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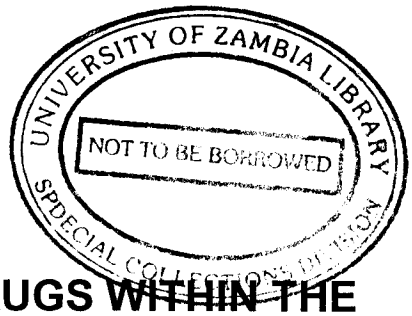


# THE AVAILABILITY OF HIV / AIDS DRUGS WITHIN THE PATENT SYSTEMS

by

**CHILUFYA WANCHINGA**
**Computer No. 20007451**

Submitted to the University of Zambia in partial fulfillment of the requirement of the Bachelor of Laws (LLB) Degree Programme

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University of Zambia
Lusaka.

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# UNIVERSITY OF ZAMBIA

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## DEDICATION

To my dear parents Dr and Mrs Wanchinga, your support and inspiration is without expression, thank you for everything, again I say thank you. To my beloved wife, Lynette and precious children David and Mwiche Gracious, it has not been easy. To God we give the glory.

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## TABLE OF LEGISLATION

The Patents Act Chapter 400 of the Laws of Zambia.

Statutory Instrument No. 83 of 2004.

Medicines and Related Substance Control Act No. 1 of 1965 ( South Africa)

## ACRONYMS AND ABBREVIATIONS

| | | |
|---|---|---|
| AIDS | – | Acquired Immuno Deficiency Syndrome |
| ARV | – | Antiretroviral Drug |
| COMESA | – | Common Market for Eastern and Southern Africa |
| CRC | – | Convention on the Rights of the Child |
| EU | – | European Union |
| FDI | – | Foreign Direct Investment |
| GATT | – | General Agreement of Tariffs and Trade |
| FTA | – | Free Trade Agreements |
| HIV | – | Human Immunodeficiency Virus |
| ICJ | – | International Court of Justice (World Court) |
| IPRS | – | Intellectual Property Rights |
| IP | – | Intellectual Property |
| ICCPR | – | International Covenant on Civil Political Rights |
| ICESR | – | International Covenant on Economic, Social and Cultural Rights |
| LDC | – | Least Developed Country |
| MFN | – | Most Favoured Nation |
| NGO | – | Nongovernmental Organisation |
| NT | – | National Treatment |
| R&D | – | Research and Development |
| RTA | – | Regional Trade Agreement |
| SADC | – | Southern African Development Community |
| TRIPS | – | Trade Related Aspects of Intellectual Property |
| UN | – | United Nations |
| UNAIDS | – | United Nation Aids program |
| UNDP | – | United Nations Development Programme |
| WHO | – | World Health Organisation |
| WIPO | – | World Intellectual Property Organisation |
| WTO | – | World Trade Organisation |

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# CHAPTER ONE

## 1.1 ABSTRACT

The aim of this study was to investigate the adequacy of the main intellectual property (IP) rights regimes, including the Zambia's patents system in HIV/AIDS drugs accessibility.

The thrust of the research hinges on demonstrating how the Decision of the General Council on TRIPS to Implement Paragraph 6 of the Doha Declaration on TRIPS Agreement of 2001(Doha) substantially solves the problems of poor countries being unable to use the TRIPS flexibilities due to insufficient or no capacity to utilize compulsory licensing which is a major option under TRIPS

However, a fair examination of other flexibilities under TRIPS has also been studied.
The study mainly asks the question; What are the relevant provisions on the matter?

The study has found that the IP regimes concerned adequately provide for drug accessibility, But the Zambian patents law needs to align itself with TRIPS so as to have easier access to compulsory licensing for medicines.

The main recommendations is that the TRIPS agreement has a number of flexibilities which should be utilised by developing and poor countries to the full in order to combat HIV/AIDS.
The main method of research was by way of desk research, interviews with non governmental and government authorities as well as the internet.

## 1.2 PROBLEM STATEMENT

A lot of countries, particularly developing countries are still inadequately supplied with HIV/AIDS drugs. This is mainly as a result of misconceptions or a clear lack of appreciation of the flexibilities available in the TRIPS Agreement as well as in other declarations and regulations by the World Trade Organisation (WTO) which could be utilized by developing countries in need of better access to vital medicines. The main misunderstanding is that the IP regime is a constraint to drug accessibility. That its mechanisms are too complicated and are unable to be utilized by countries without adequate or no financial capacity and hence are contrary to the human rights regime to health.

This study will therefore seek to demonstrate that the IPR regime locally and internationally sufficiently provides for accessibility of HIV/AIDS drugs even for the poorest countries and is therefore consistent with the human rights to health.

## 1.3 OBJECTIVE

The objective of this study is to demonstrate that the international IPR regime such as TRIPS Agreement provides adequate provisions for the accessibility of HIV/AIDS drugs even for poor countries, viz-a-vis paragraph 6 of Doha and other WTO regulations, hence attempting to dispense the notion by some quarters that the IPR regime is a constraint to drug accessibility for poor countries or countries without capacity to utilize flexibilities in the TRIPS Agreement and other WTO IP regulations. In the process, the dichotomy of the need to protect intellectual property (particularly patents) versus the right to good health, life and drugs as enshrined in international human rights instruments will be examined, as well as expounding and exploring other possible avenues for the cheaper

availability of HIV/AIDS drugs in Zambia and other developing countries within the frame works of the patent systems.

## 1.4 SIGNIFICANCE OF THE STUDY

This research is significant because a clear demonstration that the legal mechanisms of the TRIPS Agreement is not a constraint of drug accessibility will promote the appreciation and utility of its provisions by poor and developing countries. Paramountly, the significance of the research hinges on the hope to encourage national law and policy makers in Zambia and other developing and poor countries to maximize the provisions provided in the TRIPS Agreement and other WTO declarations and regulations in attempting to access cheaper drugs for millions of HIV/AIDS patients.

## 1.5 METHODOLOGY

Data collection was qualitative, thus by desk research, interviews with government and non-government authorities and the internet.

## 1.6 ESSAY OUTLINE

The chapter one gives an abstract of the research, the problem statement, objectives of the study, significance, and methodology, There after the chapter introduces the definition ,significance and rationale of intellectual property concepts. Chapter two is a brief explanation of the problems and challenges faced by developing countries in accessing cheaper HIV/AIDS drugs. Chapter 3 explains the relevant provisions which could be utilized for enhancing access to developing countries. Chapter four examines the adequacy of instruments in addressing the problem of providing access to cheaper drugs for poor and developing countries. Chapter 5 explores other alternatives for the availability of cheaper HIV/AIDS drugs in Zambia and other developing countries. Chapter six has the conclusion, recommendatition and bibliography.

## 1.7 THE NATURE, RATIONALE AND SIGNIFICANCE OF INTELLECTUAL PROPERTY AND THE PATENT SYSTEM

### 1.7.1 INTRODUCTION

Intellectual property and patent law is that law that ensures that creators and inventors of intellectual property receive the economic benefit for their investment.[1]

Intellectual property law enables an inventor or creator to economically exploit his or her creation to the exclusion of unauthorized persons.
It is on this basis that pharmaceutical companies are motivated to research and discover new medicines. Their discoveries if patented cannot be exploited by others unless the latter have secured consent from the inventor or creator known as the patentee.

But once these essential drugs are in "existence" human rights dictates that it is the duty of humanity to uphold the right to health and ensure that these drugs reach the people that critically need them even at the expense of the patentee.

The rationale being that the needs of the patients which are health and life are superior to the needs of the patentee which is predominantly the financial reward for the labour.

The WTO Trade Related Intellectual Property Agreement (TRIPS Agreement) which is the most significant international instrument on

[1] Kanja, G. (2006) *Intellectual Property Law*. Lusaka : UNZA Press at page 2.

intellectual property has the purpose of raising and setting minimum standards of intellectual property rights's (IPRs) protection in WTO members states. Article 27(1) states 'Patents shall be available for any invention, whether products or processes, in all fields of technology. 'The TRIPS Agreement, however, the TRIPS Agreement also provides flexibilities, which can be utilized by countries that cannot comply with the normal standards in the TRIPS Agreement. In this case the TRIPS Agreement has not failed to yield to its human rights compliance.[2] The Declaration on the Trade Related Aspects of IPRs has further clarified and strengthened the TRIPS Agreement compliance with human rights standards.

This chapter will aim to define and discuss the nature, rationale and significance of intellectual property rights and were possible, briefly taking note of the merits and demerits of intellectual property law justifications in developing countries within the international human rights context.

The chapter will also introduce the particular subject of patents and discuss the history of the patent system from the United Kingdom to its place in Zambia today.

