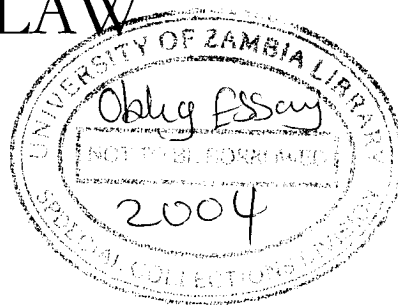


# THE UNIVERSITY OF ZAMBIA

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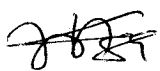
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**THE EFFECT OF PATENTS ON DRUGS, ON THE AVAILABLE  
OF ARVs IN THE SUB-SAHARAN REGION  
A CASE STUDY OF ZAMBIA**

**By**

**BARNABY BWALYA MULENGA**

**Submitted in partial fulfilment of the requirements for an award of a  
Bachelor of Laws (LLB) degree of the University of Zambia**

**FACULTY OF LAW**

**LUSAKA**

**December 2004**

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## **DEDICATION**

This work is unreservedly dedicated to my beloved Fiancée Niza Kaulule.

## **ACKNOWLEDGEMENTS**

This work is could not have been possible if it were not for the input of individuals, certain, who laboured to offer valuable advise and information that has rendered the work easier.

I am indebted to Mr George Mpundu Kanja, for his supervision of this work from the onset right through to the end.

I am even more indebted to my God and Saviour Jesus Christ for the manner he deals with me so graciously and the grace granted me to produce this work.

## **LIST OF APPENDICES**

1. STATUTORY INSTRUMENT No. 83 of 2004

*The statutory instrument is called the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004.*

## **LIST OF STATUTES**

1. The Constitution of Zambia, Chapter 1 of the Laws of Zambia
2. The Patents Act, Chapter 400 of the Laws of Zambia



## **ABBREVIATIONS**

|                           |                                                             |
|---------------------------|-------------------------------------------------------------|
| ARIPO                     | African Regional Industrial Property<br>Organization        |
| ARVs                      | Anti-Retroviral Drugs                                       |
| GDP                       | Gross Domestic Product                                      |
| HBC                       | Home-Based Care                                             |
| HIV/AIDS                  | Human Immunal Virus/ Acquired Immune<br>Deficiency Syndrome |
| IPRs                      | Intellectual Property Rights                                |
| LDCs                      | Lowly Developed Countries                                   |
| NZP+                      | Network for Zambian People Living with<br>AIDS              |
| OAPI                      | Organisation Africaine de la Propriété<br>Intellectuelle    |
| PWAs                      | People living with HIV/AIDS]                                |
| R & D facilities          | Research and development facilities                         |
| TRIPS                     | Trade Related Aspects in Intellectual property              |
| VCT                       | Voluntary Counselling and Testing                           |
| World Health Organisation | WTO                                                         |

## 1.0 CHAPTER ONE

### 1.1 Introduction

This paper seeks to investigate the impact of intellectual property on the availability of Anti-Retroviral Drugs (ARVs) in countries in the Sub-Saharan/SADC region, with special attention to the Zambian situation. The paper will investigate the impact, if any of intellectual property, and in particular patents, on the distribution, manufacture and use of essential Drugs in this third world region. With the HIV/AIDS problem continuing to affect the region there are fears that the pandemic will wipe out most the population. The cost of ARVs is beyond the reach of an average Zambian, especially that most people live on less than a dollar per day. One in every five Zambians is infected with HIV or AIDS, which has orphaned more than 800,000 children and killed nearly 700,000 Zambians since the first case was reported in 1984. The national average infection rate is around 20%, with some districts such as Livingstone recording rates as high as 33%. The pandemic has affected all sectors of society.<sup>1</sup> AIDS has killed more than 650,000 Zambians since the first case was recorded in 1984, more than Zambia's other triple-killers, malaria and tuberculosis<sup>2</sup>. Over 80% of the nation's population is living below the poverty datum line; the average yearly income is about \$300<sup>3</sup>. In a country where the Per Capita GDP as at the year 2000 stood at US\$284, with an average worker earning an average K125, 000 per month, the question, which arises, is ' what has made the drugs so expensive and beyond the reach of an average person?' There has been a lot of speculation on the cause of the unavailability of these drugs, including the cost of procuring the same, which in turn has been blamed on the patenting of these drugs.

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<sup>1</sup> [http://deeprroots.org/akin/index\\_add\\_sidebar.htm?/akin/zambia/](http://deeprroots.org/akin/index_add_sidebar.htm?/akin/zambia/) Retrieved 12/07/2004

<sup>2</sup> <http://www.reliefweb.int/w/rwb.nsf/0/331d88644ca8bdbac1256c91004d9eac?OpenDocument>

<sup>3</sup> Supra note 1, or K125,000/month (the US dollar rate to a Kwacha as at 10/08/2004 stands at K5000/ dollar)

