sound advice and ideas.

My sincere gratitude also goes to all who helped me with information regarding patents as covered in this thesis when I conducted my research at the Patents and Companies Registration Agency (PACRA) and the Ministry of Health. A special thank you to Ngosa Makasa, for her confidence in me and her assistance with some literature required for this research. You are indeed a great person.

I am also grateful to my family for their constant faith in me. Mum and Dad, many would ask for parents like you. You raised me, supported me, taught me and loved me. You have gone out of your way and have done all that is possible to ensure that I get to where I am today. Thank you would be an understatement of how much I am indebted to you. May God continue blessing you.

A great thank you to my young sister Chilela Kabalu (Leila). The way in which you look up to me has pushed me in times when the going gets tough. There would be no me without you. All the Nakambas, Siames, Muwowos and Kabalus, especially Nkambaku Siame, Ngao Nakamba Mumba, Mr Morris Siame, Judge and Mrs Siame, Dr and Mrs Sinjela, your support will never go unappreciated.

I wish to thank Bernard Banda, my soulmate, without your endless love, support and inspiration, this research would not have gone the way it did. Thank you for assisting me with data collection and for always pushing me to do the best I can. You will forever be an inspiration to me and I will continue leaning on you for support. My thank you would not be complete without thanking the Banda family, a family I made during my life on campus. You have been there to offer any assistance possible to make my academic life a success.

Finally, to my colleagues Mwambi Kasakwa, Situlile. N. Khumalo, Theresa Nambaya, Etambuyu Mulele, Chanda Katongo, Chitowo Sakala, Christabel Mambwe, Harriet Ndala, Kondwani Sibande, Suwilanji Namusamba, Natasha Chilambwe, Nchimunya Katowa, Layeni Phiri and my roommate Yvonne Saina, the endless debates and the light moments we shared helped me view both my personal and academic life from a different perspective.

*Merci tres beaucoup.*

## **ABSTRACT**

Several scholars have agreed that a forceful patent system providing for adequate patent protection is an indispensable incentive to creative and inventive work. Such a system becomes crucial to establishing and maintaining an attractive commercial environment. An adequate patent system, effectively administered, ultimately stimulates domestic innovation, fosters new industries and creates jobs and therefore facilitates countries' development. Various theories have therefore been developed to support why the patenting of inventions is important to the sustained development of any given country. However, it is arguable the extent to which these patents are necessary, especially with regard to the pharmaceutical sector.

This research examines the challenges that result from the grant of patents. It examines the relationship between patents and human rights in general, where it discusses the arguments brought forward for the support of patents. It thereafter discusses the right to health in relation to other rights and intellectual property rights. It then discusses the issues which arise from such grants that affect developing countries. Afterwards, specific aspects of this problem are analysed, using Zambia as a case study. Finally a conclusions is drawn and recommendations given on how to address the issues that arise from the discussion.

## **TABLE OF STATUTES**

Agreement on Trade Related Aspects of Intellectual Property

Doha Declaration on TRIPS Agreement and Public Health 2001

International Covenant on Economic, Social and Cultural

Patents Act Chapter 400 of the Laws of Zambia

Patent Cooperation Treaty

Pharmaceutical Act Number 14 of 2004

Universal Declaration of Human Rights, 1948

## **TABLE OF CASES**

Biogen Incorporation v Medeva Plc (1997) RPC 1

Herbaman v Jackel International Limited (1995) FSR 683

William v Nye (1890) 7 RPC 62, C.A

Reid v Covert 354 U.S. 1 (1957)

## **TABLE OF CONTENTS**

<b><u>CONTENTS</u></b>	<b><u>PAGE</u></b>
Title.....	ii
Declaration.....	iii
Dedication.....	iv
Acknowledgments .....	v
Abstract.....	vii
Table of Statutes.....	viii
Tables of Cases.....	ix

### **Chapter 1: Patents, Human Rights and Developing Countries**

1.1 Introduction	1
1.2 Statement of Problem	2
1.3 Objectives of the Study	3
1.4 Significance of the Study	4
1.5 Methodology	4
1.6 Outline of Chapters	5

### **Chapter 2: Patents, the Right to Health and other Human Rights**

2.1 Patents and Human Rights	8
2.1.1 Introduction	8

2.1.2 Patents	9
2.1.3 Theories of Patents	9
2.1.4 Critique of Patents	11
2.1.5 Criteria for Patentability of Inventions	14
2.1.6 Critique on Criteria	17
2.2 The Right to Health versus Other Human Rights	
2.2.1 Introduction	17
2.2.2 The Right to Health	18
2.2.3 Why Protect this Right?	19
2.2.4 The Right to Intellectual Creativity	20
2.2.5 Intellectual Property and the Right to Health	21
2.3 Conclusion	26

### **Chapter 3: The Effects of Patents on the Right to Health in Developing Countries**

3.1 Introduction	28
3.2 Generic and Patented Drugs	29
3.3 Comparative Analysis of Medicine Prices	31
3.4 Compulsory Licensing	33
3.5 The Grant of Drug Patents for Developing Countries in 2016	35
3.6 Conclusion	37

## **Chapter 4: A Case Study of Zambia**

4.1 Introduction	38
4.2 Patent Legislation	38
4.3 Protection of the Right to Health in Zambia	40
4.4 Affordability of Drugs on Zambia	42
4.5 Conclusion	45

## **Chapter 5: Conclusion and Recommendations**

5.1 Conclusion	46
5.2 Recommendations	47

<b>Bibliography</b>	<b>50</b>
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## **Chapter 1**

### **PATENTS, HUMAN RIGHTS AND DEVELOPING COUNTRIES**

#### **1.1 Introduction**

The subject of health is said to be fundamental to human beings. It is surprising to note that despite the fact that many states are parties to human rights treaties which recognise the right to physical and mental health, there is still a prevalence of diseases. Prominent among these diseases are tuberculosis, malaria, High and Low Blood Pressure (commonly referred to as BP) and HIV/AIDS. One way of attending to the issue of health can be by ensuring that there are adequate health facilities so as to make it possible for a greater number of people to be treated<sup>1</sup>. It follows also that drugs must be available and that their price must be one that is affordable by people in need of them.

Access to drugs can be affected by the price at which they are sold. It therefore follows that if some medicines are patented and have a high price set for them by the inventor, it would directly lead to their inaccessibility to those that cannot afford them<sup>2</sup>. In recent years, the patentability of health-related innovations has come under debate world-wide. Large amounts of money are being invested by countries, especially developed ones, each year in pharmaceutical research, but the fraction of people who can afford potentially life-saving drugs remains minuscule.

Under various human rights instruments such as the International Covenant on Social, Economic and Cultural Rights (ICESR) and the Convention on the Rights of the Child (CRC), the provisions of essential drugs, equitable distribution of all health facilities, goods and services are considered vital. In addition, measures to prevent, treat and control epidemic and endemic diseases are also said to be core human rights obligations for all countries, rich or poor. Therefore, states have a duty towards their citizens to respect the right to health by refraining from the adoption of laws or measures that directly infringe upon the people's health. Further, states have an obligation to adopt

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<sup>1</sup> P. Cullet. "Patents Bill, TRIPS and Right to Health" (commentary). XXXVI/43 Economic and Political Weekly, 27 October, 2001

<sup>2</sup> P. Cullet. "Patents Bill, TRIPS and Right to Health"

measures to protect their citizens from effects of policies imposed upon them by pharmaceutical companies or third parties<sup>3</sup>.

In the same way, treaties that deal with patents like the agreement on Trade-Related Aspects of Intellectual Property (TRIPS) recognise that a balance should be attained between patents and human rights. It should therefore follow that for such a balance to be attained, society's interests must supersede those of the inventor. Almost every country in the world is party to at least one human rights treaty that addresses these health-related rights.

This research investigates the consequences of granting monopolies on drugs and the processes for their manufacture on the right to health. It reviews various international instruments that grant the right to health and the extent to which they are adhered to in countries where an inventor's patenting of medicine is also upheld. Using Zambia as a case study, the review focuses on the instruments to which it is a party and the measures that have been put in place to ensure their protection.

## **1.2 Statement of the Problem**

Patents are said to act as an incentive to the inventor so as to motivate him to create more inventions based on the knowledge that they will be protected. They are also said to be a source of revenue to the inventor for if the invention is patented and the inventor sets a price for it, he is able to recoup the money he had spent on it. The inventor is also able to make profits depending on what price he chooses to set it at. It is also said that the property rights of the patent holder should be considered as of great importance and that states should therefore advocate for a further strengthening of such rights<sup>4</sup>.

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<sup>3</sup> M. Ozden. The Right to Health (Brochure prepared on behalf of CETIM's Human Rights) Geneva [www.healthrights.am/eng/more/867](http://www.healthrights.am/eng/more/867). Accessed on 15th December, 2010

<sup>4</sup> R. Nathan. The True Value of Intellectual Property, Trenwith Valuation Llc. Intellectual Property Today, May 2007

Despite the diverse reasons attributed to the significance of patenting inventions, the obligation of any country to protect and promote human rights is of great importance as well. The patents granted should therefore be those that do not infringe human rights. The protection of human rights is a responsibility of the state which is expected to ensure that activities in the country are in line with such protection<sup>5</sup>. Although the patenting of inventions is necessary, there has been growing concern as to what the extent such patents are an infringement on human right. Of great importance among these concerns is the effect of patenting of drugs on the right to health.

### **1.3 Objectives of the Study**

- a. To examine the extent and the grounds upon which the patenting of drugs or processes of their manufacture can be justified
- b. To evaluate the role played by the patenting of medicines and processes for their manufacture and whether the patenting of medicines has in fact been abused by Developed Countries.
- c. To conduct an analysis of the interrelationships between patents and the right to health and to determine whether such interrelationships are advanced or hindered vis-a-vis access to medicines in *Developing Countries*
- d. To analyse how Developing Countries have been affected as a result of the granting of medical patents in Developed Countries. Has this helped promote or infringe the right to health in Developing Countries?
- e. To consider whether there is need for reforms of any kind in the legislative framework to achieve the full protection of the right to health

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<sup>5</sup> A. Mabika and L. London. Paper produced as part of an EQUINET Chaptercity Building Programme, January 2007

## 1.4 Significance of the Study

This study is important as it is carried out during a period when there are attempts by many countries to deal adequately with the problems brought about by the incidence of diseases. In some countries, attempts have been made by improving health facilities with the view of enhancing the health status. However, another problem persists that relates to the price of medicines. Most patented medicines have a higher price than those that are not. Therefore, the issue of the protection of pharmaceuticals, especially drugs, by means of intellectual property rights has stirred up various differences in opinion especially between developed and developing countries.