### 1.7.2 Intellectual Property Defined

Intellectual property (IP) is a term that describes those rights which protect the product of one person's work by hand or brain against unauthorized use or exploitation by another.[3]

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[2] Making Trade policies more accountable and Human Rights – consistent : http://209.85.129.104/search?q=cache : eLYsELqOh4J:www.3dthree.org/pdf-3D/DOvcttHatpage3Accessed 03/10/2007.

[3] *Osbron's concise law Dictionary, 8th Ed.* NewDelhi, Sweet and Maxwell.

More simply put, intellectual property is a term that refers to the legal rights which result from intellectual creations in the industrial, scientific, literary and artistic fields.

In other words, intellectual property comprises creations that result from the mind, the human intellect.

Every area of our lives is in one way or another affected by intellectual property. From the clothes we wear, things we buy or sell, what we eat, where we sleep, what we watch on television or listen to on the radio, the books we read and so on, are all products, processes and works of the human mind and the subject of intellectual property

The term 'intellectual property' implies that intellectual works are analogous to physical property; hence, in order to appreciate the term it is useful to approach it in terms of the notion of 'property' in general.[4]

As with all other types of property, that is immovable property such as land or movable property such as cars, books, etc, the owner of intellectual property may use it as he wishes and nobody else can lawfully use his property without his authorization. This legal right is referred to as "exclusive", because it gives the owner the 'exclusive' right to use his property. The proprietor may authorize others to use his property, but without such permission the use would be illegal.

Therefore, if somebody invented a machine that cures cancer by simply using water and salt, the inventor would have the exclusive right to make and reproduce such a machine. In addition the inventor or owner of the patent right would have the negative right to prevent others from doing

[4] Kanja, G. (2006) *Intellectual Property Law*, Lusaka, UNZA Press, at 2

certain things in relation to the invention such as preventing others to reproduce models similar to his own without a licence from him.

### 1.7.3 Types of Intellectual Property

Traditionally, intellectual property is divided into two main branches, namely, Copyright and Related Rights, and Industrial Property.[5]

Literary, artistic and scientific works belong to the copyright branch of intellectual property. Performances of performing artists, phonograms and broadcasts are called 'related rights', that is, rights related to or neighbouring the copyright.[6]

Industrial Property on the other hand covers all IPR's except copyright and related rights. Industrial property includes inventions and industrial designs. Inventions are simply new solutions to technical problems, and industrial designs are authentic creations determining the appearance of industrial products. Industrial property also includes trademarks, service marks, commercial names and designations, geographical indications and the protection against unfair competition.

Unlike the protection of inventions, copyright law protects only the form of expressions of ideas, not the ideas themselves.

There is also a difference in legal protection accorded to copyright and inventions. Since copyright prevents only unauthorized use of expression of ideas whereby a person who discloses to the public an idea cannot prevent third parties from using the idea hence the legal protection for

[5] Ibid at 3
[6] Ibid.

literary and artistic works is often much longer than in the case of inventions.[7]

Inventions, on the other hand, are given much shorter protection mainly so that society can have sufficient opportunity to exploit the invention and benefit from it, which wouldn't be the case if the protection accorded, was too long. In Zambia, the protection is for 16 years.[8]

### 1.7.4 Patents

The term "patent" originates from the Latin word *patele* which means " to lay open" (i.e., make available for public inspection), and the term "letters patent" originally denoted royal decrees granting exclusive rights to certain individuals or business.[9]

However, patent may be defined as "an exclusive right granted for the protection of an invention, which is a solution to a specific problem in the field f technology."[10]

An invention may relate to a process, such as a new method of manufacturing baby food or it may relate to a product such as a new lotion to treating dry skin or acne.

In order for the invention to be protected by a patent it must satisfy some conditions namely, it must be new or novel; it must involve an inventive step that is, it must not be obvious to a person skilled in that art, and it

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[7] Intellectual Property from Wikipedia, the free encyclopedia. File://\\EIGHT/mba2/Intellectual%20property%20 -%20Wikipedia,%%20the%20free%20encylopedia... Accessed 7/13/2007.

[8] Kanja, G. (2006), Intellectual Property Law, Lusaka UNZA Press, , page 3.

[9] Nature of Patents and Patents Rights:File//\\EIGHT/mbaz/Nature%20of%20Patent%20and20Patent%20Rights.htm. Retrieved 7/13/2007

[10] Ibid at 3

must be capable of industrial application and must fall within the patentable subject matter.

As alluded to earlier, the grant of a patent gives the inventor a monopoly to work the invention to the exclusion of others for the duration of the invention which is 16 years in Zambia.

In return for the monopoly enjoyed by the inventor, he or she is required to disclose details of the invention so that any person skilled in the particular art or a person having knowledge and experience of the science or technology, would be able to work the invention.[11]

There are a number of mechanisms that ensure checks and balances so that the patentee does not abuse the monopoly he has over the invention. An example is compulsory licences which may be available after three years of the grant of the patent or it may be registered on the patent that a license is available as of right.[12]

A compulsory licence may be a remedy where the patent was not being worked or if the proprietor was limiting supply of the patented product so as to manifest unreasonably high prices.

Once an invention is protected, it is basically up to the owner of the patent to enforce his rights, mainly by bringing an action for any infringement of his patent rights.

### 1.7.5 History of Patents

Patent law in Zambia traces its roots from the patent system from the United Kingdom. This is because Zambia is a former colony of the United

[11] Section 14 of the Patents Act, Chapter 400.
[12] Kanja, G. *(2006) Intellectual Property Law*, Lusaka, UNZA Press, page 272

Kingdom. And like many other former colonies of the United Kingdom, the latter extended its patent laws to Zambia.[13]

The origins of patens for inventions are not very clear, however Britain does have the longest continuous patent tradition in the world which traces its origins from as far back as the 15th century, when the crown started making specific grants of privilege to manufacturers and traders.[14]

Such grants were signified by letter patent, open letters marked with the 'King's great Seal'. The earliest known English patent for invention was granted by Henry VI to John Utynam who had invented a method of making stained glass.

With an increase in inventions a demand for patents arose and the Tudor Monarchs that followed were more than glad to shower their favourite subjects with grants giving them monopolies over various properties.
Under both Elizabeth I and James I, that is between 1561 to 1610 monopolies for particular commodities became increasingly subject to abuse. In 1610, due to mounting judicial criticism and public outcry, James 1 revoked all previous patents except for "projects of new invention". The words of James 1 against monopolies were enacted into the Statute of Monopolies of 1624.[15]

After the enactment of the Statute of Monopolies the patent system developed through the work of lawyers and judges in the courts without government regulation.

During the reign of Queen Anne, the condition that 'the patentee must by an instrument in writing describe and ascertain the nature of the invention

[13] Ibid at page 216
[14] Ibid, page 216.
[15] Ibid at page 217.

and the manner in which it is to be performed' was added to the requirements for acquiring a patent.

At this stage, the British patent system had served the country well for a number of years all the way through to the industrial revolution.
But by the mid 19th century, the system had become inefficient and complicated.

In 1852 the Paten Law Amendment Act was passed which completely overhauled the British patent system and made it much simpler to obtain a patent.

In 1883, the Patents, Designs and Trademark Act was passed which gave effect to the reciprocity provisions in the Paris Convention of the protection of industrial property.

The Patent Act of 1902 instituted a limited investigation into the novelty of the invention before a patent was granted.

The Zambia Patents Act which was passed on 1st April 1958 drew its inspiration from the United Kingdom's patent system.

The Patents Act provides for the establishment of the patent office, procedure for the registration of both local and foreign patents, rights granted to the owner of the patent as well as the limitations on the said right, infringements and related offences.[16]

It is important to note that the patent system in the United Kingdom had evolved over a very long period of time responding to various social, political and economic factors. The patent laws only became more

[16] Ibid, page 218.

instrumental as the need for patents protection became more and more acute.

This must be contrasted with the way the patent protection standards have been advanced on to developing countries in recent times such as through the TRIPS Agreement in 1994 without strongly taking into account the particular "preparedness" of developing countries.

## 1.8 The Rationale and Significance of Intellectual Property

There are a number of reasons that are advanced to justify the existence of intellectual property rights, and these include the following:

### 1.8.1 Creative Incentive

In order to develop or produce intellectual property products or works, there must be an investment of money, skill and time. In order to stimulate a drive in creators, inventors or innovators to take risks of investing their capital, skill and time, they must be rewarded by being granted exclusive rights to control the use or exploitation of their invention, innovation, creation or works. They must, therefore, be protected from the riders who might copy or reproduce the inventions, innovations or work at minimal costs or no cost at all.[17]

However, it can be contended that in practice an inventor is not always deterred to invent in a venture merely because there are weak or no protection of IPRs e.g. China has weak IP laws but it is still an attractive market for IP investment. What is usually cardinal to know is whether good profit returns can be made or not.

### 1.8.2 Reward for Labour

[17] Ibid, page 9.