According to an investigation by Oxfam, most of the essential drugs have patents on them, estimating approximately 90 percent of the drugs are patented. A further search at the Central Board of Health has indicated that most of the essential drugs related to the treatment of HIV/AIDS are patented, whereas a fair quantity of drugs are generic imported from countries with developed R & D facilities such as India. This debate has continued while the facts on the ground remain that majority of the people are suffering greatly because of little or no access to these essential drugs. The Political leaders have admitted the gravity of the problem, for instance Zambia's former Finance Minister Emmanuel Kasonde was quoted as saying that the country needed to raise at least \$270 million from foreign donors and local sources to provide free Anti-Retroviral Drugs and expand existing programmes aimed at reducing infection and caring for AIDS orphans.<sup>4</sup> More than 85% of the world's population live in developing countries, and the vast majority of them have no or limited access to drugs that sustain the lives of people in richer, developed countries. In the developing world, where 95% of the 40 million people with HIV/AIDS live, 20 million people have already died from AIDS. Every day, over 8,000 more people die and another 15,000 are infected with HIV. The global epidemic is devastating entire countries and regions. Similarly, tuberculosis (TB) and malaria kill massively and mainly among the poorest and most vulnerable of the global population, given their extremely limited access to effective forms of treatment.<sup>5</sup>

The paper will therefore investigate how the local legislation views the war on the availability of drugs and whether there are ways in which patented drugs can be reproduced in this

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<sup>4</sup> <http://www.reliefweb.int/w/rwb.nsf/0/331d88644ca8bdbac1256c91004d9eac?OpenDocument>

<sup>5</sup> <http://www.umich.edu/~spp638/Coursepack/ipr-msf.pdf>

region without the cost of the same being out of reach of an average Zambian. On the international front the paper will also review how international instruments like the TRIPS agreement have responded to such challenges.

There is a need to balance between the need to encourage and inspire creativity by upholding patents on the one hand, while on the other hand produce and distribute the essential drugs at an affordable rate to an average family. By the word Patent is meant a document granting an inventor sole rights to an invention. Government grants a patent for an invention to the inventor, giving the inventor the right for a limited period to stop others from making, using or selling the invention without the permission of the inventor. When a patent is granted, the invention becomes the property of the inventor, which, like any other form of property or business asset - can be bought, sold, rented or hired. Patent right are territorial in nature. With myriads of people raising concern on patents as the cause of the high cost of ARVs, it becomes essential to investigate whether Patents are the real cause.

## **1.2 HIV/AIDS in Sub-Saharan Africa**

The HIV/AIDS pandemic has negatively affected the Sub-Saharan region of Africa and continues to threaten the region. The total world figures for HIV infection stand at 36.1 million, of which 1.4 million are children. 25.3 million of these were in sub-Saharan Africa.<sup>6</sup> It has further been found that approximately 95 percent of all AIDS orphans in the world live in sub-Saharan Africa. Sub-Saharan Africa is the region of the world that is most affected by HIV & AIDS. An estimated 25.4 million people are living with HIV and approximately 3.1 million new infections occurred in 2004. In just the past year the epidemic has claimed the lives of an estimated 2.3 million people in this region. Around 2 million

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<sup>6</sup> UN Confirms AIDS Is Worst Epidemic In Human History <http://www.rense.com/general5/his.htm> Retrieved 25/11/2004

children under 15 are living with HIV and more than twelve million children have been orphaned by AIDS.

The extent of the epidemic is only now becoming clear in many African countries, as increasing numbers of people with HIV are now becoming ill. In the absence of massively expanded prevention, treatment and care efforts, the AIDS death toll on the continent is expected to continue rising before peaking around the end of the decade. This means that the worst of the epidemic's impact on these societies will be felt in the course of the next ten years and beyond. Its social and economic consequences are already being felt widely not only in health but in education, industry, agriculture, transport, human resources and the economy in general. In 2003 alone, 2.2 million people died from AIDS.<sup>7</sup>

The statistics for adults & children living with HIV/AIDS, the statistics of the estimated number of deaths from AIDS, and the number of orphans in individual countries in Sub-Saharan Africa at the end of 2003 are shown below.

| Country    | Adults    | Adult Rate % | Women   | Children | AIDS Deaths Among Adults & Children | Orphans due to AIDS |
|------------|-----------|--------------|---------|----------|-------------------------------------|---------------------|
| Angola     | 220,000   | 3.9          | 130,000 | 23,000   | 21,000                              | 110,000             |
| Botswana   | 330,000   | 37.3         | 190,000 | 25,000   | 33,000                              | 120,000             |
| Lesotho    | 300,000   | 28.9         | 170,000 | 22,000   | 29,000                              | 100,000             |
| Malawi     | 810,000   | 14.2         | 460,000 | 83,000   | 84,000                              | 500,000             |
| Mozambique | 1,200,000 | 12.2         | 670,000 | 99,000   | 110,000                             | 470,000             |

<sup>7</sup> HIV/AIDS Statistics In Africa, Avert <http://www.avert.org/subaadults.htm> Retrieved 23/11/2004

|                          |            |      |            |           |             |            |
|--------------------------|------------|------|------------|-----------|-------------|------------|
| South Africa             | 5,100,000  | 21.5 | 2,900,000  | 230,000   | 370,000     | 1,100,000  |
| Swaziland                | 200,000    | 38.8 | 110,000    | 16,000    | 17,000      | 65,000     |
| Tanzania                 | 1,500,000  | 8.8  | 840,000    | 140,000   | 160,000     | 980,000    |
| Zambia                   | 830,000    | 16.5 | 470,000    | 85,000    | 89,000      | 630,000    |
| Zimbabwe                 | 1,600,000  | 24.6 | 930,000    | 120,000   | 170,000     | 980,000    |
| Total Sub-Saharan Africa | 23,100,000 | 7.5  | 13,100,000 | 1,900,000 | 2.2 million | 12,100,000 |