It is perhaps in the field of health and medicine that most questions have been asked about intellectual property and its role in enhancing development. This has received particular attention because health is a factor that is crucial to the continued existence and wellbeing of mankind. It is widely perceived that there is massive extortion when a person seeks to purchase patented drugs.

Therefore, this research examines the challenges faced by people who cannot afford to purchase these drugs and ultimately how their right to health is infringed in this manner. To this extent the research is a contemporary tribute of different people's need to get cured of whichever disease they are suffering from and how much their access to drugs is a vital part of their being cured. The research acts as a contribution to the protection of the right to health in developing countries for this right is considered inalienable an inherent in all human beings.

## 1.5 Methodology

The first part of this research will seek to address the issue of *examining the extent and the grounds upon which the patenting of drugs or processes of their manufacture can be justified* and *evaluating the role played by the patenting of medicines and processes for*

*their manufacture and whether the patenting of medicines has in fact been abused by Developed Countries.* This will be done by a desk study of the various literature, treaties and other documents that will be of relevance to the topic.

Beyond the desk study, interviews with officers at the Patents Companies Registration Agency (PACRA) will be conducted in order to *evaluate the interrelationship between patents and the right to health and how patenting of drugs hinders or promotes the right to health and analyse the various problems that have sprung up in Developing Countries as a result of the medical patents granted in Developed Countries.*

Evaluations of their publications on cases discussed or dealt with by them will also be necessary. It will therefore entail an engagement of academic visits to this institution. In addition, visiting the PACRA website will also be necessary to this study.

Authoritative materials such as articles, journals and books from the internet will also be consulted. The above ways will ensure the achievement of the research objectives. However, media reports relevant to the topic under research will also be researched as will the various sources of information provided through the internet on the World Wide Web.

To that end the desk review and interviews of key informants are proposed to be a main feature of the methodology.

## **1.6 Outline of Chapters**

### **Chapter 1**

This chapter discusses patents, human rights and developing countries in general terms. It gives an introduction to the essay, gives a statement of the problem, objectives of the study, significance of the study, methodology and an outline of the chapters.

## **Chapter 2**

### **PATENTS, THE RIGHT TO HEALTH AND OTHER HUMAN RIGHTS**

#### **A) PATENTS AND THE RIGHT TO HEALTH**

The first section defines what patents are. It afterwards discusses the reasons given as to why the patenting of medicines is important and why some medicines are simply thrown in the public domain. It analyses whether there could be other reasons, such as charity work and concerns for the community, which would motivate people to manufacture even though there was no possibility of them patenting. It examines the criteria for patentability and whether it is enough to have uniform criteria for both developed and developing countries.

#### **B) THE RIGHT TO HEALTH VERSUS OTHER HUMAN RIGHTS**

The second section enlightens on the Right to Health and the legal regime dealing with its protection such as the International Covenant for Economic, Social and Cultural Rights (ICESCR) and the Unilateral Declaration for Human Rights (UDHR). It asks why it is viewed as important to protect this right and how this right is said to be inter-related to other rights. It further examines the Right to Health as provided under intellectual property laws such as the agreement on Trade-Related Aspects of Intellectual Property (TRIPS). It analyses whether there is in fact the Right to Intellectual Creativity and will examine to what extent conflicts could arise between different rights.

## **Chapter 3**

### **THE EFFECTS OF PATENTS ON THE RIGHT TO HEALTH IN DEVELOPING COUNTRIES**

This chapter examines the differences between generic and patented drugs. It in addition establishes whether it is necessary to patent any drugs or processes for their manufacture at all. It gives a comparative analysis of prices of some medicines in Developing Countries and those in Developed Countries. It then analyses to what extent

the right to health is affected by the prices at which these patented medicines are sold. It will examine the criteria that need to be fulfilled for a country to use compulsory licensing. It furthermore discuss whether by the year 2016 (the year in which Developing Countries will be required to start granting licences) Developing Countries will be ready for this kind of change as expected of them.

## **Chapter 4**

### **A CASE STUDY OF ZAMBIA**

This Chapter analyses the national law that governs patents in Zambia, that is, the Patents Act. It subsequently considers whether patents, even though not granted in Zambia, affect access to medicines in Zambia. This is done by examining the price of medicines that are patented and imported into the country and to what extent they are affordable by those that are sick in the country. It studies the standards of living of people in the country and whether these coincide with the prices of medicines.

## **Chapter 5**

### **RECOMMENDATIONS AND POSSIBLE AREAS OF REFORM**

This chapter brings forward recommendations and possible areas of reform in the laws that provide for the patenting of drugs as seen to be necessary by this research. It also advances arguments for better protection of the right to health given the political, social and economic context of Zambia.

## Chapter 2

### 2.1 PATENTS AND HUMAN RIGHTS

#### 2.1.1 Introduction

It is increasingly becoming evident that the interconnection between Intellectual Property Rights (hereafter referred to as IPRs) and Human Rights cannot be overlooked. In many instances the promotion of IPRs has been alleged to be to be an infringement of a certain human rights<sup>6</sup>. Of particular interest is where IPRs are assumed to conflict with the right to health. A possible tension between the interests of inventors and the interests of society at large in benefiting from scientific advances has therefore been realised and the balance between the two must definitely be tilted in favour of society in general rather than the inventor<sup>7</sup>.

Human rights treaties also make it clear that the interests of the inventors are not fundamental human rights like the right to life, freedom of movement and other rights. They are rights that are protected so as to award inventors for the effort manifested in advancing society but whether they are to be termed ‘fundamental’ is an issue discussed in this chapter. Therefore, the interests of inventors must be understood within the context of all the other human rights protected<sup>8</sup>. Particularly, the grant of medical patents which in a way restrict a person’s access to medicines can in a way be included as a direct infringement of the right to health.

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<sup>6</sup> G. Dutfield. “IPR Rules and Human Rights: Is there a Conflict?”, 1 October, 2001 (SciDev.Net) Accessed on 17<sup>th</sup> February, 2011

<sup>7</sup> P. Cullet. “Patents Bill, TRIPS and Right to Health” (commentary) XXXVI/43 Economic and Political Weekly, 27 October, 2001

<sup>8</sup> P. Cullet. “Patents Bill, TRIPS and Right to Health”

### 2.1.2 Patents

A patent is defined as a set of exclusive rights granted by a State or a national government to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention.<sup>9</sup> It is a right granted to one who has invented an object or article or has made an improvement to it. It is also said to be, in other words, a grant made by government that confers upon the creator of an invention the sole right to make, use and sell that invention for a set period of time.<sup>10</sup> A patent may be granted even in a case where the medicine in issue is made of one or more than one active substance. If a medicine is composed of or prepared from several material drugs and the composition is newly created, or a medicine is composed of or prepared from one active non-known substance which may be a material drug, it possesses the patent inventiveness provided that facts to prove its effectiveness are submitted.<sup>11</sup>

### 2.1.3 Theories of Patents

There are various reasons put forward in advocating for the monopoly resulting from patents. These reasons are in certain instances referred to as the *Theories of Patents*. These theories insist on the stimulus behind people's desire to have exclusivity of their inventions. Among these reasons is one known as the "*Incentive Theory*". This theory entails that the knowledge that one's invention will be protected acts as an incentive for creation<sup>12</sup>. This is because with exclusivity, an invention receives the value that it deserves, that of not being easily available to any person or body that does not acquire the permission of the inventor. In this sense, the economic value of the innovation is retained solely in the inventor. Without a patent, competitors could copy the invention at relatively low cost and free ride on the original creator's work without incurring the

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<sup>9</sup> C. Soanes and S. Hawker. Oxford English Dictionary. Oxford University Press, Oxford, 2006

<sup>10</sup> M. Woodley. Osborn's Concise Law Dictionary. Sweet and Maxwell, London, 2005

<sup>11</sup> Z. Yongfeng. "The Means and Experiences of Patent Protection of Traditional Medicine in China". The Patent Office of State Intellectual Property, China, 2002. page 5-6

<sup>12</sup> H.L. Maqueen. Innovation, Incentive and Reward. Edinburgh University Press, Edinburgh, 1997. page 61

now-sunk research and development costs of the original creator. This free-riding would allow competitors to sell the good at a lower price than the original innovator.<sup>13</sup>

The second theory is that called the “*Reward Theory*”. This theory states that an inventor is encouraged to invent when they possess the knowledge that they will be rewarded for their work<sup>14</sup>. Under this theory, it is argued that inventions require the input of vast research which utilises a great deal of time and resources. Although the time cannot be replaced by whichever means, the resources can be and are so replaced when a patent is acquired for the inventor can set a price which he knows will be sufficient for his efforts.

A further reason given for the encouragement of patents is that they promote disclosure of innovations. This is made possible by the fact that inventions have to fulfil the criterion of disclosure for them to be patented. This therefore makes it possible for other inventors to work on further progression of the invention and the more progress is made the more development occurs in a country. This view is what is referred to as the “*Contract Theory*”<sup>15</sup>.

Several scholars are of the opinion that patent disclosures have the potential to cause research and development spillovers, which are a key source of productivity growth.<sup>16</sup> However, some suspect that the inventions that are patented are those easy to reverse engineer (and therefore the disclosure is of limited value),<sup>17</sup> others believe patents can

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<sup>13</sup> T.R. Holbrook. “Possession in Patent Law” 59 SMU L. REV. 123 2006

<sup>14</sup> V. Denicolò and L. A. Franzoni, *The Contract Theory of Patents*, 23 *International Review and Economics*, 2004. pages 365-368

<sup>15</sup> A. Kumbhat. “Disclosing Commercial Incentives in Patent Specification” National Law University, Delhi, 2006

<sup>16</sup> W. M. Cohen et al., “Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not)”. National Bureau of Economic Research, Working Paper No. 7552, 2000. page 24

<sup>17</sup> F. Machlup and E. Penrose. “The Patent Controversy in the Nineteenth Century” 10 *J. Economic History* 1, 1950. pages 26–28

still encourage the disclosure of some inventions that would otherwise be kept secret.<sup>18</sup> Patents are also said to play an active role in the development of a country. This is seen when one is granted monopoly for his invention. Others would then aim at improving that invention and such improvements contribute to the development of the society.