Intellectual Property is a channel by which authors or inventors of intellectual property products or works are able to obtain a reward for the time, skill, money and patience they have invested in production of intellectual property. The basis for this reason is that a creator or an author of a work must be able to participate in all the economic benefits realized from the use of his work.[18]

Here again, it can be argued that not all authors or investors work for "reward". Quite often it is not the author or inventor of a work that pursues a reward for the work, but the businesses houses who are ready to exploit the work on the originators behalf. e.g. A Scientist's sole motive for discovering a cure would be to save lives, but it would be his employers who would want to maximize profits from the cure.

### 1.8.3 **Promotion of the Economy**

Intellectual property promotes the publication and dissemination of information and widens the store of available knowledge. The patent system requires that details of patents are published and are available for inspection. In due courses when the patent expires, any one is free to make the product or use the process, as the case may be. But a country without industrial capacity to exploit the information when the patent expires, such a rationale for intellectual property would have no real meaningful value.

### 1.8.4 **Prevention of Piracy and Conterfeit**

Piracy and counterfeit are a disincentive to the development and creation of intellectual property products and works. Piracy and counterfeit present a serious problem by enabling substandard products to penetrate the consumer market.

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[18] Ibid, page 9.

Where intellectual property is weak, piracy flourishes. Where piracy flourishes potential investors with intellectual property avoid investing in such environments. Moreover, local industries are impeded and local intellectual property owners or authorized dealers of intellectual property rights can neither make a living from their work nor recoup their investment.

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### 1.8.5 Attracts Foreign Direct Investment

When strong protection of intellectual property is instituted in developing countries foreign directed investment is boosted.[19] This is generally correct. However strong IP laws are not a guarantee for investment. If a country has no attractive investment to offer then such a country may not see the investment boosted despite good IP laws.

### 1.8.6 Stimulate Economic Development

The rationale for patents is that they stimulate economic and technical development and promote competition by creating a financial motivation for invention. The evidence is seen in terms of manufacturing enterprises established and respective jobs created, the products put on the market and the sales generated by the said products, the amount of royalties and other revenues from licences granted for use of inventions as well as the huge budgets for research and development(R&D) by enterprises producing IP.[20]

However, many developing countries are yet to see much more meaningful technology transfer or any increase in local industries because of tightened IP laws.

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[19] Ibid, page 7.
[20] Ibid

## 1.9 Conclusion

It is very clear that intellectual property law has value in the economic growth of any country. Some criticisms against IPR's however do exist, such as, that intellectual property law causes prices to increase, that it is prone to abuse, e.g. deliberate stiffening of competition by threatening legal action or, that it blocks access to new technology and that the system generally favours developed countries who often fail to take in account their international human rights obligations through narrow interpretations of the IPR regime to their favour.

These criticisms, however valid or invalid they may be, do not offset the fundamental purposes of intellectual property, which is to ensure that the creations and inventions of the human intellect are protected from piracy and counterfeits.

The following chapter will now give an explanation of the legal, economic, social and political challenges in accessing HIV/AIDS drugs.

## CHAPTER 2

## 2. INTRODUCTION

Is a brief explanation of the relevant social, economic, legal and political challenges faced by developing countries in accessing cheaper HIV/AIDS drugs (vis-a-viz human rights versus the need to protect intellectual property rights of inventors.)

The focus of the legal challenges shall be implications of Article 31(f) of the TRIPS Agreement and the impact of the 'paragraph 6 system' of the Decision of 30th August, 2003 by the trips general Council on the matter.

## 2.1 HIV/AIDS in the Developing World and the Sub-Saharan Region

Over 95% of the estimated 36 million people living with HIV/AIDS worldwide are in developing countries[21] 20 million people have already died of AIDS [22] globally.

Latest estimates[23] indicate that 24.5 million adults and children are living with HIV in Sub-Sahara Africa. In 2005 alone it was estimated that 2 million people died of AIDS in Sub Saharan Africa[23]. The epidemic has left behind some 12 million Orphaned African children[25]. Sub-Saharan Africa

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[22] Imaply, P (2005) HIV/AIDS Prevention and Care in Resources Constrained settings. Virginia, USA, Family health International at p.59

[23]UNAIDS 2004 Report on the global AIDS epidemic, 4th global report at p. 13

[24]UNAIDS/WHO 2006 Report on the global AIDS epidemic AIDS and HIV statistics for Sub-Sahara Africa: http://www.avert.org/subaadults.htm.retrieved 23/ 08/ 2007.

has just over 10% of the worlds population but is home to close to two thirds of all people living with HIV[24].

Zambia is home to an estimated[26] 1,100,000 people infected with HIV. In 2003 Zambia had 830,000 infected people, with 89,000 deaths. By July 2007 the deaths had increased to 98,000 for 2006/2007 July period.

The need for antiretroviral drugs and AIDS related medicines is evident, yet there are still obstacles to the accessibility of the medicines. The United Nations, the World Health Organisation, WTO and all stake holders are aware of the need to provide urgent solutions to this problem.

The WTO TRIPS Agreement has accommodated the problems being faced by developing and poor countries in accessing vital drugs and has thus provided various options which such countries could utilize. But despite these flexibilities drugs access is still a major problem. Some of the obstacles shall be discussed below.

## 2.2 The challenges of Accessing drugs for Persons Living with HIV/AIDS in developing and poor countries.

Improving access to HIV/AIDS drugs in developing and least developed countries (LDCs) presents difficult legal, political, social and economic challenges.

These include the following:

(a) The legal challenges: Much of the legal challenges being faced by developing andpoor countries in accessing the much needed drugs seems to be a result of lack of information concerning the legal provisions in the

[24] 2006/2007 Report on global aids epidemic http://wwwavert.org/subaadult .last updated July 31, 2007. retrieved 23/ 08/ 2007.

fundamental IP regimes which actually provide accessibility to vital medicines.

There have been concerns that certain members [25]of WTO with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in utilising flexibilities such as compulsory licencing under the TRIPS Agreement (Article 31) because the TRIPS Agreement in subsection (f) of Article 31 states compulsory licences should 'be authorized predominantly for the supply of the domestic market of the Member only'.

Although WTO members can issue compulsory licences for importation as well as for domestic production, the problem is that the production under Article 31 is limited to predominantly for domestic consumption and cannot be exported to countries in need of the drugs and with insufficient or no manufacturing capacity. A country like India with capacity to manufacture generic drugs would then be limited by Article 31(f) not to export to a poor country in need of the drugs.

This problem was noted by the WTO Ministerial conference, fourth session 2001, better known as the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and in Paragraph 6 of the Declaration the General Council was instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

On 30th August 2003 the Decision on the Implementation of Paragraph 6 of the Doha Declaration was adopted by the General Council. Basically the decision allowed for a waiver of Article 31(f) for as long as notification of such waiver was made to the General Council and a fulfilment of other conditions.

[25] Ibid.

Paragraph 2 of the Decision reads in part :

> 'The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its exports to an eligible importing Member(s) in accordance with terms set out below in this paragraph...'

The conditions put in place are essentially to ensure that this option for WTO members who are in need of pharmaceutical products is not abused.

Some critiques have said such conditions make the Decision on Paragraph 6 difficult to utilise. But such assertions are without merit because the conditions are reasonable and are bare minimum IPR protection. Other legal challenges to accessibility of cheaper HIV/AIDS drugs was Article 31(h) of TRIPS which required the WTO Member granting compulsory licence to pay remuneration to the patent holder. Here again Paragraph 6 states in paragraph 3,

> 'Where a compulsory license is granted for the same products in the eligible importing member, the obligation of that Member shall under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of...' has been paid.

This is simply avoiding double remuneration for the same product.

Paragraph 6 of the Decision on Paragraph 6 also allows for a waiver of Article 31(f) to allow any least developed country or developing country part of a regional trade agreement where at least half of the members are LDC's to grant compulsory licenses collectively.

Thus this study has laboured to show that there are really no critical legal challenges or obstacles to the accessibility of HIV/AIDS drugs by developing and least developed countries under the international IPR system. The constraints which are still there serve to strike a balance between drug accessibility and IPR protection.

Perhaps developing countries only need to ensure that their domestic legal regimes utilise to the full and are consistent with TRIPS and its flexibilities.

What has to be noted however is that patents are territorial. Therefore, where a drug has not been patented in a country of concern that country is free to make generic versions without the need to grant a compulsory licence.

(b) Political challenges: Political challenges in the recent past have been in the form of pressures and threats from developed countries and pharmaceutical firms not to use the TRIPS 'flexibilities'. Such pressure is aimed at wrongly ensuring that IPRS safeguard their economic and financial interests.

The ***Pharmaceuticals v South Africa Case*** is another recent example of how political pressure may influence drug accessibility. The pharmaceuticals however dropped the case. Such pressures are perceived to send wrong signals to 'other' countries that may want to use TRIPS flexibilities such as compulsory licenses in order to access cheaper drugs. But with the broad interpretation of the TRIPS Agreement by the Doha Declaration a lot of pressure from developed countries has apparently subsided.