(Source the Avert HIV/AIDS statistics in Africa from <http://www.avert.org/subadults.htm> )

As can be observed from the report, the HIV/AIDS situation is a disaster for the region. The statistics given above are estimates at the end of 2003 published by UNAIDS in their 'Report on the Global HIV/AIDS Epidemic, July 2004'. The estimates include all people with HIV infection, whether or not they have developed symptoms of AIDS, alive at the end of 2003. Adults in this report are defined as men and women aged 15-49. This age range captures those in their most sexually active years. While the risk of HIV infection continues beyond the age of 50, the vast majority of people with substantial risky behaviour are likely to have become infected by this age. Since population structures differ greatly from one country to another, especially for children and the upper adult ages, the restriction of 'adults' to 15-49 has the advantage of making different populations more comparable.

Children in this report are defined as under the age of 15 at the end of 2003, whilst orphans are children aged under 17 who have lost one or both parents to AIDS.

### 1.3 The history and Status quo of HIV/AIDS in Zambia

Zambia has a history of HIV/AIDS dating back to the mid 1980s when the first cases were recorded. Ever since the statistics have been increasing at a very alarming rate. It is now estimated by the WHO that 1 in every 4 Zambians is infected with the HIV virus. The country has insufficient medical facilities spread throughout the country making it doubly difficult for an average person to receive medical care. Zambia is situated in the southern part of Africa covering an area of 752,612 square kilometres. The Population of Zambia is 10.3 million. The country has an estimated HIV/AIDS prevalence rate of 19.7 percent among 15 to 49-year-olds. The prevalent rate among women in some areas was as high as 27 per cent in 1993, but by 1998 it had declined to 17 per cent. During these same years, there was a 42 per cent reduction in HIV/AIDS prevalence rates among 15 to 19-year-olds in Lusaka. This trend was found in other urban areas, and to a lesser extent in some rural areas.<sup>8</sup> The HIV Prevalence in Pregnant Women is 19.1%. Furthermore the estimated number of HIV-Infected People, according to Central statistics Office 2004 estimate, is 775,080 adults; 90,218 children. The Estimated Number of Individuals on Antiretroviral Therapy as at May 2004 was at 5,586. The Estimated Number of AIDS Orphans stood at 750,504<sup>9</sup>

The HIV/AIDS situation is a major public health problem in Zambia, which has led the State to declare it a national disaster. The National HIV/AIDS Intervention Strategy Plan 2002-2005 has drawn up a very aggressive programme. Its vision is to free the nation from HIV/AIDS under the mission to provide national leadership for a coordinated fight against

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<sup>8</sup> ICT Enhances Delivery of Health Services in Zambia <http://209.250.143.167/atp/disc1/0000000f.htm>

Retrieved 04/12/2004

<sup>9</sup>Office of the United States Global AIDS Coordinator

[http://www.usaid.gov/our\\_work/global\\_health/aids/Countries/africa/us\\_zambia.pdf](http://www.usaid.gov/our_work/global_health/aids/Countries/africa/us_zambia.pdf)

Retrieved 23/11/2004

HIV/AIDS in order to eliminate the virus and associated opportunistic infection for the benefit of the society with a goal to reduce HIV/STD transmission among Zambians and reduce the socio-economic impact of HIV/AIDS. It is for this reason that the Ministry of Health is trying to approach this problem from many angles using different types of interventions. Primary Health Care strategy seems to be a right intervention in terms of basic preventive methods but it needs to be supported by other strategies as well to close the gaps. This is difficult for most PWAs [people living with HIV/AIDS] because they are not in regular employment due to bad health, so they have to keep harassing friends and relatives for money. Some families can no longer afford to support HIV-positive relatives, but instead opt to "dump" them on the hospitals, however the patients are sent back to their families for HBC [home-based care] because there is a shortage of nurses, drugs, and bed space. Zambia has adopted an HIV/AIDS health policy in an attempt to reduce infections and help with treatment. But the implementation of the framework has been slow because of a lack of finances in a country and an economy donor dependent.

A report by the National AIDS Council noted that 48 percent of hospital bed spaces are occupied by PWAs. The government has tried to decentralise services and resources to clinics and health centres to improve PWA access to health care and relieve the pressure on hospitals. But with over 21 percent of Zambian adults HIV positive, the demand remains high. Apart from the acute shortage of drugs, many health centres, especially those in rural areas, do not have sufficiently well trained personnel to manage AIDS-related conditions. Clinics and health centres often also do not have enough information on voluntary counseling and testing (VCT) and support services to help people cope with the effects of HIV/AIDS. This entails that the expensive treatment of opportunistic infections from