In terms of revenue again, the varying fees charged by the patent registration office are added to the national revenue. Some countries base these fees on the number of pages of the patent application; some base the fees on the number of claims in the patent application while others have a fixed fee for all patents. These fees are both for patents awarded to citizens as well as to non-citizens who wish to have their invention protected. The money gotten from here is hereby a form of revenue to the country<sup>19</sup>.

#### **2.1.4 Critique on Patents**

It is the view of this essay that one aspect to delve into when discussing patents is the number of years which this monopoly lasts. According to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), a patent could last up to 20 years. This means this for this period, the patented drugs cannot be of benefit to any person who cannot afford the price as set by the patent holder. This period becomes too long when one possesses the knowledge concerning the low incomes and standards of living in developing countries<sup>20</sup>. It is therefore true that this will affect a great number of people who may have the disease that can be cured by the drug, but are not able to afford it. It does not necessarily follow that the drugs should be administered for free but some moderation should be put in place which could ensure that in as much as one considers prices as per those affordable in developed countries, developing countries should as well be contemplated.

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<sup>18</sup> V. Denicolò & L. A. Franzoni, *The Contract Theory of Patents*, 23 *International Review of Economics*, 2004. pages 365-368

<sup>19</sup> G.M. Kanja. *Intellectual Property Law*. University of Zambia Press, Lusaka, 2006. page 219

<sup>20</sup> F. Cherunilam. *International Economics*. Tata McGraw –Hill Publishing Company, New Delhi, 2008. page 644

However, an interesting question that could be posed is this: Could people (whether artificial or natural) invent even in a situation where they are not granted patents? In other words, it becomes necessary to look into whether there are other reasons that could stimulate inventions other than the foregoing. This is necessary to establish especially in the area of drug patents where it is necessary to establish whether a situation where there would be no drug patents would inhibit the invention of medicines or not.

This research argues that the question could be answered in the affirmative in that certainly, the possibility of creating for charity cannot be overlooked. There are indeed some people who are advocates of change and put in enormous efforts to contribute to global development. An example of this would be the Mosaic Charity which works to inspire young British Muslims aged 12 to 25 to overcome social and economic barriers to success. Despite this being a purely charitable movement, many of their projects can and do benefit non-Muslims living in the areas where the charity operates<sup>21</sup>. It then becomes possible for people to invent new drugs to respond to the social needs of their society even without being able to patent. Right now innovators don't have very much incentive.

Another possibility to consider is that some would invent due to mere concern for the community and their interest in improving the lives of those in the community without any benefit for themselves. One cannot overlook the group of inventors whose aim is to attend to the necessities of mankind. For this group, their aim is to make life easier or improve the way mankind lives. They do not need a patent to be satisfied but their satisfaction streams from the knowledge that they have made a contribution that has benefited mankind. The gratitude of the society acts as sufficient compensation for them.

Patents have also been criticised in the area that some inventions are not as a result of ingenuity but are accidents. For instance, the invention of the microwave oven in 1945, by Percy Spencer who had been experimenting with a new vacuum tube called a magnetron while. He was intrigued when the candy bar in his pocket began to melt, so

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<sup>21</sup> <http://ulasbagci.wordpress.com> Accessed on 17<sup>th</sup> February, 2011

he tried another experiment with popcorn. When it began to pop, Spencer immediately saw the potential in this revolutionary process and later invented the microwave oven<sup>22</sup>. This proof therefore makes it possible to debate from the perspective that if some inventions are by accident, why then should people get credit for them, especially if they are medicines. Such discoveries should then be shared freely for any person would have discovered them had they been placed in the same situation at that particular time. This would mean no inventive step was taken for it was an accident.

The practicability of patents is also questionable as for it is factual that communities are quite reluctant to adopt and utilise new products or ideas. One may then consider the possibility that some inventions, despite being patented and fulfilling the utility criterion, may not be used at all for a long period that follows the invention or may not be used at all. For instance, the method and device for recognition of a collision with a pedestrian which uses sensors in the car's bumper and engine hood and is able to decide whether what has been hit is a pedestrian. This invention has very rarely been put into use and has in some events been referred to as an invention not worth patenting<sup>23</sup>.

Another area of concern is this: despite many efforts to ensure that inventors from developing countries benefit from their inventions, it has become well known fact that they are more at a disadvantage than developed countries. This has been taken into consideration and the World Intellectual Property Organisation (WIPO) has created a 'Cooperation for Development Program' in which it assists developing countries in this area<sup>24</sup>. The efficacy of these commissions in developing countries is another issue of doubt because in Europe, for example these have been observed to be consistently at work. For instance, Microsoft has been constantly commanded to disclose their products to other computer companies so as to ensure that they do not monopolise the market to an extreme.

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<sup>22</sup> Editors of Publications International Limited, Atlanta. "9 Things Invented or Discovered by Accident". 19<sup>th</sup> September, 2007

<sup>23</sup> Article 33 of Agreement on Trade Related Aspects of Intellectual Property

<sup>24</sup> WIPO Intellectual Property Handbook (<http://www.wipo.int>), page 163. Accessed on 12<sup>th</sup> December, 2010

This research proposes that in place of patents, inventors should be rewarded in other ways. This could be done by offering them an incentive of a kind through progressive initiatives such as the ones that different organizations have been providing for the development of diseases. An example of an organisation that has been practising this is the Gates Foundation. The foundation has been implementing incentives that are oriented towards the development of the world at large. They work towards the development of medicines that serve the advanced needs of aging populations in developed countries. The same principle could be applied when it comes to patents in that these should be the kind of incentives that should be implemented to motivate creators. Although they would not amount to an incentive like the profit envisioned when one is creating pomade of loss of hair, it would eventually strive serve its purpose.

Another aspect discovered by this essay is that TRIPS makes no differentiation in terms of considerations between products that are to be patented. It would be right if not reasonable for the agreement to recognise that some products are more essential than others. For example, the requirements for cosmetics to be patented and those of medical rugs are the same. There should be some technique imposed according to the field of technology that is being considered. It is true to say that a lady who goes without perfume will surely not die, but the possibility of one's demise if denied access to drugs is very high.

### **2.1.5 Criteria for Patentability of Inventions**

In as much as inventions are encouraged in every society, it does not follow that all inventions are patentable. To be eligible for a patent, a creation must meet certain criteria. As patent laws are different in different countries, the patentability criteria also vary from country to country. The invention must satisfy the requirements under the context of a national or multinational body of law to be granted a patent. Although the patentability criterion differs between countries depending on the laws there present, there exists some commonality between them<sup>25</sup>.

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<sup>25</sup> U. Mishra. "Patentability Criteria in Different Countries". Bangalore - India, March 2006.

These standard requirements include firstly, that of novelty. This means that the particular invention is one that should not have existed before. It is not enough that the inventor has been creative or innovative; it should be that he has created something new. It should be something that will confer a benefit to the public<sup>26</sup>. In Zambia, the Patents Act<sup>27</sup> states that novelty includes the invention not having been known or used anywhere, not having worked anywhere on trial or experiment by the applicant for the exclusive right, not described in a patent for public inspection and bearing a date of less than fifty years prior to such effective date, not described in writing in any publication of which there was a copy anywhere nor claimed in any complete specification<sup>28</sup>.

Secondly, there is the criterion of inventive step. This means that the invention must be one that is not obvious. The step taken should not have been obvious to the person skilled in the art at that particular time. If the creation involves putting together of two already existing items, then it cannot be patented. This law was propounded in the case of *William v Nye*<sup>29</sup>. This person skilled in the art must be an ordinary practitioner in that field and not one with exceptional skills.

In the case of *Herbaman v Jackel International Limited*<sup>30</sup>, the court delved further into what inventive step meant and established factors that are to be considered for this criterion to be satisfied. These are: the problem addressed by the claimed invention, the period of time that problem existed, the significance of the problem, how widely known the problem was and how many were likely to have been seeking a solution, the prior art known to those seeking a solution, , alternative solutions that had been put forward, factors that may hold back exploitation of the solution if it had been obvious, how well was the patentee's development received and the extent to which it could be sown that

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<sup>26</sup> R.P. Merges, Patent Law and Policy: Cases and Materials. The Michie Company, Charlottesville VA, 1997. page 221

<sup>27</sup> Chapter 400 of the Laws of Zambia

<sup>28</sup> Section 2 of Chapter 400 of the Laws of Zambia

<sup>29</sup> (1890) 7 RPC 62, C.A

<sup>30</sup> (1995) FSR 683

the commercial success was due to the technical merits of the development because it solves the problem. If these factors are present, the invention is patentable.

The third one is that the innovation must have Industrial Applicability. This means that for an invention to be patentable, it must be one that can be applied for practical purpose, not just in theory. It can be a process for as long as that process is able to be carried out or a product for as long as that product is Chapterable of being produced or manufactured.<sup>31</sup> In addition, it must fall within the ambit of items referred to as patentable subject matter. What this is can be established by statute, and is usually defined in terms of the exceptions to patentability, the general rule being that patent protection shall be available for inventions in all fields of technology<sup>32</sup>. Therefore, some inventions may be excluded from patentability. These include the following, among others: discoveries of materials or substances already existing in nature; scientific theories or mathematical methods and diagnostic methods practiced on humans or animals but not products for use in such methods<sup>33</sup>. The TRIPS Agreement further stipulates that Members may eliminate from patent protection inventions whose commercial exploitation would disregard public order or morality<sup>34</sup>.

Finally, there must be Disclosure. For one to be given a patent, they must disclose the steps taken or the details of that invention so that they can be available to the public. This does not disturb the monopoly of the invention but makes it possible for other researchers to use the invention in their research. These details are termed as the 'enabling disclosure' and they are included in the patent specifications at the patent office. This disclosure advances technology for others will also be able to perform further research on it that may be useful for its improvement<sup>35</sup>.