Accessibility of drugs also depends on the political will of governments to maximise every opportunity in order to meet the demand for the drugs. Political will is reflected in the nature of bilateral and multilateral agreements government enters. The question that may be asked is do the bilateral and multilateral agreements strengthen drug accessibility or are the agreements; such as the notorious Free Trade Agreements, only enhancing the protection of I.P? Political will, is also reflected in government policies and in its commitment to health infrastructure development and matters such as the respect for human rights among others. When there is no political will then government commitment and the duty to uphold the right to health is compromised.

(c) Social challenges: Lack of information of drug accessibility, poor public health infrastructure and logistical systems, contribute significantly to the inadequacy of the availability of drugs. A lack of appreciation of the role of the TRIPS Agreement, wrong attitudes based on wrong misconceptions IP generally contribute to low accessibility of drugs in developing and poor countries.

(d) Economic Challenges: A weak economy cannot adequately empower its people toeffectively access HIV/AIDS drugs because the drugs are costly. This is reflected by a countries incapacity to attract the necessary investment to produce drugs locally or import the drugs adequately. If the economy of country is weak then it limits its capacity to utilise the flexibilities in the patent systems for accessing cheaper HIV/AIDS related drugs.

The IPR legal systems however, have accommodated the position of poor countries. For instance, apart from the role played by paragraph 6 of Doha, Article 66(1) of TRIPS allows LDCs to extend their

exemption from complying with the TRIPS Agreement if their economic position is weak.

We shall now examine the dichotomy between IP and human rights.

## 2.3 Patent Rights versus the Right to Health

Patents rights and the human right to health are seemingly opposing interests of a vibrant society. In order for a nation to develop it must invest in R & D.

The promotion of science and technology is the engine of any modern economy. Economies are based on the trade of things associated with intellectual creations. Research and development or science and technology would come to a stand still if there was no intellectual property protection laws. IPRs protect inventor or creators of works from losing financial returns for their labour because of "free riders."

When the products of human intellect are protected from unauthorised use or copying by third parties (Article 28 of TRIPS) scientist are motivated to research further and innovate new products that advance the quality of living because their efforts are able to "exclusively" give back a financial return. Intellectual property rights are in the core of the fabric of social existence, from within our homes to the shops, or work place and is usually associated with goods and services in these places.

However, when ever IPRs come into conflict with the right to health or life, the IP regime has generously provided by implication that the latter should prevail. The human right to health and life prevails over IPRs, not because the latter are not important, but simply because international law holds the former to be more important the former is more important. It is in this light

that the WTO has made provision for WTO Member states in Article 8(1) to 'adopt measures necessary to protect public health.'

The human right to health is an inherent and inalienable right that is, it is God given and can never be given or taken by human means. IPRs on the other hand are private rights and are created by statute and human contracts or treaties. IPRs have a time limit for patents, e.g. 20 years is the general standard time. (Article 33 of TRIPS).

Most importantly all human beings, individually or as a state have a duty to uphold and respect human rights above anything else. The protection and respect of human rights is declared in several international human rights instruments. These human rights instruments contain obligations which states must take into account in their entire government policy making, including trade policy, thus when ever disputes arises before the courts concerning the interpretation of the TRIPS Agreement and other IPR legal instruments, such interpretations must be made against the background of human rights law.

## 2.4 The Human right to life and Health

*The Right to Life*

The right to life is a supreme right under international human right law that cannot be derogated from even in times of a public emergency. This is set out in Article 6 of the ICCPR and human rights treaties such as Article 6 of the convention on the Rights of the Child. State parties are required to 'adopt positive measures to eliminate epidemics and to increases life expectancy; Access to affordable medicine emerges as an inherent element of the right to life.

*The Right to Health*

Access to affordable medicines is also an integral part of the right to health. Article 12 of the ICESCR and Article 24 of the CRC are notable provisions that protect the right to health. The committee on the Economic, Social and Cultural Right (CESCR) the (body that monitors the application of ICESCR) stated in General comment No 14 (2000) on the right to health: that the normative content of the right to health includes accessibility of health facilities, goods, and services on a non – discriminatory basis.

The right to health under the ICESCR is progressive right over a period of time, but the state has on immediate obligation to take (deliberate, concrete and targeted steps) towards the realisation if the right to health. A state therefore has a duty to ensure that its policies do not conflict with its ratified human rights obligations. Even states that have signed but not ratified the ICESCR or CRC, like the USA are bound by a good faith legal obligation[26].

## 2.5 The South African Pharmaceutical Case

The conflict between IPRs and the human right to health can best be demonstrated by reference to the ***pharmaceutical companies case with South Africa.*** Faced with an alarming increases of HIV cases and high prices for antiretroviral drugs, the South African government tabled a Bill in parliament in 1997 to amend the country's Medicines and Related subsistence control Act of 1965 (the Medicines Act) with a view to giving the country a new drug policy which would facilitate availability of affordable medicine.

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[26] Article 18 of the 1969 Vienna Conversion on the law of Treaties Making Trade Policies More Accountable and Human Rights – Consistent://209.85.129.104/search?q=cache: lysElqOh4J:www.3dthree.org/pdf_3D/DovettH... Retrieved 03/10/2007.

South Africa was probably inspired by Brazil which succeed in making HIV treatment available to a significant population when it had invoked Article 31 of TRIPs Agreement in order to make generic version under a "national emergency". The American government sued Brazil but later withdrew the matter. South African, motivated by the Brazilian story, went ahead with amending the Act. The US and European governments and pharmaceutical companies opposed and criticised South Africa vehemently for allegedly violating intellectual property rights and the national constitution and commenced legal action. South Africa, however soldiered on and the Bill was assented to and signed by then President Nelson Mandela on 28th November 1997. The law suite was eventually withdrawn.

It would be safe to infer from the case that if it were not for the role human rights plays in stressing the importance of the right to health and life and South African's reliance on human rights the USA, European governments and Pharmaceutical companies would not have relented so easily.

## 2.6 Conclusion

This chapter has endeavoured to show briefly the seriousness of the HIV/AIDS epidemic. It is against this global crisis that the chapter has tried to highlight the conflict that exists between promoting the right to health and the protection of intellectual property rights in the developing and developed countries respectively.

The chapter has demonstrated that reconciliation between the two interests vis-a-viz IPRs versus the Human right to health is achieved by understanding the superior status the human right to health is accorded by international law over IPRS.

The chapter also enlightened on the challenges faced by developing countries in accessing vital drugs. The legal concerns that Article 31(f) and (h) are a hindrance to drug access have been dispelled significantly in the light of the Decision to Implement Paragraph 6 of Doha which provides a waiver to Article 31(f)(h) so as to effectively use compulsory licences as an option by importing generic versions .

It has been noted that patents are territorial, where they have not been patented a country may manufacture or import the generic drug without seeking consent from the patent holder.

The next chapter will now identify the significant and more relevant provisions in the IPR regime which could be utilised for enhancing drug accessibility for poor and developing countries.

# CHAPTER 3

## 3. INTRODUCTION

This chapter identifies significant and relevant provisions in the IPR regime which includes; the Doha Declaration 2001, the General Council Decision on Implementing paragraph 6 of Doha, the TRIPS Agreement and the Zambian Patents Act Cap 400 which could be utilised for enhancing access to cheaper HIV/AIDS drugs by developing countries and Zambia respectively.

## 3.1 The TRIPS Agreement salient provisions for accessing cheaper HIV/AIDS Drugs

### 3.1.1 Background of TRIPS

Before the Uraguay Round talks, member countries of the World Trade Organisation (WTO) were free under the Paris and Bern Convention[27] to determine how the patents were granted as regards the scope of protection according to their individual needs and priorities of the countries without according protection to pharmaceuticals if so desired. This allowed a number of developing countries to have access to cheap generic drugs.[28]

However, over the years, developed countries realised that development and international trade would suffer if Intellectual Property Rights (IPRS) were not made uniform in all WTO member countries.

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[27] Paris Conversion for the Protection of Industrial Property of 1967 and the Bern Convention for the protection of Literary and Artistic Works of 1971.

[28] Khor, M (2007) patents compulsory license and access to medicines: some recent experiences. File//E:\ chapter. htm at page 2. Accessed 6/ 18/ 2007.

The standardisation of IPRS was aimed at controlling counterfeit and pirated goods which threatened to diminishing the value of innovation and inventions by developed countries. Hence, proposals were made by developed countries that action should be taken through the General Agreement on Tariffs and Trade (GATT) as early as the Tokyo Round of Negotiations. And so the final result was the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994.