AIDS, most of which would require admission, continues to place an unprecedented burden on the delivery of health services in Zambia. The development of Home Based Care (HBC) models has helped alleviate some of the pressure on hospital beds. However, most HBCs are run by NGOs whose facilities are limited. These organisations are informal and manned by volunteers, placing a lot of pressure on those carrying for them. This development of HBC services raises more challenges on the availability of ARVs because an average family is already struggling to make ends meet, how then can they willingly sacrifice a K40,000 per month<sup>10</sup> to procure ARVs. Currently the state has pegged the price of obtaining ARVs at K40,000 per month per infected person, but this has caused an outcry because 80% of Zambians live on less than K5000 per day, making the price beyond the reach of most PWAs. Recently, the government imported a consignment of ARVs to distribute free of charge to about 10,000 PWAs. However one challenge, which comes with the free distribution of these drugs, is the state's capacity to continue supplying free ARVs. There have already been widespread reports of PWAs running out of drugs and complaining that the rural districts are not supplied adequately and on time. This development has introduced another perception of avoiding ARVs all together. For instance the Network for Zambian People Living with AIDS (NZP+) has urged its members not to start ARV treatment until there are guarantees from the government that there will be a continuous supply of the drugs. There have been reports from parts of Zambia where the few people who were put on ARVs were complaining of a lack of consistency of supply and late delivery. This has serious repercussions on the health of PWAs whose condition; it has been argued may worsen because the virus may mutate into a more advanced and unknown virus and further they may acquire resistant strains. The Network for Zambian People Living with AIDS

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<sup>10</sup> The Government policy on ARVs for an individual living with HIV is that they are being sold for K40,000 per month per dosage for a month, except for a few on free ARVs.

(NZP+) argues that if the state cannot afford basic drugs like panadol, how will it afford ARVs consistently. The network further argues that since most of its members do not have enough money for a decent meal, poverty is making the situation worse, hence their appeal for food supplements from the state over and above the ARV supply.<sup>11</sup> Some AIDS activists have accused the Zambian officials of deliberately letting HIV/AIDS people to die than to give the drugs without the proper supervision. This has arisen because the officials agree with the drug companies, that anything less than a full course of treatment with the right drugs could result in the HIV virus mutating into something even more deadly. The report admits that no evidence is presented that the Zambian government is choosing to allow people to die although in reality Zambia does not have the resources to provide drugs to its AIDS-stricken population even if it wants to.

#### **1.4 The Economy of Zambia and the Pharmaceutical industry**

Zambia is one of Sub-Saharan Africa's most highly urbanized countries. About one-half of the country's 10 million people are concentrated in a few urban zones strung along the major transportation corridors, while rural areas are under-populated. Unemployment and underemployment are serious problems. Per capita annual incomes are currently at about one-half their levels at independence, and at \$300, it places the country among the world's poorest nations. Social indicators continue to decline, particularly in measurements of life expectancy at birth (about 35 years) and maternal and infant mortality (95 per 1,000 live births). The high population growth rate of 2.3% per annum makes it difficult for per capita income to increase. The country's rate of economic growth cannot support rapid population

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ZAMBIA: Poor health services further hurdle for HIV-positive patients <http://www.irinnews.org/report.asp?ReportID=31545>  
Retrieved 27/11/2004

growth or the strain which HIV/AIDS related issues (i.e., rising medical costs, street children decline in worker productivity) places on government resources.

The Zambian economy has historically been based on the copper mining industry. Output of copper has fallen, however, to a 1990s low of 228,000 tonnes in 1998, continuing a 30-year decline in output due to lack of investment, and more recently, low copper prices and uncertainty over privatization. In 2001, the first full year of a privatized industry, Zambia recorded its first year of increased productivity since 1973. The future of the copper industry in Zambia was thrown into doubt in January 2002 by investors in Zambia's largest copper mines, who have yet to return the privatized assets to profitability.<sup>12</sup> An average family lives on less than K5000 per day and unemployment is very high. In terms of the pharmaceutical base, Zambia has a very poor R & D industrial base making it difficult to produce essential drugs. The few pharmaceutical companies do not manage to meet the Zambian drug needs. The high interest rates coupled with other constraints make Zambia unpopular as a place for developing and manufacturing ARVs because there are better options such as the far east economies and in the middle east where economies, labour costs and interest rates are more affordable.

## **1.5 The impact of HIV/AIDS**

HIV & AIDS have a widespread impact on many parts of society. In many countries of Sub-Saharan Africa, AIDS is erasing decades of progress made in extending life expectancy. Millions of adults are dying young or in early middle age. Average life expectancy in Sub-

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<sup>12</sup> ECONOMY <http://www.traveldocs.com/zm/economy.htm>

Retrieved 02/12/2004

Saharan Africa is now 47 years, when it could have been 62 without AIDS. In Zambia life expectancy is at 35 years, when it stood at 59 in the 1970s.

The toll of HIV/AIDS on households has been and continues to be very severe. Many families are losing their income earners and the families of those that die have to find money to pay for their funerals. Many of those dying have surviving partners who are themselves infected and in need of care. They leave behind children grieving and struggling to survive without a parent's care. HIV/AIDS strips the family assets further impoverishing the poor. In many cases, the presence of AIDS means that the household eventually dissolves, as the parents die and children are sent to relatives for care and upbringing.

In all affected countries, the HIV/AIDS epidemic is bringing additional pressure to bear on the health sector. As the epidemic matures, the demand for care for those living with HIV rises, as does the toll amongst health workers. Health-care services face different levels of strain, depending on the number of people who seek services, the nature of their need, and the capacity to deliver that care. As has been observed opportunistic diseases are on the increase because of the HIV/AIDS pandemic.