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<sup>31</sup> G.M. Kanja. Intellectual Property Law. University of Zambia Press, Lusaka, 2006. page 235

<sup>32</sup> Article 27.1 of TRIPS Agreement

<sup>33</sup> Rule 67 of Patent Cooperation Treaty

<sup>34</sup> Article 27.2 of TRIPS Agreement

<sup>35</sup> WIPO Intellectual Property Handbook (<http://www.wipo.int>) Accessed on 12<sup>th</sup> December 2010. page

The case of *Biogen Incorporation v Medeva Plc*<sup>36</sup> supports this view. In the holding the House of Lords declared the following:

“Biogen did not disclose the method of producing the antigen...allowing claims of this scope, without requiring sufficient enabling disclosure would be an impediment to scientific development”.

### **2.1.6 Critique on Criteria**

With regard to the criteria as expounded above, it is noticeable that all objects or methods that desire to be patented must meet these. However, such generalisation seems to suggest that medicines or drugs are at the same level and should meet the same criteria as all other inventions. This issue is quite debatable at law for if human genetics cannot be patented, how then should drugs be patented? Despite the fact that they do not exist in nature, some drugs are actually products of herbal medicines that naturally exist but are made easier to administer by altering their form into pills or Chaptersules. These should hereby be termed “unpatentable”. In addition, medical treatment processes are also excluded from patents. This essay argues that it should then follow that medicines are excluded too for sometimes a medical process cannot be utilised, for example, by bone suffering from malaria. But such a person does need medicines. Therefore medicines become vital to human survival and if too expensive cannot be bought and human lives can be lost.

## **2.2 THE RIGHT TO HEALTH VERSUS OTHER RIGHTS**

### **2.2.1 Introduction**

This section discusses the right to health in relation to other rights. Amongst these rights is one that is termed as the right to intellectual creativity. At times these rights conflict and the right which is more critical at the time is said to be protected first. It will begin

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<sup>36</sup> (1997) RPC 1

by discussing the right to health and the instruments under which it is protected then it will move on to discussing the rationale behind the protection of this right. It will afterwards discuss the right to intellectual creativity. An analysis of intellectual property and the right to health will then follow and thereafter a conclusion will be drawn.

### **2.2.2 The Right to Health**

The right to health is one of the rights that are guaranteed in many international human rights instruments. These international instruments are ratified by whichever countries would like to recognise them and are in some instances thereafter domesticated (made part of the laws of the country so as for one to be able to sue for their infringement in the national courts of law). One such instrument is the International Convention on Economic, Social and Cultural Rights (ICESCR). Under this instrument, member states have the obligation to promote universal respect for, and observance of, human rights and freedoms. In its Article 12 (1), the ICESCR states the following:

“The State parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”<sup>37</sup>.

This provision entails that countries are required to take steps to ensure that this right is not infringed. The steps to be taken will depend on the situation in the country as no countries experience the same economic, social or cultural situations<sup>38</sup>. It has been observed that despite such differences however, there is no country can be exempted from the protection of these rights once they declare their intention to be bound by it. Once bound, they manifest that they can be held accountable for any actions that would amount to the infringement of this right.

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<sup>37</sup> Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights

<sup>38</sup> Article 2 of the International Covenant on Economic, Social and Cultural Rights stipulates that it should be according to the available resources

This right was explicitly recognised by the drafters of the Universal Declaration of Human Rights (UDHR), who situated the right to health in the context of the right of everyone to:

“A standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services”<sup>39</sup>.

From the above, it could be implied therefore the Universal Declaration recognises that declines in ‘standards of living’ will negatively influence health. The UDHR might, thus, be said to have been an attempt to establish as a principle the duty of global society to assure global minimum standards of living as a measurement for the right to health.

### **2.2.3 Why protect this Human Right?**

Human rights are said to possess certain characteristics or to comply with certain principles. Among them is the principle of indivisibility and inter-dependence. Human rights are indivisible, whether they are civil and political rights. It entails that the improvement of one right facilitates advancement of the others. In the same way, the deprivation of one right adversely affects the others. Indivisibility and interdependence of human rights means that rights are interrelated<sup>40</sup>.

This principle also means that they are co-equal in importance such that no right is more important than the other. They form an inseparable whole and it is only when they are guaranteed that an individual can live decently. One Philippines’ lawyer Jose W. Diokno commented on this issue with the following words:

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<sup>39</sup> Article 25 of Universal Declaration of Human Rights, 1948

<sup>40</sup> E. Morton Winston (editor). *The Philosophy of Human Rights*. Wadsworth Publishing Company, Belmont California, 1989. page 13

*"We cannot enjoy civil and political rights unless we enjoy economic, cultural and social rights, anymore than we can insure our economic, social and cultural rights, unless we can exercise our civil and political rights. True, a hungry man does not have much freedom of choice. But equally true, when a well fed man does not have freedom of choice, he cannot protect himself against going hungry."*<sup>41</sup>

In this sense, whether a country has domesticated the right to health as to make it a right that one can approach the courts for its infringement makes no difference. For as long as that country protects civil and political rights, then the right to health should also be uplifted. With this regard, one can claim that since health is of special moral importance, states have obligations to protect, promote and restore health and ensure access to health care is equitable.<sup>42</sup> It is an inclusive right, extending to suitable and appropriate health care and also to the underlying determinants of health. These may be said to include access to clean water and sanitation, adequate housing and nutrition as well as social determinants such as gender, racial and ethnic discrimination which might spring up differences in the way people are treated when they approach health care facilities.

#### **2.2.4 The Right to Intellectual Creativity**

The right to intellectual creativity has been argued by inventor to be a right on its own. Their argument is advanced based on the fact that in the same way that private property in land and other tangible resources has been given a place in law, so should the right that inventors have in their creations. It is argued that although this right has taken a twist in that it creates the right in intangible property, there is not much of a disparity because it acknowledges ownership and appreciates the efforts made in the creation

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<sup>41</sup> Quoted in speech delivered by Attorney R.V. Sarmiento at the PAHRA-Sponsored Forum on Human Rights held at Max's Restaurant, Scout Tuazon Street, Quezon City, Philippines on June 20, 1995

<sup>42</sup> Abroad View Magazine, Interview with Steven Rockefeller Fall 2001. [www.abroadview.org](http://www.abroadview.org). Accessed on 22<sup>nd</sup> November, 2010

process<sup>43</sup>. They add that investments in new technologies may be restricted in cases where one possesses the knowledge that their 'rivals' or competitors would enter the market and dissolve the profits.

Some inventors have further advanced the argument by stating that intellectual property rights must also be classified under human rights<sup>44</sup>. Their reasoning for this could be because creativity is as a result of the intellect, whether as a result of an unconscious mind or cumulative collaboration. However, this essay criticises arguments in favour of this for they can be said to be aimed at that advancement of economic rights which are totally different from human rights and do not possess the same characteristics .

### **2.2.5 Intellectual Property and the Right to Health**

It is not in every instance that the promotion of rights will occur simultaneously. At times, a clash between same or different human rights, which are held by the same or different holders, may occur. This may occur in diverse occasions, depending on what human rights is or are in conflict and by whom they are held<sup>45</sup>. A practical example would be that during 2002 and 2003, a Severe Acute Respiratory Syndrome (also referred to as SARS) epidemic spread from China into a number of regions. The global response was that they implemented quarantines restraining the movement of people so as to control the spread of infectious disease.

In this case, there occurred a conflict between the freedom of those who had contacts with SARS patients (as well as those who were misdiagnosed as SARS patients) and the interests of public health and public safety (including the right to life and health of

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<sup>43</sup>F.B. Cross. West's Legal Environment of Business: Text and Cases. South-Western Educational Publishing, United States of America, 2008. page 329

<sup>44</sup> As stipulated in Article 27 of the Universal Declaration for Human Rights, 1948

<sup>45</sup>P. Montague. Article on "When Rights Conflict". Published in Legal Theory by Cambridge University Press, 3rd April 2002 online publication, pages 257-277

others); the rights of the former were constrained<sup>46</sup>. It follows therefore that, the issue of whether intellectual property rights are human rights is in the present case not in contention. This is because whether they are to be classified under human rights, conflicts may occur between them and the other rights. Therefore it becomes necessary to examine the situations under which these conflicts may occur.

From the research in this essay, it is this essay's view that intellectual property treaties today have significant impacts on the realization of some human rights such as the right to health. The view has been supported by scholars who argue that it protects pharmaceutical products by granting the producers exclusive rights under patents thereby granting them monopolies<sup>47</sup>. Patents particularly create monopolies since only the producer will have the right of production as well as distribution and thereby the competition is limited. When this ensues, the individual or group with the patent is able to set the price for the drugs that it desires without any regard to how people will afford this drug. The aim here is profit maximisation.

One aspect of this right is the issue of access to drugs in developing countries and this is chiefly influenced by the Agreement on Trade Related Aspects of Intellectual Property (herein referred to as TRIPS). This agreement stipulates that amendments must be made to existing patent laws in some countries so as not to infringe the right to health<sup>48</sup>. The changes are to be made in relation to the international obligations that states have under agreements that protect human rights as mentioned above.

The grant of drug patents however can be argued to have an adverse impact on prices and availability of medicines. It makes it difficult for countries to comply with their obligations to respect, protect and fulfil the right to health. The inability of populations

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<sup>46</sup> P.A. Singer "Ethics and SARS: Learning Lessons from the Toronto Experience". Working group of The University of Toronto Joint Centre for Bioethics, Toronto, Canada 2003. page 327

<sup>47</sup> J. B. Taylor and A. Weerapana. Principles of Microeconomics, South Western Educational Publishing, United States of America, 2007. page 288

<sup>48</sup> R. S. Barchichat . "Trade Related Aspects of Intellectual Property Rights – TRIPS" April 26<sup>th</sup>, 2009 [ezinearticles.com](http://ezinearticles.com). Accessed on 17<sup>th</sup> January, 2011

to access medicines is partly due to these high costs. In the context of HIV, for instance, as of 2007, only 31% of people living with HIV in Africa who needed treatment received it. Furthermore, it is estimated that people living with HIV will become resistant to their first-line medicine regimens and will need second-line treatment which can currently cost between 9 and 19 times as much as first-line medicines.<sup>49</sup>

Generic competition in the field of pharmaceuticals has the potential to significantly lower prices and increase access. This essay therefore advocates for the production of such drug types for they prove to be affordable and serve the same purpose served by the patented ones. For instance, in 2001, the HIV crisis was at its peak and the need for Anti-Retroviral drugs (ARVs) was the most acute. However, the availability of cheaper generic ARVs from developing countries helped lead to a reduction in prices from over \$10,000 per patient per year to less than \$350 per patient per year for a first-line combination therapy<sup>50</sup>. Today, generic competition has helped reduce prices of ARVs by more than 99%.