Developing countries tried to resist this because they felt among other social, political and economic reasons that it would lead to increase of royalties and licence fees for products they had previously acquired cheaply. The deal was a "take it or leave it" offer, with the consequence of being excluded from the W.T.O. if any country chose the latter. Many developing countries reluctantly agreed.[29]

The TRIPS Agreement is, by its coverage the most comprehensive international instrument on intellectual property rights. It lays down minimum standards for IPR protection.[30]

However, the Agreement also recognised the need to provide exceptions to the protection of IPRS especially when they were in conflict with significant public interest such as the right to health. It is on this premise that we shall now examine some of these exceptions in the light of the need for HIV/AIDS drugs in developing countries.

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[29] Mwakyembe, H and. Kanja, G.M. (2002) Implications of the TRIPS Agreement on the Access to cheaper Pharmaceutical Drugs by Developing Countries: A Case study of South Africa and the Pharmaceutical companies, *Zambia Law Journal*, volume 34 at 115.

[30] Making trade policies more accountable and human rights consistent: //209. 85. 129.104/ search? = cache: lysElgOh4J:www.three d. org/ pdf. 3D/ D ovettH ... Retrieved 03/ 10/ 2007

## 3.2 Available options in the TRIPS Agreement for accessing AIDS Drugs

Despite the apprehension developing countries had or still have about the TRIPS Agreement a number of significant options or "flexibilities" exist which can be "fully utilised" by developing countries, including Zambia, to access cheaper HIV/AIDS drugs.

Though Article 28 of TRIPS grants monopoly rights to the patent owner for 20 years, they are not absolute but subject to certain limitations and exceptions.

It is within these limitations and exceptions that significant options exist to access to cheaper HIV/AIDS drugs.

As alluded to earlier in chapter two, much of what can be gotten from TRIPS also depends on how the Agreement is interpreted.[31]

The best approach of interpretation is to consider the individual provisions in the total context of the holistic spirit embedded in the Agreement, thus according to the preamble, the main goal of the TRIPS Agreement is 'to reduce distortions and impediments to international trade'.

In accordance with article 7, the protection of IPR's is not intended to promote 'technological innovation', but the 'transfer and dissemination' of technology which are of importance to developing countries.

This means that the recognition and enforcement of IPRS is not an end in itself but are meant to enable each country, within the limits defined by TRIPS to define a balanced regime of protection conducive both to producers and users of technological knowledge.[32]

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[31].Mwakyembe, H. and Kanja G.M. (2002) *Zambia Law Journal* volume 34 at 129.

[32] Shashikant, S. (2007). *Implementing TRIPS flexibilities*, Oxford, University Press at 223.

Article 8 of TRIPS stipulate that 'members may' in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio economic and technological development, provided that such measures are consistent with this Agreement".

This means that no member country can be prevented from taking into account its own public interest when legislating its IPRS as long as the legislation is within parameters of TRIPS.

Furthermore Article 8(2) provides for appropriate measures that can be taken to prevent abuse of IPRS by rights holders when for instance they unreasonably restrain trade or adversely affect the international transfer of technology.

Some of the measures developing countries could utilise through national legislation to promote competition and balance between the rights of pharmaceutical patent holders and users of the technology are as follows: compulsory licencing, admissibility of parallel important, exceptions to exclusive rights and use of public policy measures outside the field of intellectual property rights on issues of access to and prices of drugs.[33] We shall now examine them in more detail.

### 3.2.1 Compulsory Licencing

A compulsory licence is the licence issued by a government to a third party, whether a private company or government agency, for the right to use or exploit a patent without the patent holder's consent.

Under Article 31 of TRIPS, five possible grounds for the granting of compulsory licences by a government or the courts, allowing either

[33] Mwakyembe, H. and Kanja G.M. (2002) *Zambia Law Journal* volume34. p. 120- 128.

government, an individual or a company to use, produce or import a drug or the generic version without the authorisation of the patent owner. The grounds are as follows:

(a) Refusal to deal (b) in an emergency and extreme urgency, (c) for public non- commercial use, (d) anti-competitive practices, (e) dependant patents.

However certain restrictions limit the use of compulsory licences.

Normally there must be an effort first negotiate a voluntary licence with the patent owner on reasonable commercial terms and conditions and within a reasonable period of time.[34] But were the drug required is to be used for public non-commercial use or for a national emergency or other situation of extreme urgency or when there is anticompetitive practice the need to negotiate a licence is waived.[35]

3.2.1.1 **The Major Concern on Compulsory Licencing under TRIPS : Article (f) and the Decision to Implement Paragraph 6 of Doha.**

According to Article 31 (f) of the TRIPS Agreement, a compulsory license, i.e a licence issued by the public authorities to use a patent invention without the consent of the patent holder is to be issued mainly with a view to supplying the domestic market.

This provision has been widely regarded as the main obstacle to the effective use of compulsory licensing by WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find a solution to the difficulties faced by these members.

[34] Article 31 of TRIPS Agreement of 1994.
[35] Ibid at article 31

The Decision by the General Council of 30th August, 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health makes exceptions to this limitation on exports for pharmaceutical products. The Decision makes possible for states that lack manufacturing capacity to import pharmaceutical products produced under compulsory licence.

But there are some conditions that must be complied with not withstanding that the licence shall last only to the extent necessary for the purposes of production of a pharmaceutical product(s).

Paragraph 2 (a) of the Decision stated that a notification has to be made to the council for TRIPS of the;

(i) specifications of the products as well as the quantity needed. This is in order to promote transparency and all accountability to the council TRIPs.

(ii) Confirming that the eligible importing country other than a least developed country Member has established that it has insufficient or no manufacturing capacities.

The rationale is to ensure that the right category of members use the flexibility.

(iii) Confirming that if the pharmaceutical product is patented in its territory it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS without prejudice to Article 66.1 which gives LDCs room not to comply with aspects of TRIP until 2016, but even this deadline can be extended further. Patents

are territorial, so if there is a patent for a drug the IP law required that the country must issue a compulsory licence in order to manufacture a generic version.

Furthermore, paragraph 2 (b) (i) states that a compulsory licence issued by the exporting member under the Decision shall contain the following conditions:
(i) Only the amount necessary to meet the needs of the importing country(s) maybe manufactured under the licence and the entirety of this production shall be exported to the members which has /have notified its needs to the council for TRIPS. This is to ensure that the products are produced for the purpose intended only.

(ii) That the products will be well marked and distinguishable. This is for easy identification and it is easier to regulate and protect the drugs against counter faults;

(iii) And that before shipment the licencees shall post on website the quantities being supplied and the distinguishing features between the products and section (c) of paragraph 2 also requires the exporter to notify the council for TRIPS on issues such as the name and address of the licencee the quantity and type of the product, its destination etc. This is for accountability purposes.

Where a compulsory licence has been granted by the exporter as well as the importer, remuneration for the product cannot be paid twice for the same product. This is to ensure that there is no unjust enrichment on the part of the patent holder.

According to the decision, the importing country must ensure that the products are safeguarded against trade diversion etc. and must ensure that effective legal systems are in place to prevent the importation into and sale in, of products produced under the system set out in the decision. Then rationale is to ensure that the products under the system do not find themselves in the commercial domain. All these conditions under the decision serve to ensure that the flexibilities are not abused by some unscrupulous elements.

An excerpt from the General Council Minutes of August 2003 quotes the General Council Chairman stating that "Members (of WTO) recognize that the system that will be established by the decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not to be an instrument to pursue industrial or commercial objectives"

### 3.2.2 **Parallel Importing**

The TRIPS Agreement in Article 6 clearly states that nothing in it can be used to prevent a country from allowing parallel imports.

Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder.

The underlying concept for parallel imports is based on the principle of exhaustion of rights, which is promised on the fact that where the patent holder has been rewarded through the first sale or distribution of

the product, he no longer has the right to control the use or resale of the product.

This means that the moment a product is not marketed, the patent holder can no longer control its shape circulation.

Parallel imports allow consumers to effectively shop on the world market for the lowest price for a patented good. They are of particular importance for public health interests, since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines.[36]

### 3.2.3 Exclusive Rights Exceptions

Article 30 allows member countries to TRIPS to provide limited exceptions to the exclusive rights conferred by a Patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the Patent owner taking into account the interests of third parties.

Normally the exceptions include compulsory licences in public interests, scientific research and experiment.

In the context of Pharmaceuticals, the most common exception to the exclusive rights of the patent holder is the "Bolar Provision'. This provision allows interested (generic) manufacturers to start producing test batches

[36] Elliot, R, (2001) TRIPS and Rights : International Human Rights how. Access to Medicines and the Interpretation of WTO Agreement on Trade – Related. Aspects of Intellectual Property, Toronto, Canadian HIV/AIDS Legal Network, November 2001. File http : //www/aidslaw.PDFpdf Accessed :7July 2007.

of a product before the patent expires. This reduces the delay of generic products to enter the market after the patent has expired.[37]

### 3.2.4. Use of Public Policy Measures

Within the spirit of article 7, the purpose of TRIPS is not solely to promote "technological innovation" but the transfer and dissemination of technology, which are of importance to developing countries.