Another effect has been on the educational sector. Schools and other educational institutions are not able to cope with the changing socio-economic circumstances. Unlike the era when the state would pay for children in school from pre-school though to university, Zambia now requires a cost sharing arrangement, which has made some schools struggle to obtain fees because bread earners are dying before their off-spring reach crucial educational institutions. A decline in school enrolment is one of the most visible effects of the HIV/AIDS epidemic on education in Africa.

HIV/AIDS dramatically affects labour, setting back economic activity and social progress. The vast majority of people living with HIV/AIDS in Zambia are between the ages of 15 and 49 - in the prime of their working lives. Employers, schools, factories and hospitals have to train other staff to replace those at the workplace that become too ill to work.

Through its impacts on the labour force, households and enterprises, HIV/AIDS can act as a significant hindrance to economic growth and development. HIV/AIDS is already having a major affect on Zambia's economic development, and in turn, this affects the country's ability to cope with the epidemic.

## 2.0 CHAPTER TWO

### 2.1 LEGAL FRAMEWORK BEHIND THE PATENT SYSTEM

This chapter seeks to analyse the legal framework behind the patent system in Zambia. It will look at the various statutes that have a relationship with the question of accessibility of essential drugs. It will also give a brief outline of the meaning of a patent and how it operates.

A patent is a set of exclusive rights granted by a government to an inventor or applicant for a limited amount of time (normally 20 years from the filing date). The term "patent" originates from the term *to patent* which means to lay open (to public inspection) and the term *letters patent*, which originally denoted royal decrees granting exclusive rights to certain individuals or businesses. Per the word's original definition, one theory of patent legislation is to induce the inventor to disclose knowledge for the advancement of society in exchange for a limited period of exclusivity. Therefore a patent is a monopoly right.<sup>13</sup>

A patent for an invention is granted by government to the inventor, giving the inventor the right for a limited period to stop others from making, using or selling the invention without the permission of the inventor. When a patent is granted, the invention becomes the property of the inventor, which - like any other form of property or business asset - can be bought, sold, rented or hired. Patents are territorial rights; a Zambian Patent will only give the holder rights within the Zambian jurisdiction and rights to stop others from importing the patented products into the Zambian Jurisdiction.<sup>14</sup>

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<sup>13</sup> **Definition of Patent** <http://www.wordiq.com/definition/Patent> Retrieved 03/10/2004

<sup>14</sup> Patents protect working parts and processes [www.patent.gov.uk/patent/](http://www.patent.gov.uk/patent/) Retrieved 23/09/2004

Patents are generally intended to cover products or processes that possess or contain new functional or technical aspects; patents are therefore concerned with, for example, how things work, what they do, how they do it, what they are made of or how they are made.

**There are special conditions that an invention must fulfil before a patent application can be approved?**

To be patentable an invention must:

- **Be new**

The invention must never have been made public in any way, anywhere in the world, before the date on which an application for a patent is filed.

- **Involve an inventive step**

An invention involves an inventive step if, when compared with what is already known, it would not be obvious to someone with a good knowledge and experience of the subject.

- **Be capable of industrial application**

An invention must be capable of being made or used in some kind of industry. This means that the invention must take the practical form of an apparatus or device, a product such as some new material or substance or an industrial process or method of operation.

"Industry" is meant in its broadest sense as anything distinct from purely intellectual or aesthetic activity. It does not necessarily imply the use of a machine or the manufacture of an article. Agriculture is included.

Articles or processes alleged to operate in a manner clearly contrary to well-established physical laws, such as perpetual motion machines, are regarded as not having industrial application.

- **Not be "excluded"**

An invention is not patentable if it is:

- a discovery;
- a scientific theory or mathematical method;
- an aesthetic creation such as a literary, dramatic or artistic work;
- a scheme or method for performing a mental act, playing a game or doing business;
- the presentation of information, or a computer program.

If the invention involves more than these abstract aspects so that it has physical features (such as a special apparatus to play a new game) then it may be patentable.

In addition, it is not possible to get a patent for an invention if it is a new animal or plant variety; a method of treatment of the human or animal body by surgery or therapy; or a method of diagnosis.



## 2.2 Generic and Patented Drugs

It is important to distinguish between a patented drug and a generic drug. A patented drug is one that can only be made, used, imported/exported or sold by the patent holder. According to the World Health Organization's Action Programme on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention. A generic drug is a pharmaceutical product usually intended to be interchangeable with the original patented drug ("bioequivalent") because it does the same thing. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the patentee. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name. Generic drugs should not be confused with counterfeit drugs. "Counterfeit goods are generally defined as goods involving slavish copying of trademarks. According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging.

The significance of the concept of the distinguishing between the patented drugs and the generic drugs lies in the fact that Zambia, as a nation can better plan the roadmap to accessible drugs if these ARVs are assessed with that understanding. For instance, since the HIV/AIDS pandemic became a crisis, how many effective ARVs have been manufactured or invented? Can Zambia wait until the expiry of patent rights held by the patentee of patented rights? AIDS first became identified in 1985, but ARVs only started coming on the

market in the late 90s. The debate therefore becomes relevant because any efforts by Zambia to produce Generic drugs have to be done in consultation with the patent holders.