It can be suggested hereon that an improved market for generic drugs would help ameliorate the problem of limited access to drugs. This is because generic drugs have previously been considerably less high-priced as compared to patented drugs. If these drugs however are not marketed or advocated for, patent-holders are able to set monopolistic prices for AIDS drugs well above the cost of manufacture, making them prohibitively expensive for many people in developing countries.

Another suggestion to improving access to drugs is by addressing a tendency known as “Evergreening” which is practised by many inventors. This term refers to the practice of obtaining new patents on a patented medicine by making minor changes to it. Inventors would in this case obtain patents on new uses, varieties, combinations as well as mixtures of known medicines with the intention of extending the period of the patentee's

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<sup>49</sup> P. Chopra. “World AIDS Day 2008” World Health Organisation, India: Saturday, 27<sup>th</sup> February 2010

<sup>50</sup> WHO/UNAIDS/UNICEF “Towards Universal Access: Scaling up priority HIV/AIDS Interventions in the Health Sector” 2010

monopoly<sup>51</sup>. This tendency affects access to drugs because or as long as the same inventors have monopoly, the competition on prices which is non-existent. It also enables delays of competitive generic medicines into the market. This essay proposes that a way in which this abuse could be addressed is by changing the standards that are required for the inventive step so as to exclude patents of this kind.

Another suggestion being made by this research is that countries could employ the use of TRIPS flexibilities. One of these flexibilities is that of “compulsory licensing”. Simply defined, compulsory licensing occurs when a government allows somebody to produce the patented product or process without the consent of the patent owner<sup>52</sup>. It is one of the flexibilities on patent protection included in the TRIPS Agreement. TRIPS does not expressly list the grounds that might be used to justify compulsory licensing. In addition, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences<sup>53</sup>. This could thereby be employed in instances where there arises an epidemic and the HIV/AIDS pandemic could therefore qualify here.

Another flexibility is that Least-developed countries have been allowed to delay protecting pharmaceutical patents until 2016. This means that as long as a medicine is not patented in a least-developed country, the government cannot in any case issue a compulsory licence to import it. The supplying country though can issue a compulsory licence to export a generic copy of a medicine that is patented in that country. The significance of this transition period given to Least-developed countries is because absence of product patents on medicines is said to can help establish local manufacturing Chapteracity and promote generic manufacturing.<sup>54</sup> This, in a way, facilitates the import of affordable medicines from other countries in place of the costly

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<sup>51</sup> J.R. Thomas . “Patent “Evergreening”: Issues in Innovation and Competition” Nova Publishers, United States of America, 13<sup>th</sup> November, 2009. page 4

<sup>52</sup> M. Woodley. Osborn's Concise Law Dictionary. 11th edition. Sweet & Maxwell Limited, London, 2008

<sup>53</sup> Paragraph 5 (b) of the Doha Declaration 2001

<sup>54</sup> In Focus Magazine “Is time Running out for LDCs to Utilise TRIPS Transition Period?” Geneva, In Focus: IQsensato, Friday 5 November 2008

patented ones. In a strict sense, this flexibility has aided the improved accessibility of medicines in these countries.

On the other hand, TRIPS can be also be criticised on infringing the right to health because the patenting of drugs can and does encourage development of the types of drugs with the least social utility<sup>55</sup>. This is because there is less spur to create an effective vaccine that may be used once in a lifetime for the producers will desire a drug that will constantly be used so as for them to constantly reap the profits from the invention. For example, pharmaceutical companies invest in ‘lifestyle’ drugs for weight loss, hair growth, breast enlargements due to the fact that drugs for these will be used by consumers numerous times in their lives.

In retrospect, and as contended by this essay, the patent legislation also affects the kind of research carried out because it does not create incentives for inventors that invest in drugs that have therapeutic benefit for society. A suggestion is that it would be more advantageous if incentives were granted for research that is undertaken into the most deadly diseases plus those that affect the largest number of people<sup>56</sup>. However, the current patent system seems to leave room for research into drugs that might have minimal therapeutic benefit. For instance, inventors that are identified as practising evergreening, invention of drugs that are similar to existing patented drugs, should not be allowed to get a new patent. This kind of research does nothing to relieve the global disease burden, but increases the profits of pharmaceutical companies who attempt to evergreen their patents. The legislation should be made more stringent on this issue.

It follows that it is unlikely that an inventor company could produce drugs that cannot re-coup its investment<sup>57</sup>. For example, although there are many people who need malaria medication, they are not viable customers for the pharmaceutical companies,

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<sup>55</sup> J. DeGiulio. “Patent Simulation Study Indicates that Patent Protection May Not Encourage Innovation or Promote Societal Wealth” Canada, 6<sup>th</sup> January, 2010

<sup>56</sup> E. Combe and P. Zuniga. “Pharmaceutical Patents, Developing Countries and HIV AIDS Research”. Paper from International AIDS Economics Network System, Barcelona, 2003

<sup>57</sup> E. Combe and P. Zuniga. “Pharmaceutical Patents, Developing Countries and HIV AIDS Research”

since people in the developing world would generally not be able to pay for it. If a company were to develop such a drug, there would also be pressure on the company to sell it cheaply or to give it away because of the disease is most prevalent in developing countries. Hence, there is motivation to produce the drugs that will have market in the countries that are able to afford high priced drugs. The contemplation on this issue is that the realisation of the right to health could be promoted if a fund were created to reward companies on the basis of the impact of their innovations. Subsequently each company facing the choice of how to develop a medicine would have a choice of either opting into the existing patent-protection system or this fund patent.

### **2.3 Conclusion**

From the above discussion, one could conclude that in as much as intellectual property rights are sought to be protected, the effect of these rights especially on human rights should not be overlooked. There must exist a system under which the TRIPS framework may find ways of balancing intellectual property rights with the right to health. The problem hereby is not TRIPS *per se*, but the fact that despite the available use of such flexibilities, this does nothing to solve the underlying problem faced in research and development. Indeed, the flexibilities may even discourage investment in diseases faced in the Least-developed countries for the reason that pharmaceutical companies may view these as areas where their intellectual property rights will be least protected. This will occur more especially if the course of compulsory licensing is taken.

However, countries must exercise the freedom to bar certain inventions such as new forms and new or second uses, and combinations from patentability of medicines so as to address “evergreening” and facilitate entry of generic medicines. Countries should be able to deny patents on new uses or forms of known medicines.

It can further be deduced that in as much as patents are said to be a necessity for an innovator to be encouraged to constantly invent, there are other reasons that should perform this function. Financial gain should therefore cease to be the sole reason for people’s willingness to invent. On the contrary, whether medical patents fulfil the laid down criteria should not be an issue, what should however be the case is that products such as medicines should as well cease to fall within the realm of patentable subject

matter for the patenting of these in a way is seen to be an infringement of the right to health.

## **Chapter 3**

# **THE EFFECTS OF PATENTS ON THE RIGHT TO HEALTH IN DEVELOPING COUNTRIES**

## **3.1 Introduction**

Although it is a well known fact that patents are advantageous to the innovators and the countries in which they are granted, it is also an arguable fact that they are disadvantageous as well. There is also wide consensus throughout the world that the full enjoyment of the right to health still remains a distant goal because the right is generally not justiciable. It is also evident that this right has become a mere illusion especially for the large number of people that are living in poverty, particularly those living in developing countries. However, this does not change the view that this right is one that is to be protected in accordance with the ratified international instruments<sup>58</sup>.

This chapter seeks to examine the effect of patents particularly on developing countries vis-à-vis the right to health. In attaining this, it will compare and contrast generic and patented drugs and will move on to analyse whether these make up for essential differences in their effect on patents. It will also compare the purchase prices of different drugs in their innovator and generic forms and will discuss whether this can affect the right to health positively or negatively. The issue of compulsory licensing which is viewed as a way in which developing countries are catered for under TRIPS will also be discussed in relation to whether it actually can perform the function that it is claimed to perform in terms of promoting the right to health. The other aspect of TRIPS which provides for developing countries grant of patents in 2016 will then be discussed in terms of whether this is actually feasible and how this will affect the right to health.

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<sup>58</sup> Instruments such as the Universal Declaration for Human Rights and the International Convention on Economic, Social and Cultural Rights

### 3.2 Generic and Patented Drugs

Almost every country's government has begun to intervene in the purchases medicines for its health sector. These medicines are either given to patients in the health institutions for no fee at all or at a fee that is relatively lower than that which is found in private institutions. A close inquiry conducted by this research discloses that in developing countries, there is often need to prioritise when it comes to what medicines are to be purchased for the governments are unable to procure all required medicines at the same time<sup>59</sup>. This failure can be partly attributed to the limited finances allocated to this sector in the national budgets. An observation made is that this could be the reason why only life-saving drugs such as those that cure malaria, tuberculosis and other life threatening diseases are found in hospitals whereas those that cure flus and colds are usually in short supply.

There are high costs of experimentation as well as numerous hours put in when a new drug is being created. These make it necessary for the inventor to be granted a patent so as to be able to recoup what was spent on the invention<sup>60</sup>. Drugs for which a patent is granted by the government are what are referred to as 'patented drugs'. These drugs have to be protected from the possibility of copying by other drug companies so as to avoid free-riding<sup>61</sup>. A 'generic drug' on the other hand is one which is produced and distributed with no patent protection. It may become generic if it was patented as soon as the patent expires. It may also be generic if from the on-set its inventor did not patent it<sup>62</sup>. A drug in this category can be freely gotten by others and copied without any restrictions whatsoever.

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<sup>59</sup> S.Oguntola. "How High Medicine Costs Make Patients Poorer". Nigerian Tribune, Nigeria, 7<sup>th</sup> September, 2010. page 3

<sup>60</sup> V. Denicolò and L. A. Franzoni, The Contract Theory of Patents, 23 International Revolution and Economics , 2004. pages 365-368

<sup>61</sup> T.R. Holbrook. "Possession in Patent Law" 59 SMU L. REV. 123 2006

<sup>62</sup> A. Stephen et al. Drug Use and Abuse. Wadsworth Publishing Company, United States of America, 2007. page 111

It is necessary to mention here that these generic drugs are often identical to the patented ones in terms of composition. They two types also deal with or treat the same diseases. It has also been proven that they have equivalent effectiveness in dealing with whichever illness is in question<sup>63</sup>. They are also regulated by the same authorities so as to ensure that they are safe for use by people. For example, in Zambia, the Pharmaceutical Regulatory Authority ensures that medicines and allied substances that are made available to the Zambian public conform to the required standards of quality, safety and efficacy<sup>64</sup>. This is done through licensing of bodies involved in the importation, manufacture and supply of medicines.