Therefore, in this light, article 8 states that member countries may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance".

This means member countries can pursue policies that protect public health as long as they are consistent with TRIPS and this includes measures against IPR holders who unreasonably restrain trade or adversely affect international transfer of technology.[38]

## 3.3 The Zambian Patents Act : Salient provisions for Accessing cheaper HIV/AIDS Drugs

### 3.3.1 Introduction

The Patent Act of Zambia Cap 400 traces its origins from the United Kingdom Patent System. The Zambian Patent Act provides for two types of compulsory licences. The first category is granted to prevent abuse of a patent that might result from the exercise of

[37] Mwayembe H and Kanja G (2002) Implications of the TRIP Agreement on the access to cheaper pharmaceutical drugs by developing countries: case study of south Africa v the pharmaceutical companies. Volume 34, Unza Press Lusaka p. 126

[38] Ibid. p. 275.

the exclusive right. The second category is granted in cases where public interest such as defence, health, food, is deemed necessary.[39]

### 3.3.2 Compulsory Licence in Case of Abuse of Patent

Section 31(1) of the patent Act provides that any person may apply to the registrar for compulsory licencing three years after patent is sealed or four years after it was filed on a number of grounds. A significant ground in line with the topic of discussion is found in section 37(6) (b) thus a compulsory licence may be granted if the demand for a patented article in Zambia is not being met to an adequate extent and on reasonable terms.

This is an avenue for drugs where the patentee may be producing inadequate amounts and on unreasonable terms.

### 3.3.3 Grant of Compulsory Licences in the Public Interest

The Act provides for the grant of a compulsory licence where such grant is deemed necessary to protect the public interest and is in two groups namely, those granted in favour of private parties and those granted in favour of the government or persons acting on behalf of government.[40]

Whether granted to a private person or to government, compulsory licences in the public interest are a channel for necessary drugs as long as the process is within the scope of article 31 of the TRIPS Agreement.

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[39] Ibid. p. 275
[40] Ibid at 277

Article 31 provides that the granting of compulsory licences must be subjected to judicial review. That the licence must be authorized predominantly for the supply of the domestic market of the member that authorizes the licence and that the Patent owner must be paid adequate numeration subject to judicial review among other conditions of the article.

### 3.3.4 State Use of Patents

Section 40 (1) of the Patents Act permits any government department or any person authorized by the Minister in writing to deal with a patent without the patentees consent as long as the patent is no longer required for it original purpose or it is being used for defence purposes.

This is in line with article 30 of TRIPS which provides that a country may include in its patent laws limited exceptions to the rights of a patent owner taking into account the legitimate interest of others. But these exceptions must not unreasonably conflict with the normal exploitation of the patent.

Hence this is another route for accessing needed drugs although it has limited application.

### 3.3.5 Conclusion

This chapter has identified the relevant provisions both in the TRIPS Agreement, the Doha Declaration, the Decision to implement Paragraph 6 of Doha and the Zambian patents Act for the availability of HIV/AIDS Drugs and has shown that a number flexibilities do actually exists in the patent regimes for accessing vital drugs.

The chapter more importantly has revealed that Article 31(f) and (h) are no longer legal problems for drug access as the Decision on Paragraph 6 has granted significant waivers so that drugs are not supplied for

domestic use only and hence increasing drug access for countries without or insufficient capacity to manufacture their own drugs. The next chapter shall discuss and analyse the adequacy of the relevant IP instruments in drug accessibility.

# CHAPTER 4

## 4.0 INTRODUCTION

This chapter discusses the adequacy of the Zambian Patents Act[41] as well as the Trips Agreement in addressing the problem of providing access to cheaper drugs for developing countries as well as an examination of the impact of the Doha Declaration 2001 on this subject.

## 4.1 The Zambian Patents Act : How adequate are the Provisions in providing Access to HIV/AIDS Drugs?

As mentioned earlier the Patents Act in Zambia provides for two types of compulsory licences. The first type is granted to prevent abuse of a patent that might result from the exercise of the exclusive right. The second category is granted in cases where public interest such as defence, health, food is deemed necessary.[42]

In the case of the former category, section 37(6)(b) provides for a relevant ground for granting a compulsory licence, which is that if a patent article is not being adequately supplied and supplied on unreasonable terms, the compulsory licence may be granted.

This provision implies that the country granting a compulsory licence has capacity to manufacture the patented drug, so that it is supplied more cheaply locally. But even where there is no capacity to manufacture drugs, a generic version of the patented drug may be imported if in the importer territory the drug is not patented.

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[41] Chapter 400 of the Laws of Zambia

[42] Kanja G .(2006) *Intellectual Property Law*. Lusaka UNZA Press, Lusaka at 275

## 4.2 CONSTRIANTS IN THE ZAMBIAN PATENTS ACT IN DRUG ACCESS.

Section 38(1)(a) of the Patents Act states that were a patent is in force in respect of (i) a substance capable of being used as food or medicine, or in the production of food or medicine (ii) a process for producing food or medicine, or (iii) any invention capable of being used as or part of a surgical or curative device, the High Court on application made to it by any person interested, can order the grant to the applicant of a licence under the patent on such terms as it thinks fit, unless it appears to the court there are good reasons for refusing the application.

This section is an under utility of Article 31 of TRIPS. Article 31 of TRIPS provides for a wide latitude under which compulsory licences may be granted. This procedure under section 38(1) is too beaurocratic and may prove to be time consuming.

However, a number of developing countries with domestic legislation that provides for compulsory licences have recently taken advantage of this option of compulsory licences or plan to use it. These include countries such as Rwanda, Malaysia, Mozambique, Indonesia, Zimbabwe, Thailand, Ghana and even Zambia. Zambia has granted a compulsory licence to Pharmo Ltd for local manufacturing of AIDS drugs but awaits for a "go ahead" from the World Health Organisation (W.H.O).[43] Zambia, through the Ministry of Commerce, Trade and Industry enacted statutory Instrument No 83 of 2004 to provide authorisation for the manufacturing of patented antiretroviral drugs in Zambia.

[43] Khor, M. (2007) *Patents, compulsory licences and Access to Medicines : Some Recent Experiences.* Third World Network File ://E:chapter.htm (draft) Retrieved at 6/18/2007 at 3.

## 4.3 Statutory Instrument No 83 of 2004

Section 4 of the statutory Instrument (SI) No.83 of 2004 states that ARVs drugs manufacturers pursuant to section 3 of the Instrument shall not be exported to any place outside Zambia.

This SI fails to utilise to the full the provisions of the Decision to Implement paragraph 6 of Doha. If Zambia sees itself as a future manufacturer of ARVs then it should update its laws so that it can even export to eligible importing Member countries of WTO.

## 4.4 The Trips Agreement: How Adequate Are The Provisions In Providing Access To HIV/AIDS Drugs?

The adequacy of the TRIPS Agreement in providing accessibility of HIV/AIDS drugs can be best examined with the background that the right to health is superior to intellectual property rights as is evidenced by international human rights instruments.[44]

The right to health is a non derogable right[45] and is within the core of the United Nations Charter[46] and other human rights instruments. The charter clearly provides that its provisions override all treaties by member countries.[47] Intellectual property rights on the other hand are derogable and maybe subjected to limitations especially in cases of conflict with public interests such as health issues (but subject to agreement).[48]

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[44] Art 53 of the Vienna Convention 1969. Art 2 paragraph 1 of the International Covenant on Economic, Social and Cultural Rights provides that states must take positive measures towards the fulfillment of the right to health

[45] Theodore.(1989) *Human Rights and Humanitarian Law.* London.

[46] Charter of the United Nations, 26 June 1945, Article 1

[47] Ibid Article 103

[48] Calabresi , G and A.D. (1972) Melamed, Property Rules. Harvard Law Review, 1972. p. 1089.

It is in this context that the provisions in the TRIPS Agreement must be interpreted and enforced.

The TRIPS Agreement does acknowledge the right to health. Article 7 recognises that IPRS should benefit both producers and consumers of IPR products. Article 8 states member countries may make necessary measures to protect public health or even measures against practices which unreasonably restrain trade.

The challenge which has been there is that developed countries have tended to interpret the TRIPS Agreement narrowly often over looking the obligations towards the rights to health and merely focusing on the patent holders rights.[49]

This was the case in the ***South Africa v Pharmaceuticals*** as well as in the ***Generic Medicine Case***.[50] In the latter case, Canada, according to its patent laws (within the provision of Article 30 of the TRIPS Agreement), has laws which limited the patent rights as long as they did not unreasonably conflict with the normal exploitation of a patent by allowing generic drug companies to stockpile their version of a drug for sale as soon as the patent expired, (the Bolar provision). Canada argued they did this in the public interest. The EU countered by stating that Canada was "discriminating" against the pharmaceutical industry. The WTO panel took a narrow approach taking into account only the patent holders interest.