Production of generic drugs admittedly drastically reduces the price of drugs. For example in Thailand, AZT (One of the renowned ARV brands) costs 37 cents per tablet, but sells for \$2.08 per tablet in the Netherlands. Fluconazole, used to treat cryptococcus prophylaxis, cost \$7 per day in Thailand before July 1988 but with generic production the price has dropped steadily and now stands at 67 cents a day.<sup>15</sup>

### **2.3 Patents and the Constitution**

In the Zambian context the legal framework begins with the Constitution of Zambia<sup>16</sup> where property rights of individual are protected.

Article 16(1) provides that except as provided in this Article, property of any description shall not be compulsorily taken possession of, and interest in or right over property of any description shall not be compulsorily acquired, unless by or under the authority of an Act of Parliament which provides for payment of adequate compensation for the property or interest or right to be taken possession of or acquired.

In other words, the article guarantees the Protection from deprivation of property. The article uses the words '*property of any description*' meaning that even intellectual property rights are included. It follows that any person whose intellectual property rights are deprived on a

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<sup>15</sup> UNAIDS Report on Patents on HIV Drugs in developing countries <http://www.cptech.org/> Retrieved 23/07/2004

<sup>16</sup> Chapter 1 of the Laws of Zambia

ground other than that provided for under the constitution can seek recourse from the court of law. The Constitution is the supreme law of the land, and if any other law is inconsistent with the Constitution that other law shall, to the extent of the inconsistency, be void.<sup>17</sup> It is therefore worth exploring whether compulsory licences or any other involuntary licence can validly deprive the rights of the patent holder.

The Constitution however gives exceptions under which property rights may be deprived. In relation to patents on drugs, the constitution gives a broad category in which the exception may be granted. Article 16(2)(m) provides that property rights can be deprived by reason of a dangerous state or prejudicial to the health or safety of human beings, animals or plants. The involuntary licence or compulsory licence provided for under the Patents Act can therefore fall within the acceptable limits of the Republican Constitution.

## **2.4 THE PATENTS ACT, CAP 400**

This is the principle Act that deals and makes provisions relating to patents for inventions and for other purposes incidental thereto. Section 28 (1) states that subject to the provisions of this Act, a patent shall have the same effect against the State as it has against a subject. This provision is of significance because the Act is saying that a person will not be unreasonably deprived of his rights as an inventor even by the State, except as provided for under the Act.

Another salient feature in the Patents Act is the effect of the patent granted under the Act. According to section 28 (4), the effect of a patent shall be to grant to the patentee, subject to

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<sup>17</sup> Article 1(3) of Cap1 of the laws of Zambia

the provisions of this Act and the conditions of the patent, full power, sole privilege and authority by himself, his agents and licensees during the term of the patent to make, use, exercise and vend the invention within Zambia in such a manner as to him seems meet, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention during the term of the patent.

As a window of hope, the Act provides for circumstances in which the patentee may not enjoy the whole profit and advantage accruing by reason of the invention during the term of the patent through compulsory licences. A compulsory licence is an involuntary licence granted by the state to third parties who wish to exploit the invention on the ground that it has not been sufficiently exploited.

Section 37 provides that any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed or four years subsequent to the date on which the application in respect thereof was lodged, whichever period last expires, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the *reasonable requirements of the public* with respect to the invention in question have not been or will not be satisfied. Section 37(6) further provides for the assessment of what amounts to '*reasonable requirements of the public*'. One ground that has been associated with the question of accessibility to drugs has been Section 37(6)(c) where the Act provides that a compulsory licence may be granted if the demand for the patented article in Zambia is not being met to an adequate extent and on reasonable terms. This provision is mainly concerned with a private individual or organization being concerned with the manner in

which an invention is being exploited. There is another salient provision in the Patents Act that has a close relationship with the need for the state to intervene in a matter, which is considered to be an emergency.

Section 40 of the Patents Act provides for the use of patented inventions for services of the State. It provides that: -

“...any Government department or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with the provisions of this section.”<sup>18</sup>

The Act however provides for such a situation only in special circumstances, and in Section 41 the need for a period of emergency to be declared has been emphasized. Section 41(1) provides that:-

“For the purposes of this section, the expression "period of emergency" means any period beginning on such date as may be declared by the Minister by statutory notice to be the commencement, and ending on such date as may be so declared to be the termination, of a period of emergency.”

The government has with effect from September 2, 2004 declared HIV/AIDS as an emergency for a period of five years to allow the manufacture of cheaper Anti-Retroviral drugs (ARVs).

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<sup>18</sup> Section 40(1)

As a consequence, the Zambian government has recently passed **Statutory Instrument No. 83 of 2004** in recognition of the HIV/AIDS pandemic after declaring the HIV/AIDS an emergency.