Generic drugs are argued to be cheaper than patented drugs. The reason for this would be due to the fact that when a drug is open to be manufactured by all, there is more competition among its producers. This competition is especially in terms of prices because for people to purchase a particular company's drug more than another's, they would have to be less expensive<sup>65</sup>. This essay is of the view that the other reason for this would be because the drug had already been created by another company, therefore the companies that follow in such production. It therefore would aid developing countries in terms of being able to afford these medicines if the concept of patents was done away with.

However, it is true to say that when people purchase medicines in these countries and they have an option between patented and generic drugs, most will hold the view that the more expensive drug is more effective hence its higher price. This reasoning would be supported by the fact that several studies that were conducted in Nigeria demonstrated that patented medicines are the most common source of malaria treatment in that country. For example, a survey in three communities found that patented drugs

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<sup>63</sup> M. Jeffries. "How Generic Drugs Work". 11<sup>th</sup> October, 2007

<http://health.howstuffworks.com/medicine/medication>. Accessed on 21st January, 2011

<sup>64</sup> Pharmaceutical Act Number 14 of 2004

<sup>65</sup> Congressional Records Volume 149- Part II United States Government Printing Office, Washington, 2003. page 15127

were the first choice for malaria medicines for 49% of children below five years of age<sup>66</sup>.

### 3.3 Comparative Analysis of Medicine Prices

In order to find out whether the arguments against the prices of patented drugs are as high as alluded to by some scholars, this research carried out an inquiry that compared the prices at which the drugs are imported into Zambia. It examined the patented drugs and their generic equivalents which are either produced in another country where they do not hold a patent or used as examples to illustrate:

Firstly, the generic drug Amoxicillin costs ZMK75 for each 250mg Chaptersule. On the other hand, its patented version called Amoxyl costs ZMK400. This means that the patented one costs about five times more. Another example would be the generic drug Ciprofloxacin costs ZMK60 per 250mg tablet while the patented equivalent, Ciprobid, costs K1000 making it almost 17 times more expensive than the generic. Paracetamol would serve another example, at a price of ZMK17 per 500mg tablet its patented equal, Panadol, is about eleven times more expansive at a price of ZMK200 for the same tablet. The next drug this research examined was Sulphadoxine, a malaria drug which costs ZMK8 for each 250mg tablet in comparison to Fansidar which is patented and costs ZMK90, also about eleven times more. Finally is Mebendazole which is sold at ZMK12 for every 500mg tablet while its innovator equivalent, Vermox, costs ZMK665, about fifty five times the price<sup>67</sup>.

The differences in prices between the two types of drugs are very evident as from the above study conducted under this research. It can therefore be argued to be indicative of the extent to which the companies that have patents make profits as compared to those without. Some companies argue that these differences are due to the fees firstly that are

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<sup>66</sup> L.A. Salako et al. "Treatment of Childhood Fevers and other Illnesses in Three rural Nigerian Communities". Journal of Tropical Pediatrics. Oxford University Press, Oxford, 2001. page 230-238

<sup>67</sup> Comparison made using the Ministry of Health Indicative Prices. Ministry of Health, Zambia

paid to the researchers that work in these institutions and have to be paid large amounts of money for the time spent in processing and manufacturing new medicines.

Another aspect that should be considered here is the cost of anti retroviral therapy in when there are patented drugs used and when there are generic drugs used. This is because such cost differs depending on whether one is using generic or patented Anti-retrovirals. From a study as was conducted in South Africa, a significant difference between the two, which acts as proof of this argument, was noted. The cost of antiretroviral therapy using patented drugs was found to be \$730 per year while that for generic anti retroviral therapy as negotiated by the government was \$181 per year<sup>68</sup>. This vast difference in the two could be said to make it preposterous for any country to opt for the use of these patented medicines.

However, in retrospect to the money spent during research, it is the opinion of this essay that some of these high prices spring up not merely due to the expenditure on research but also due to the money spent on activities that are remote to the research but which had some money spent on them which needs to be recouped. An example of this would be the air travels made by researchers to other countries. Some of these have even been observed to be flying first class instead of cutting their expenses to the minimal and yet when it comes to price setting all of these expenses will need to be earned back by the company through profits from the drug. For example, the salaries paid to employees from entry-level at some of these institutions such as Smith Kline and Beckman may be up to \$150000<sup>69</sup>. Therefore, the price is a factor of many aspects of the research.

This essay recommends that there should be a way of forcing these companies to move away from the trend of adding such factors. There must be a system which will ensure that as the manufacturers set the price, there is accountability as to what they are considering as well as how it was done and for what reason which should all be related to the research. Factors that are not necessary to such research must not be calculated. It

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<sup>68</sup> M. Badri et al. "Cost-Effectiveness of Highly Active Antiretroviral Therapy in South Africa". PLoS Medicine United Kingdom, January 2006

<sup>69</sup> The Black Enterprise Executive Recruiter Directory Magazine Volume 18, Number 7. Earl G, Graves Limited, New York, February 1998. page 112

could also be made certain that those that do not adhere to such requirements are dealt with so as to serve as an example for the other countries. When this is done, the protection of this right will be done at a global level as needed.

### **3.4 Compulsory Licensing**

Compulsory licensing as alluded to in the previous chapters is implemented when there is a need to overcome imposed high price or short availability of drugs which could have been brought about by an activity of the patent holder. Intellectual Property instruments such as the TRIPS Agreement, the process is provided for when the agreement stresses that members are permitted to grant compulsory licensing without authorisation from the patent owner and the public<sup>70</sup>. This license may be granted when the applicant seeking the license has made efforts to obtain a license from the patentee but has not been successful within a reasonable period. However, it is important to note that this requirement can in a way be ignored if the case is one of a national emergency or if there are other circumstances of extreme emergency.

From this exposition, it is the opinion of this essay that despite the issue of compulsory licensing being viewed as a flexibility under this instrument, it is true to argue that most of the developing countries in which this license can be granted do not even possess the technology or the manufacturing capacity so as to make full use of this provision. This can be because some of the machinery that is needed for different levels of production unavailable in the country and so the fulfilment of the needed production would be quite a challenging if not impossible altogether. This is because some of the machinery used is too expensive for developing countries and that the cost of buying it would be equivalent to the cost of purchasing the needed drugs.

In addition to this, it is further provided that a country that produces items through the use of compulsory licensing is not allowed to export them to other countries<sup>71</sup>. This

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<sup>70</sup> Article 31 of TRIPS

<sup>71</sup> Article 31 (f) of TRIPS

leaves the countries that do not have the knowledge in a disadvantaged position. It is true to state that the countries that are in this position are developing countries. This essay argues that developing countries in the first instance have little incentive for the protection of patent rights in pharmaceutical products because even if they were in a position where they would be granting patents, TRIPS puts up many restrictions relating to how this provision should be implemented.

The Doha Declaration has taken a step in loosening this step by providing the following:

“Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses may be granted.”

It has also further provided that:

“We recognize the WTO members with insufficient or no manufacturing capabilities 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.”<sup>72</sup>

There was also the waiver that was set forth to make it easier for developing countries to be able to import drugs that were produced under compulsory licensing from other countries. I would argue that compulsory licensing is a way in which TRIPS tries to distract people from the negative effects that TRIPS has on the right to health. However, it becomes impossible to grant compulsory licenses for each drug that is required all the time in some of these countries because they literally need a number of drugs at a time. In some instances, the drug required as a matter of health emergency may be one which is not even produced in the country that requires it and in this case, no license is even possible. Therefore, it can be argued that the fact still remains that such a provision, as long as there are patents, cannot fully satisfy or address the right to health which has been massively affected.

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<sup>72</sup> Paragraph 6 of Doha Declaration on TRIPS Agreement and Public Health 2001

Another aspect that can be criticised is that when scholars are advocating for compulsory license, they are seen to ignore how the concept has been applied so far and whether it has actually helped the countries that have implemented it or not. To establish this issue, the essay will take a look at the situation that occurred in Rwanda where the country wished to grant a compulsory license to a Canadian Company, Apotex, to manufacture its AIDS drugs. The experience of Rwanda was that there was unnecessary delay in the grant and that this delay worked to the detriment of those that needed the medicine for treatment. It can therefore be questioned as to why the process cannot be fast tracked so as for it to address the emergency that it aims managing.

### **3.5 The Grant of Drug Patents for Developing Countries in 2016**

Developing countries have up to the year 2016 before they are obliged to extend protection to pharmaceutical products<sup>73</sup>. This is according to a 2002 Decision of the TRIPS Council, based on the 2001 Doha Declaration on the TRIPS Agreement and Public Health. These countries are exempt from implementing, applying or enforcing the TRIPS provisions on patents and the protection of undisclosed information with respect to pharmaceutical products.

However, as a consequence of this ban, developing countries have been culprits of copying illegally the drugs that are patented in developed countries. This allows for the manufacture of drugs that cost a fraction of the original ones which is contrary to the maximisation of profits by the manufacturing companies. In addition, also dangerous in that some of these drugs are not well tested or analysed and therefore may in effect prove hazardous to human health. An example of such counterfeits occurred when there was the dummy contraceptive pill and false anti cancer drugs in Brazil in 1998<sup>74</sup>. In

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<sup>73</sup> K. Losse et al. "The Viability of Local Pharmaceutical Production in Tanzania". German Agency for Technical Cooperation, Germany, 2007. page 6

<sup>74</sup> August Chronicle. "Phony Birth Control Pills Sold in Brazil". Associated Press, New York. 7<sup>th</sup> April, 1998

1995, there occurred the death of 2,500 people in Nigeria due to a meningitis epidemic that had been addressed by administering counterfeited vaccines<sup>75</sup>.