It is because of such narrow interpretations of the TRIPS Agreement that led to the formulation of the Doha Declaration 2001 by the WTO.[51]

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[49] Doha Declaration November 14 2001 paragraph 4 clearly states that TRIPS Agreement should not prevent Members from tasking measures to protect public health.

[50] Canada – Patent Protection of Pharmaceutical Products, Panel Report, WT/DS 114/R (17 March 2001)

[51] Khor M.(2007) Patents, compulsory licence and Access to Medicines. TWN File://Echapter,htm(draft) at p.2 Retrieved 6/18/2007

The Doha Declaration has made it clear that Member states of WTO are free to make measures that guard the health of its people and to utilise the flexibilities in the TRIPS Agreement.

### 4.4.1 Compulsory Licences: Its Adequacy Under Trips In Accessing HIV/Aids Drugs for Poor and Developing Countries.

Compulsory Licenses is an option for developing or poor countries to access cheaper HIV/AIDS drugs.
As alluded to in chapter three, this option is no longer a doubtful alternative for developing countries to utilize.

The decision on the implementation of paragraph 6 of Doha has effectively responded to the call under paragraph 6 of the Doha Declaration which was to find an expeditious solution to the problem of WTO Members with insufficient or no manufacturing capabilities in the pharmaceutical sector that would face difficulties in making effective use of compulsory licensing under the TRIPS agreement.

The decision has provided a waiver subject to conditions on transparency and safeguards to the application of Article 31(f) and (h) which were a great concern as they required that once a compulsory license was granted to manufacture or import drugs, it was predominantly for the domestic market only and that where a compulsory license is granted for the same products in the eligible importing member of WTO, the obligation of that member under 31(l) shall be waived in respect of those products for which remuneration was already met for.

This entails that if it is now more possible for developing and least developing countries to have greater access to HIV/AIDS drugs through compulsory licenses. The **case of Rwanda** is a good example of a country

that is already using the new system the decision of implementing paragraph 6 of Doha.

On 17th July 2007 the Council for TRIPS received a notification from Rwanda's Government according to paragraph 2(a) of the decision of August 2003 on the implementation of paragraph 6 of the Doha Declaration.

It can safely be said therefore, that compulsory license is an adequate option now to access vital medicines such as ARV's for developing and least developed countries.

The August 2003 decision addressed the health problem for importing WTO member countries (Article 31(h) ) and the legal problem for the exporting members (Article 31 (f ) as discussed above.

A third waiver under Article 31 (f) is to any LDC or developing country part of a regional Trade Agreement where at least half of the LDC's are WTO members

**Paragraph 11** of the August 2003 Decision instructed the TRIPS Council to initiate work on amending TRIPS by the end of 2003 with a view to adopting the paragraph 6 waiver into a "permanent" form within 6 months.

The general Council decided on 6th December 2005 to adopt and submit to the members for acceptance the Protocol amending the TRIPS Agreement. The Protocol was open for acceptance by members until 1st December 2007 or such late date as maybe decided by the Ministerial Conference.

The amendments will come into force only when a sufficient number of member countries accept it in accordance with Paragraph 3 of article X of the WTO agreement

Once the TRIPS agreement is amended, the new provision will be referred to as Article 31 *Bis*

Though slightly different in its construction to the Paragraph 6 system, it is substantially the same in content and implication.

### 4.4.2 Parallel Importing: It's Adequacy Under Trips In Accessing HIV/AIDS Drugs

Parallel importing which incorporates the principle of international exhaustion of rights is a very valuable option for a country with limited resources to import the drugs from a cheaper source than the actual manufacturers of the same drug.[52]

A country without any capacity to manufacture drugs on its own can also utilise this option. However, utility also depends on the financial capacity to import the drugs as sometimes importing can also be costly. But one main advantage of this option is that you can access the original product with all the quality guarantees that go with it at a cheaper price than the local source which could be more expensive.

### 4.4.3Exclusive Rights Exceptions: Their Adequacy In Accessing Cheaper HIV/AIDS Drugs Under Trips.

[52] Article 6 of TRIPS

In the context of pharmaceuticals the most common exception to the exclusive rights of patent holders is the "Bolar Provision". Theoretically such an exception is allowed under Article 30 of TRIPS, but the problem is that the language is not explicit on the matter. Such an exception hinges on the interpretation of TRIPS, this then leaves it to "battle of interpretation" between developed countries who favour a narrow interpretation and developing countries who support a more flexible interpretation of TRIPS taking into account Article 8 and other international human rights instruments on health.

### 4.4.4 Exclusion From Patent Admissibility: Its Adequacy in Accessing Aids Drugs Under Trips.

Under Article 27 (2) of TRIPS a country may prevent the commercial exploitation of some inventions if necessary in order to protect human life and health by refusing to recognise their patent admissibility. The problem with this option is that no criteria has been clearly put forward. It does however remain an option worth considering.

### 4.4.5 The Doha Ministerial Declaration on the Trips Agreement and Public Health 2001; its Adequacy.

The conflicts that have persisted between IPRS and the right to health led to negotiations for a better and flexible interpretation of the TRIPS Agreement. As a result, on 14 November, 2001 the Declaration on the Trade – Related Aspects of Intellectual Property Rights Agreement and Public Health was adopted by WTO. Its purpose was to respond to the concerns that had been expressed about the possible implication of TRIPS to drugs accessibility.

The Declaration reaffirmed and clarified the flexibilities available under TRIPS Agreement, and proclaimed: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health... We affirm that the Agreement can and should be interpreted in a manner supporting of WTO Members' right to protect public health and in particular, to promote access to medicines for all".[53] It spells out several flexibilities that WTO members can use to the full, such as the right to grant compulsory licences and the freedom to determine the grounds for these.[54]

If the Doha declaration is to benefit patients of AIDS and other ailments in developing countries, these countries now have to establish appropriate provisions in their national patent legislation by using "to the full" the flexibilities in the TRIPS Agreement.

The Declaration is important for developing countries in that it strengthens the position of countries that want to take advantage of the existing flexibilities within TRIPS.

This important Declaration and others like it, signal an acceptance by all WTO Members that they will not seek to prevent other Members from using the TRIPS provisions to the full.

For instance, the Doha Declaration recognizes that Members have the right to grant compulsory licences and Ministers recognise that Members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency (public health crises including those relating to HIV/TB, malaria and other epidemics can be an example). This means that the grounds put forward cannot easily be challenged. The

[53] Doha declaration paragraph 4
[54] Ibid 5(b)

In Latin America ten countries joined efforts to get agreements from generic manufacturers and originators.

This may build a sufficient market to encourage generic producers to invest in generic versions of these drugs and may also strengthen the position of weaker countries in bargaining for cheaper drugs. International calls for intensified pressure and visibility of political commitment to move Doha from mere intent to practice may be a core agenda for regional collaboration thus to make clear at international platforms the rights of countries to implement TRIPS flexibilities, to reinforce capacities of countries to do so and to remove procedural and information blocks to the export and import of generic medicines[55].

### 5.1.1.1 **Rejections of Trips Plus Rules Through Regional Frameworks**

An important and critical concern is the advent of TRIPS plus rules or sometimes referred to as Free Trade Agreement (F.T.As) by North Americans.

TRIPS plus rules are bilateral or multilateral agreement that have higher standards of intellectual property protection than TRIPS.

The difficulty of such agreements is that they defeat many of the flexibilities provided under TRIPS and thus are a serious independent to the availability of cheaper drugs for suffering populations.

The United States and several European countries have been advancing such agreements to strengthen their I.P. rights. It is

[55] Such regional trade areas must have been formed within the provisions of Article XXIV of the General Agreement on Tariffs and Trade (GATT) viza-vis Paragraph 6 (i) of the decision to implement paragraph 6 of Doha.

cardinal therefore, that countries through regional frameworks and organisations to collectively resist efforts to add TRIPS – plus measures in regional or bilateral trade agreements and States should seek supports from technical and civil society organisations and international partners for this. This would be in line with Article 2(1) of the ICESCR, as interpreted by the Committee on Economic, Social and Cultural Rights (CESCR) which requires state parties to take deliberate, concrete and targeted' steps 'though international assistance and cooperation, specially economic and technical' towards full realisation of covenant rights. This can be interpreted to mean States should take into account the right to health when negotiating IP rules in all trade agreements.

International and cooperation and assistance under the right to health requires States to 'respect the enjoyment of the right to health in other countries and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means' This requires States to intervene politically and legally to ensure that third parties i.e. States that have not ratified the covenant do not have trade policies that violate access to affordable medicines in developing countries such as TRIPS – plus rules, that would restrict the supply of affordable medicines[56].