#### **2.4.1 CRITIQUE OF STATUTORY INSTRUMENT No. 83 OF 2004 VIS-À-VIS THE AVAILABILITY OF ARVs**

The critique will take a twofold approach. It will first look at whether the statutory Instrument met the statutory requirements and secondly whether the Statutory Instrument is of any significance in relation to making the ARVs available to the ordinary Zambian person

The statutory instrument is called the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004. It provides that the Minister may, in writing, authorize any Government department or person to manufacture, use or vend, in Zambia, any patented antiretroviral drug during the period of emergency.<sup>19</sup> The statutory instrument further goes on to define the “period of emergency” to mean the period commencing on 1st August 2004 and ending on 31<sup>st</sup> July 2004.<sup>20</sup> The statutory instrument was passed pursuant to section 40 of the Patents Act. The question to be posed at this stage is whether there was justification to declare the HIV/AIDS situation a crisis, necessitating a “Period of Emergency “ as provided for. In a country in which the HIV/AIDS prevalence rate stands about 20% of the adult population, with some regions like Livingstone recording rates as high as 33%, one can see that the declaration has in fact come at the right time although it may also be argued that it has been long overdue. The period of Emergency had to be

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<sup>19</sup> Section 3 of Statutory Instrument No. 83 of 2004

<sup>20</sup> Section 2 of Statutory Instrument No. 83 of 2004

declared in order to meet the requirement in section 41. In addition the statutory instrument has given a specification of exactly what can be done, being to *manufacture, use or vend*. Section 41(2)(b) states;

“During any period of emergency the powers exercisable in relation to an invention by a Government department or a person authorised by the Minister under section forty, shall include power to *make, use, exercise and vend*<sup>21</sup> the invention for any purpose which appears to the Minister necessary or expedient for the maintenance of supplies and services essential to the life of the community”

The statutory instrument has therefore defined what the government or indeed any person who will be granted the right under the statutory instrument to produce ARVs will be able to do. According to section 40 of the patents Act, the effect of employing the use of section 40 is that the rights of the patent holder to receive royalty or any other form of economic gain from his invention is temporarily suspended for the period of the emergency. The Patents Act states that

“...any use of the invention by virtue of this section may be made by such Government department or person free of any royalty or other payment to the patentee.”<sup>22</sup>

The statutory instrument *prima facie* give the impression that the statutory requirements as outlined in the principal Act, the Patents Act, have been met, however as will be shown in the second aspect more questions are raised than answers.

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<sup>21</sup> Emphasis by Author

<sup>22</sup> Section 40(2) of the Patents Act

The second aspect of the critique, as to whether the statutory instrument will infact help in making the ARVs more accessible remains to be seen. There are several challenges that raise questions as to whether the statutory instrument will infact meet the desired goal. For instance,

- i) Is Zambia currently using a lot of patented ARVs, which hitherto have been beyond the reach of most people?
- ii) Will manufacturing the drugs from within Zambia drastically reduce the cost of accessing these drugs since the cost of production in the country is very high owing to the fact that almost all resources to use in the industry have to be imported?
- iii) Are patents the real cause of the shortage of these ARVs?
- iv) Does it mean that Zambia will not benefit from future patented ARVs since the Statutory Instrument defines “Patented antiretroviral drug” as meaning any antiretroviral drug in respect of which a patent has been granted and is for the time being in force”<sup>23</sup>

The government, through the Ministry of Commerce, Trade and Industry Permanent Secretary David Chilipamushi said that in view of the pandemic and the high cost of patented anti-retroviral drugs, they were compelled to declare the period of emergency and to pass the statutory instrument. The Statutory instrument departed from the spirit of the principal Act, the Patents Act that, in relation to the granting of such a measure provides that

“The authority of the Minister in respect of an invention may be given under this section either before or after the patent is granted and either before or after the acts in

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<sup>23</sup> Section 2 of the Statutory Instrument No. 83 of 2004



respect of which the authority is given are done, and may be given to any person, whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the invention.”<sup>24</sup>

As can be seen the Patents Act gives provision for one to use future inventions whose patents may yet to be granted, the statutory instrument on the other hand restricts the definition of the Patented ARV to that whose patent has been *granted*. Further investigations at the Patents Office has revealed that no patent in respect of any ARV has been granted, raising the question, then which patented drugs have we been talking about? Further the Patents Act in section 40 assumes that the Government or indeed any person granted the permission under section 40 would have already identified which particular patent they seek to explore. However the statutory instrument and indeed the Permanent Secretary of the Ministry of Commerce made it clear that the statutory instrument was more an invitation to those who may consider producing the same in Zambia. Section 40(1) states in part that any Government or person ‘

“...may make, use or exercise any invention disclosed in any specification lodged at the Patent Office...”

The wording in section 40(1) clearly makes reference to a known patent, whose specification is at patents Office. Which patent did the Government have in mind in invoking the provisions of section 40? Failure to adequately explain away these questions may lead to the action of the government being challenged in the High Court, as provided for in section 42 by Patent holders. The Zambian government, in conjunction with the Cuban government, is exploring the possibility of producing generic drugs, through a project that hopes to produce ARVs. The challenge however remains that Zambia does not have a developed R & D

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<sup>24</sup> Section 40(4) of the Patents Act.

domestic pharmaceutical industry that can really lead to production of most essential drugs. The solution lies in developing countries also allowing the sale of generic ARVs at affordable prices, although it remains a fact that most effective ARVs are not yet in the public domain because the patent protection on most of these drugs has not yet expired.

## **2.5 The Pharmaceutical Act No. 14 of 2004 and its ability to allow more accessibility of ARVs in Zambia**

This Act was past in August 2004, with the main purpose being to regulate, and control the manufacture, importation, exportation, possession, storage, distribution, supply and use of medicines. This piece of legislation has been criticized as overlooking the HIV/AIDS crisis by not directly dealing with the issue of making available cheaper drugs to the Zambian masses.