In certain instances, despite the protection rendered to patented medicines, some countries have been observed to be perpetrators of reverse engineering of well-known drugs such as Viagra and Prozac. What makes the situation more interesting is that some of these drugs. For example, Bayer Laboratories, the patent holder of a drug called Praziquantel, was out priced by Shin Poong, a Korean laboratory that had developed a less expensive manufacturing process.<sup>76</sup> Although this example is not one that dealt with a developed country, chances are that this could occur there as well. It is this essay's contention that the Intellectual Property laws have not adequately covered what is to be done in such instances. It is therefore such loopholes that could bring about chaos as to what should be done. The laws have also not put up a mechanism in which developing countries are monitored to ensure that there is no piracy of drugs transpiring.

Finally, by the assessment conducted in this essay, the ban has acted as a deterrent to addressing diseases that affect developing countries particularly because the innovators in developed countries will concentrate solely on those affecting the countries on which they live. This view is supported by the number of tropical diseases that are still prevalent in developing countries but have not been addressed or paid attention to. It is assuredly true that these diseases affect the poorest people in the world because it is mostly developing countries that are located in the Tropics. The ban can therefore also be condemned because it does not take into consideration that research in these diseases can only occur if done by people who are affected by them, those living in these countries. Alternatively, TRIPS should have provided for ways in which developed countries would be forced to delve into such research so as to prevent the number of deaths that have occurred where they are prevalent.

One other problem caused by this is that of 'Biopiracy'. This is a term used to refer to how corporations from the Developed Countries take resources from Developing

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<sup>75</sup> A. Raufu. "Nigeria leads fight against "killer" counterfeit drugs". Bulletin of the World Health Organization Volume 84, September 2006. pages 685-764

<sup>76</sup> B. Pecoul et al. "Access to Essential Drugs in Poor Countries: A Lost Battle?" Journal of the American Medical Association, United States of America, 1999. page 361

Countries to develop profit-making products such as medicines, without rewarding the countries from which they are taken<sup>77</sup>. The fact that biopiracy has become prominent can be attributed to this and can also be criticised as a way of monopolising the use of genetic resources and knowledge from Developing Countries.

### **3.6 Conclusion**

In conclusion, there are many issues that would need to be addressed in order to uphold and protect the right to health in developing countries. It has been observed that one of the challenges is the price of the patented medicines that are sold in these countries by companies from developed countries. Some of these drugs have been seen to be much more expensive than their generic equivalents, thereby signifying the extent of the exploitation that takes place. This especially occurs where there is no generic model that can be imported into the country. It has also been observed that compulsory license though advocated for is not fully understood and that due to this, it has not worked at its optimum even for those countries that have implemented it such as Rwanda. There is need therefore for these issues to be addressed by the legislation such as TRIPS because such overlooked areas are the cause of the infringement of the right to health that is experienced by developing countries.

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<sup>77</sup> V. Shiva. *Biopiracy: The Plunder of Nature and Knowledge*. South End Press, .New York: 1997. page 24

## **Chapter 4**

### **A CASE STUDY OF ZAMBIA**

#### **4.1 Introduction**

It is a well known fact that developing countries cannot grant drug patents until the year 2016. However, it is an arguable point that this does not dispute the fact that patents affect the people that buy drugs in the countries where the patents are granted. The essay considers whether or not patents also adversely affect even the countries where they are not protected. In this essay, such countries are developing countries which cannot grant pharmaceutical patents. This is because the products with patents are still import drugs that are patent protected for use by patients in their countries. These drugs are sold in private pharmacies and chemists and are at times even administered in public health institutions if no generic equivalent of the drug exists.

This chapter aspires to narrow down the discussion to one developing country, Zambia. It will therefore scrutinise the Patent Act of Zambia in terms of whether it adequately addresses the controversial issues concerning drug patents that are faced in the country. In doing this it will examine the costs that the government has to bear because of these patents on drugs. It will also look at how the right to health is protected in the country and whether the current protection is sufficient to overcome encroachment of the right by the government or even citizens. Afterwards, it will analyse the standards of living in the country in terms of whether these standards coincide with the medicine prices in the country. In this sense, it will be attempting to answer the question of affordability of drugs in the country. A conclusion will then be drawn.

#### **4.2 Patent Legislation**

Patents in Zambia are regulated by the Patents Act Chapter 400 of the Laws of Zambia. The Act stipulates for a wide range of subjects concerning patents. Among these subjects are those concerning applications for patents, administration, infringements as

well as assignments and corrections. Although the country has its own patent law, this does not dispense it of the obligations it has under international patents treaties or instruments. Among such instruments is the aforementioned TRIPS Agreement. This is because the country ratified the instrument so as to be bound by it but it is the view of this essay that it may also be because some aspects of patents that are covered under TRIPS are not dealt with sufficiently in the domestic Act.

A close scrutiny of the Act also discloses that it pays more attention to the protection of the patent holders' rights as compared to balancing these rights with those of the users. This is evidenced by the various sections that it contains that are aimed at protecting the patentees. One of these is the part that stipulates what amounts to infringement and goes on further to give how one can proceed in an action for infringement<sup>78</sup>. It also has a section that sets out the punishments that are to be awarded to patent infringers<sup>79</sup>. As a whole, the Act can be criticised that it acts more like a guide to patents than the law. This is because it plays more of an informative than active role.

Further, the Act contains no provision that specifically addresses how the use of patents must be in line with the needs that Zambia as a developing country has in relation to patents. A question can be posed here: Is this how legislation should be? And the answer is no. For a developing country, legislation should take into account the specific underlying factors and hurdles that the country is facing so as to ensure that the people of that country are protected. This is because if it overlooks the challenge especially the economic ones, then the legislation might even work to the disadvantage of the citizens.

Another aspect of the Act that can be criticised is that most of the citizens in the country still lack information on patents. Some of these people lack any idea on what patents are or even how they work. For the purposes of this study, the research carries out a survey under which random sampling which was done in Lusaka's Town Centre revealed that the assumption of patents being far reached for some people is true. Out of the 65 passer-bys that were asked the simple question of 'whether they know what patents are or have heard of patents', either in their local language or in the official language, only

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<sup>78</sup> Part VII of Patents Act, Chapter 400

<sup>79</sup> Part XII of Patents Act, Chapter 400

about 15 possessed such knowledge. Among these 15, only 5 actually knew how one could apply for patents.

The other 10 had simply encountered the word as they overheard colleagues mention them or when they had heard of the Patents and Companies Registration Agency (PACRA), which they termed as ‘the place where companies are registered’ register for a company. They had no idea that there was such an Act. Although this is a small sample as compared to the population in the country, it can be inferred from here that this is the general situation in the country. It can be argued that this sample, especially because it was random, can therefore depict an idea of the knowledge that people possess about patents which is in fact true.

This essay proposes that there be more sensitisation and education on patents in the country if patents are to contribute to the enhancement of development in the country. It means that there must be more inventions by the local people so that there can be technological advancement in the country. The evidence attributing to lack of knowledge can be interpreted to mean that there are more ‘foreign’<sup>80</sup> people that are able to put patents to use than the indigenous people. The essay proposes therefore that people should be more educated on the fact there is no difference between generic drugs and their patent equivalents so that when one goes to purchase medicines, they may not assume that the more expansive one is more effective and opt to buy it. This in its own way will enhance protection of the right to health in that there will be no hindrance to access to drugs due to lack of knowledge on how they work.

#### **4.3 Protection of the Right to Health in Zambia**

In Zambia, all the protected rights are contained in the Constitution of the country, which is the supreme law of the land. The rights are contained in a section of the constitution called the bill of rights. Some of the rights contained in this section are the right to freedom of movement, the right to life, the right to freedom of expression and

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<sup>80</sup> Used to mean non-Zambian

the right to freedom of assembly and association<sup>81</sup>. It is noticeable that all these rights are those termed as civil and political rights. It is true to say that for one to sue for infringement of a right; it has to be a right that is contained in the constitution or in a treaty that has been domesticated. So far, the right to health is not a right that one can sue upon for infringement because it is not one of these rights. The country has claimed that it does not have the Capacity to protect this right because of lack of finances.

But again, it should be clarified that this does not mean that the state does not have the responsibility to protect it for it is party to the Universal Declaration of Human Rights (UDHR) other conventions that protect it as earlier stated. This is because the country has pledged to protect this right and therefore it has to take steps towards its protection. However, in a country that has a constitution that supersedes all other legislation, it means that if the Constitution were to be in conflict with one of these treaties, then the Constitution would trump over the treaty. This is true and has been evident in countries where the situation of supremacy of the constitution is a basic constitutional law principle.

The case of *Reid v Covert*<sup>82</sup> supports the above stated issue. This was a United States case in which the United States Supreme Court ruled that the Constitution supersedes international treaties ratified by the United States Senate. According to the decision, the Court was said to have regularly and uniformly recognized the supremacy of the Constitution over a treaties. Although not a Zambian case, the same principle can be applied in Zambia where the supreme law of the land is the constitution and all laws are required to be in conformity with it or are declared null and void.

It is the view of this essay that it is necessary to integrate the international health perspectives into national patent laws. In this way even as patents may be constantly examined when being granted as to whether they affect the right the health. This is necessary because some patents may not be medical patents but may affect the right to health invariably.

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<sup>81</sup> Chapter 1 of the Laws of Zambia

<sup>82</sup> 354 U.S. 1 (1957)

#### 4.4 Affordability of Drugs in Zambia

From the research conducted under this essay, it can be argued that the adoption of rigorous patent laws is not a direct guarantee that there will be development in the developing countries; this is so because each country has different stages and different reasons for its development. When one examines developed countries such as the United States of America, Switzerland and Canada, their development occurred in an era where there were weak or no patent laws. This could be claimed to have made it possible for technology to be shared and developed further by as many people as possible. It also made it possible for the Industrial Revolution to occur. But it was only after they themselves reached an advanced level of technology that they advocated for protection so as to stop all other parts of the world from copying and benefiting from their inventions. The patent protection system is therefore a scheme to keep the technology within their territories.