### 5.1.2.1 **Attracting Investment for Local Production**

For most developing countries the option of local production of HIV/AIDS drugs is a step that must be taken with great caution. In

[56] Making Trade Policies more Accountable and Human Rights Consistent ://209. 85. 129. 104/ search? q = cache ... Retrieved 03/ 10/ 2007.

many cases importing the drugs with or without the use of compulsory licences is more cost effective. However, relying on importing drugs can only be a short-term solution.

In the long term, it is important that developing countries become self-reliant. This is important for many reasons, one of which is that local production would guarantee better control and regulation of these essential drugs in the public interest[57].

One of the ways in which local viable production can be encouraged is by promoting a good climate for both local and Foreign Direct Investment (F.D.I).

This includes creating good incentives for investors as well as legal and policy reforms in the area of tax and tariffs locally and regionally on drug related raw materials and products. Such factors erode the potential cost advantage that local manufacturing can provide[58].

5.1.2.2 **Technology Transfer**

One of biggest problems to independent local production of drugs in most developing countries is simply lack of capacity. Thus the TRIPS Agreement has several provisions which deal explicitly with the issue of technology transfer and strengthening local industry capacity in developing countries. Article 7, for instance, states "The protection and enforcement of intellectual property rights should contribute to technological innovation and to transfer and disseminate technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to

[57] Cullet P. (2001), Patents and Medicines : the relationship between TRIPS and the human right to health. TNW file://www.soutick/5383/9/-goers-report-775.pdf(15bn/13:9-780118483/9 P. 32.
[58] Ibid p. 33.

social and economic welfare and to a balance of rights and obligations". The Doha Declaration 2001 also reaffirms the the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2 of TRIPS.

Despite such provisions, little technology transfer to developing countries has taken place. To strengthen local industry, developing countries like Zambia should pursue initiatives that absorb new technology. Public – private partnerships (PPPs) may be one mechanism to achieve this. Generally, PPPs require private sector companies to provide the technology and expertise while public sector partners provide development funding and help ensure access to the medications.

Technology transfer and capacity building also depend on internal and external political will[59].

Where a developing country is unable to implement the provisions of TRIPS it may rely on Article 67 of the TRIPS Agreement and request on mutual terms and conditions technical assistance from developed country Members.

### 5.1.3 **Voluntary Differential Pricing Arrangements**

Developing countries can pursue the procurement of affordable drugs through voluntary differential pricing arrangements. These arrangements operate through the suppliers' charity, desire for

[59] Ibid. page 14 and 15

favourable public relations, or other criteria not immediately or apparently related to market forces. Currently, limited implementation of this mechanism is applied in Ghana but not for anti-retroviral therapies. The arrangement does however; require the recipients of the drugs to sign a supply agreement so as to ensure that the drugs are not resold to developed countries again[60] .

### 5.1.4 Medical Insurance

Despite Insurance business having a long history in Zambia, the capacity of this business is evident by the limited policies and the scarce existence of such businesses. The same can be said for most developing countries[61].

Insurance policies in developing countries must be broadened to cover medical care for HIV/AIDS patients for the average workers in our communities. Government must take a keen interest in promoting such policies as this can contribute significantly in the health delivery systems in developing countries.

### 5.1.5 Conclusion

These are some of the key alternatives available by governments in developing countries in providing cheaper access of HIV/AIDS drugs. However, they should not be considered in a vacuum. The success or failure of these options also depend on such factors as political and economic pressures, infrastructure development, health delivery systems, the education of the people and policy makers and other stakeholders on subjects such as TRIPS,paragraph 6 of Doha and the Decision of 30th

[60] Ibid at page 42
[61] Mumba Malila (2006) *Commercial Law in Zambia, cases and materials*, UNZA Press at page 451 and 452.

August 2003 to implement paragraph 6 of Doha, human rights and HIV/AIDS.

The following chapter gives a conclusion to this dissertation and recommendations.

## CHAPTER SIX

### 6.1 CONCLUSION

This research has defined and examined the nature of intellectual property rights and their significance in protecting the reward of innovation versus the human right to health through drugs for HIV/AIDS patients. The underlying theme has been for the need to appreciate that the right to health is an inalienable right that must be understood to have preference over IPRS as enshrined by international law.

The paper has demonstrated the fact that the intellectual property rights regime as contained in TRIPS and various recent WTO Declarations is a system that provides sufficiently for the accessibility of HIV/AIDS drugs for poor and developing countries. It has shown that much of the concerns viz-avis Article 31(f) of TRIPS have been adequately addressed by the Decision to Implement paragraph 6 of Doha by enhancing drug access under special conditional safeguards.

The paper has shown that the conflict between IPRS and the human right to health is no longer now an enigma. That the Doha Declaration and recent events such as Brazils successful threats to use compulsory licences when negotiating for cheaper drug prices from patent owners, and South Africa's success in resisting pressure from local and foreign pharmaceutical companies in amending its laws on drugs regulations have demonstrated a new epoch in the interpretation and appreciation of the TRIPS Agreement flexibilities.

The research has also examined the relevant provisions in the Zambian Patents Act Cap 400 comparing them to TRIPS. It was noted that Cap 400 satisfactorily utilises the TRIPS flexibilities, but that the legal system

has not adjusted to the latitude provided by the Paragraph 6 system and Article 31 of TRIPS.

The paper has also suggested some other possible options under the patent system to have access to cheaper HIV/AIDS drugs outside the usual ones of compulsory licences, parallel importing, exceptions to patent rights etc to include for instance utilisation of regional frameworks for collective issuing of compulsory licences etc the rejection of TRIPS plus rules by developing countries at national and regional level, attracting investment viza-viz technology transfer, voluntary differential pricing arrangements and medical insurance schemes.

The Doha Declaration has stood out to be a vital instrument in interpretation the TRIPS Agreement as well as providing greater access to HIV/AIDS for poor and developing countries.

The General Council on TRIPS decided on 30th August 2003 on a number important areas of the TRIPS Agreement so that many of the concerns which previously existed before are no longer there for instance the intellectual property regime is no longer a constraint to drug access for poor countries.

The major concern was on the application of Article 31 (f) and (h) of TRIPS which led to the Doha Declaration to state in Paragraph 6 for the General Council to find an expedition solution to the problem of poor countries without the capacity to make effective use of compulsory licensing and to report to the General Council before the end of 2002.

Now that the decision to implement paragraph 6 of Doha clearly provides mechanisms for eligible importing countries to grant compulsory licenses to import drugs and for exporting countries mechanisms to export to

countries without capacity to manufacture their own drugs access to vital medicines has greatly been enhanced.

This study has shown therefore, that the TRIPS Agreement, as well as our own local law on patents law in Zambia to a very limited extent are sufficient mechanisms for drug access. However the Zambian patent system must be amended to fully utilise the TRIPS flexibilities and the international IP regime.

Zambia's laws on patents must abreast themselves with the greater latitude provided under the international IPR regime viz-a vis the Decision to implement paragraph 6 of Doha.

There is now no doubt, that the IP regime is consistent with human rights standards.

The international IP regime has created frameworks that take into account the need of a state to have policies that uphold that right to health and life. The flexibilities that could be utilized other than compulsory licenses include parallel importing, exclusive rights exceptions and using Regional Trade Agreement.

The onus is on WTO Member states in the spirit of co-existence to utilize to the full provisions under trips in the light of Article 66(2), 67 and 69 of TRIPS provisions which foster international cooperation so as to maximize the results that can be achieved with regard to IP law being a vehicle for eradicating HIV/AIDS.

## 6.3 RECOMMENDATIONS

Most importantly, the TRIPS Agreement flexibilities must be utilised to the full as the system has the backing of the WTO declarations.

Zambia must amend its patents law so as to categorically be in line with the paragraph 6 system and hence be an eligible exporter of vital drugs.

The TRIPS Agreement should be amended to include to it provisions expressly stating that the right health supersedes IPRS and that when the two are in conflict the former should prevail.

Though the Doha is an authoritative statement, its legal status is unclear. If its status could be expressly pronounced that could enhance its effectiveness even more.

Governments in developing countries should strongly and strategically use human rights as a shield and benchmark against pressure from developed countries when negotiating trade related agreements.

Non Government Organisations are also encouraged not to hesitate to bring matters before UN treaty monitoring bodies whenever they suspect the rights to health is being jeopardised by any planned or effective treaty concerning developing countries. The reactions from these monitoring bodies serve as useful sign posts by which many governments feel obliged to heed.

Putting the flexibilities in law is necessary but not sufficient. Developing countries face many other challenges to implementing TRIPS flexibilities even where there laws provide for this. These challenges range from information and institutional weaknesses within countries, to international trade and political pressures not to use the flexibilities e.t.c. Developing countries in most cases are too small to individually combat these issues but would be in a better position if they operated through regional frameworks such as SADC, COMESA etc.

Finally, the media must enhance public awareness on IPR and its relation to human rights.

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