Evidence of this can be supported by the fact that the TRIPS Agreement even stipulates that:

“...Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement...”<sup>83</sup>

It can also be argued that the processes by which these deals are negotiated are far from fair and just. Most poor countries played little part in the negotiations on TRIPS; those that did participate resisted it strongly and negotiated some concessions giving them some flexibility. However, they had to accept TRIPS as part of a package. However, it has been observed that even after the passing of TRIPS, some countries have continued to lobby against the protection offered to patents.<sup>84</sup>

An argument in furtherance of this would be that it is common knowledge even in everyday situations that the bargaining process between a person in high economic

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<sup>83</sup> TRIPS Agreement, Article 1.1

<sup>84</sup> E. Mekay, “Pressure Builds for Affordable Life-Saving Drugs,” Inter Press Service, 7 November 2001.

position and one in a lower economic position is difficult. This is because the one in a lower one is more vulnerable and will most likely accept whatever the other offers. This then can be true in the situation of intellectual property protection. The developing countries would definitely not desire any damage being caused to their relationship with developing countries from which they are granted aid in different forms and because they trade with these countries. Developing countries are extremely dependent on goods manufactured in developed countries because they lack the capacity to manufacture their own products.

Statistical evidence collected under this research revealed that the people and companies in developed countries hold 97% of patents worldwide. This in effect means that they ultimately control modern technologies. A study conducted in 2004 revealed that Japanese patent owners accounted for 1.5 million patents (29% of the world total) while 1.2 million patents (22%) were owned by U.S. patentees<sup>85</sup>. This is core evidence that they wish to maintain control and continue dominating global markets.

The health crises that are occurring in the country especially the HIV/AIDS pandemic is an event that should make it possible for the country to challenge the discourse of morality that is created by the pharmaceutical industry. Access to life saving drugs is a vital concern and therefore drug patents must not be protected like any other patents.

Eric Sawyer, a founding member of ACT UP/New York, addressed this issue in the following words:

“It is time to demand that pharmaceutical companies drop the prices they charge poor people for drugs to a level that is affordable in the countries where most poor people live. It is time to demand that our governments, churches, foundations, and rich people pay for the purchase of essential medicines and the provision of health care to poor people everywhere. We must never forget that access to health care is a human right. And we must not rest until every man, woman, and child has access to safe shelter, sufficient food, clean water, and good health care.”<sup>86</sup>

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<sup>85</sup> J. R. Strobel, *Law Clerk Worldwide Patent Statistics*, World Intellectual Property Organisation's Reports, 2006

<sup>86</sup> B. Shepard and R. Hayduk (editors), “An ACT UP Founder ‘acts up’ for Africa’s Access to AIDS,” From ACT UP to the WTO: Urban Protest and Community Building in the Era of Globalization, Verso London and New York, 2002. page 92

In Zambia therefore, price controls become necessary as there are no public health schemes which administer medicines. Even in public hospitals and clinics, there is a certain fee that has to be paid to be attended to and the medicine for treatment also is from one's pocket. One way in which the issue of accessibility could be addressed is by putting up price controls. In addition, there is need for a greater public involvement in policy making on the privileges society grants to patent holders. A wider range of interest groups would be able to bring to the attention of the government the areas in which they feel their right to health is being infringed according to their experience.

Finally, it becomes relevant to study the standards of living in the country. It has been stated that the conditions of living in the country are terrible. In addition to this, the standards of living in the country increase every year as essential products' prices are increased<sup>87</sup>. Among these essentials are basic foods but also included here are medical prices. The prices of medicine have been described as being prohibitive for the poor. Such cost can be said to be the reason why people visit traditional healers where there are sometimes practices that further affect their health. In cases where there is a decision to be made in a home that has for example, between buying food and buying medicine, a family will opt to buy food and visit a traditional healer.

This is the position in Zambia today. Due to the high levels of unemployment, only a small proportion of the population is able to earn enough money to sustain their entire family through the month. Most jobs that are available to the people from compounds such as Chawama compound in Lusaka are those of domestic workers, trading in market stalls or street hawking. The income earned from these jobs is very minimal and can hardly sustain a home. In such a situation, if a member of this family were to contract HIV/AIDS, it would mean they will not be able to start treatment as early as required. It is common knowledge also deferring treatment until infection has progressed has fatal results. In Zambia today, most of these instances are dealt with adequately at the public health centres where there are Anti-Retroviral Drugs (ARVS) that are given for free. But with the increased patents on ARVs, it can be projected that

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<sup>87</sup> Lusaka Times. "Zambia: Cost of Living Increases". March 15, 2010 ([lusakatimes.com](http://lusakatimes.com)) Accessed on 13<sup>th</sup> January, 2011

even this area will be adversely affected as the government might not be able to afford purchasing the drugs a few years from now. The solution therefore might be that such patents be banned so as not to infringe the right to health especially in developing countries like Zambia where people cannot afford them.

#### **4.5 Conclusion**

From the arguments out forward in this chapter, it can hereby be concluded that developing countries, and in particular Zambia, have had to face numerous obstacles when it comes to the applicability of patents in the country. Apart from the lack of knowledge that many people have, there are also different factors such as the living standards in the country that make access to medicines a farfetched dream. It has therefore been recommended inter alia, that the government should make the right to health justiciable by including it in the constitution. It is only in this way that the pathetic health conditions that are experienced by people in the country can be addressed.

## **Chapter 5**

### **CONCLUSION AND RECOMMENDATIONS**

#### **5.1 Conclusion**

As has been discussed, the right to health is firmly embedded in international and regional human rights declarations. It has been shown that despite such guarantee, it is sometimes seen to come conflict with other rights, in this case, intellectual property rights. However, it has been argued in this research that these agreements must delineate special protection for human life over and above that of intellectual property rewards in circumstances where such rewards will only infringe human rights.

Access to essential medicines is critical to the fulfilment of the right to health. However, when innovators are allowed to patent medicines and thereby set the price at which they are to be purchased, it entails that this right is placed in private hands and thus cannot be left in the hands of the market alone. Despite developing countries not being in a position to grant such patents within their territories, it still remains true that they are the most affected by drug patents. It has been shown that the prices at which these drugs are sold cannot tally with the incomes in developing countries and in this respect access to medicines is denied. Due to lack of medicines, the countries will not manage to attain their required standard in the labour force and consequently, development will be hindered in this respect. But most importantly, once access is denied, there occurs an infringement of the right to health.

Although patents protect the rights of the inventors and encourage innovation, there are certain ideas that should not be patented. Potentially life-saving technologies should be separated from other types of innovations, and money-making should not be the only incentive for drug discovery. In such instances, resort to TRIPS flexibilities does not come to their aid as these also connote their own complications of time lags and others. Despite attempts to promote public health and access to medicines through the flexibilities outlined in TRIPS and reaffirmed in the Doha Declaration on TRIPS and

Public Health, in practice there are many constraints to implementing these flexibilities as can be seen in the examples cited.

## **5.2 Recommendations**

The first recommendation being made by this research concerns the rationale that is raised in favour of patents, the claim that the innovator must be rewarded and encouraged to innovate more. This encouragement must cease to be solely monetary because this is what has caused the high prices at which these patented drugs are sold. This should be encouraged especially in the area of drug patents. Other ways of rewarding the innovators must be found. It should be responsibility of each country therefore, and not the international community, to identify what incentives can be given to innovators.

Another recommendation concerns the number of years that a patent should be protected. Under TRIPS, a patent could last up to 20 years. During such time, the patented drugs cannot be of benefit to any person who cannot afford the price as set by the patent holder. It has been noted by this research that this period is too long especially because the patent holder possesses knowledge that is beneficial to others and retains it to himself. Such protection affects a vast number of people who may have the disease that can be cured by the drug, but are not able to afford it. This essay recommends that the period for which such patent is held must be reviewed. It must be reduced so as to lessen on the number of people that suffer detrimental effects from the lack of access or affordability to drugs.

A further recommendation is that TRIPS should distinguish between rights that should be granted to different products that are to be patented. It would be right if not reasonable for the agreement should be amended in a way as to expressly acknowledge that some products are more essential than others. For these products that are essential, the protection awarded to them must be protection that leaves some room for their use by those that need them. There should be some system put in place to place products in categories. A product whose lack of use will affect the human population or will infringe any human right should not receive much protection.

In the event that making such products available for public use is viewed as being too detrimental to the producers, an alternative recommendation is that there should then be a way of forcing these companies to move away from the trend of adding such factors. At international level, there is need for price control mechanism. This mechanism should be one that which will ensure that as the manufacturers set the price, there is supervision to ensure that they are not setting extravagant prices. The profits must be calculated in a manner that considers the time and money that was spent on the research. Extraneous factors should be cut off completely in these calculations.

While such reviews and amendments are under consideration, there must sensitisation of people on issues concerning the similarity between generic and patented drugs in terms of composition and effectiveness. This will aid people make the most of their money in that they will not purchase medicines believing they work better because they are more expensive or because they are well advertised but that they should be able to purchase the generic equivalent of the drugs so as to save money.

Further, there should be review made to the local legislation in these developing countries. The legislation should reflect the economic needs of the country and should refrain from duplicating the laws in developed countries. It does not aid the progression of the country to have laws in place that play no role in assisting the development of that country or in aiding the people in that country to deal with their economic situations. In doing this, the review should encourage greater public involvement and should therefore involve various sections of the population so as to seek their views on what must be done.

The TRIPS agreement provided that the developed countries should be given an extension period in which they will not be expected to award patent protection to pharmaceutical products. Review of TRIPS agreement must also be made in this respect. This is because with only five more years before the extension elapses, there still is little or no development that has occurred in the pharmaceutical industries in developing countries. This can be said to be a sign that the countries are not ready to have such expectations placed on them.

There must also be a mechanism that will ensure that TRIPS flexibilities are not stringent so that they can be utilised to the advantage of developing countries. If there is need to have a certain procedure followed, then there must be a specific body set up which will ensure that the procedure is followed in the quickest time possible so as not to defeat the purpose for which the compulsory license, for example is required.

Developing countries must cooperate at the regional level in order for them to be able to actively oppose the increased patent protection especially that relating to medicines before the year 2016. This cooperation will help them argue out the negatives of such protection with one voice as this would make their protest more meaningful than if it were each country speaking in its own right. They must also join hands in sharing ideas on how best they can create investment incentives for generic producers so that these medicines which have proven more affordable are made available to their markets.

Finally, it is necessary to have professionals in the field of intellectual property liaising with experts in human rights so as to ensure that protection of patents does not infringe any human rights, the right to health inclusive. These must be specifically for the resolution of disputes that arise where intellectual property rights are seen to pose a threat to a person's human rights. This can be done by establishing a court that will deal specifically with issue of intellectual property vis-a-vis human rights and the judges in such courts must then be those that have exceptional knowledge in the either areas. Prior to such establishment of the court however, developing countries must amend their laws in such a way that they provide for the aforementioned suits.

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