Another weakness<sup>25</sup> with the new piece of legislation is its failure to directly provide for state intervention, through the Minister responsible for Health, by relating access to drugs with intellectual property laws as provided for in the Patents Act. Owing to the fact that most essential drugs are manufactured from other developed countries, whose pharmaceutical companies attach intellectual property rights to them such as patent rights, one would have expected the pharmaceutical Act to expressly provide for that. The advantage of that would have been to limit the monopoly rights of some patent holders and further, whereas the patents Act provides in section 40 for the Minister to intervene in relation to Patented drugs, there are other intellectual property rights that may not necessarily fall under patents that the

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<sup>25</sup> G. M. Kanja, How Pharmaceutical Bill can take advantage to promote and ensure access to cheaper medicines for HIV/AIDS (unpublished)

Pharmaceutical Act should have dealt with. Zambia is a member of the WTO and therefore is expected by 2006 to bring the national laws in compliance with the TRIPS agreement in relation to patents on pharmaceutical products, especially if it has not previously recognized these. Those countries considered “least developed” have until January 1, 2006 to change their laws, and may ask for extensions of time. One can only conclude that Zambia is not ready yet to comply with the TRIPS agreement and will probably have to ask for an extension. It is therefore a serious omission in the recently enacted Pharmaceutical Act, not to consider expressly the need to address the issue of patents on drugs, especially that Zambia, is member of the WTO.

### 3.0 CHAPTER THREE

#### 3.1 INTERNATIONAL LEGAL FRAMEWORK ON ACCESS TO MEDICAL DRUGS

International legal instruments have contributed greatly to the development of patent laws in relation to drugs. These laws have a bearing especially on poor countries because it is the poor nations that have to buy the drugs from the developed countries in some cases. Furthermore, the international legal framework has a close relationship with international trade matters, of which drugs are considered a part.

#### 3.2 DOHA DECLARATION

The Doha Declaration is a major step in the campaign to ensure access to medicines for all. This was the first time in the 50-year history of the multilateral trading system that a separate Ministerial Declaration was considered on intellectual property and public health issues. In terms of the Legal status of the Doha Declaration, the Doha Declaration is a strong political statement that can make it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle<sup>26</sup>. The Declaration is also a Ministerial decision with legal effects on the Member States and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS. It states the *purpose* of the TRIPS Agreement in the area of public health, *interprets* the TRIPS Agreement with regard to some important aspects, *instructs* the Council for TRIPS to take action, and *decides* on the implementation of the transitional provisions for LDCs. A “declaration” has no specific legal status in the framework of WTO law; it is not strictly an

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<sup>26</sup> See e.g. Weisbrot, 2002, p. 16; Raja, 2001, p. 14.

authoritative interpretation in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO. However, given the content and mode of approval of the Doha Declaration, it can be argued that it has the same *effects* as an authoritative interpretation.

The Main points of the Declaration are laid out below;

**DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH<sup>27</sup>** Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and Least-Developed Countries(LDCs), especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should

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<sup>27</sup> <http://www.who.int/medicines/library/par/who-edm-par-2002-3/doha-implications.doc>

be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: *In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
  - (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
  - (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
  - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm 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. We also agree that the Least-Developed Country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of Least-Developed Country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

### ***3.2.1 Analysis of paragraph 1 of the Doha Declaration***

While some developed countries attempted to limit the scope of the Declaration<sup>28</sup> to the HIV/AIDS crisis, the adopted text reflects the concerns of developing countries and LDCs about the implications of the TRIPS Agreement with regard to public health in general, without limitation to certain diseases. The reference to some specific “epidemics” does not

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<sup>28</sup> The disagreement on the scope of the declaration was reflected in the partly bracketed title of the draft declaration (“access to medicines”) (“public health”). Throughout the negotiations, the USA, supported by Switzerland, proposed a text that referred to “health crisis”, “pandemics” and “infectious disease” only.

imply that the Declaration is limited to them. It covers any “public health problem”, including those that may be derived from diseases that affect the population in developing as well as developed countries, such as asthma or cancer. The statement is clearly an open commitment by both the developed and the developing world and it sets a platform on which issues of public health can be argued. The Doha declaration can therefore be used by the regional bodies like COMESA and SADC to champion the quest for more favourable trading terms between the developed and the undeveloped world in relation to public health. Individual countries seeking to impose compulsory licences can also use the Doha Declaration to argue their points.

### ***3.2.2 Analysis of Paragraphs 2 & 3 of the Doha Declaration***

Paragraphs 2 and 3 of the Doha Declaration express the Members’ view with regard to the role of TRIPS and IPRs in the context of public health. Paragraph 2 stresses “the need for” the TRIPS Agreement “to be part of the wider national and international action to address these problems”. This statement, read in conjunction with paragraph 4, seems to indicate that the extent to which the Agreement is part of the problem or of the solution to public health needs, crucially depends on the way in which the Agreement is implemented and interpreted. This paragraph suggests that intellectual property rights are one but not the only factor that affects public health and, in particular, access to drugs.

The first sentence of paragraph 3 alludes to the “important” role of intellectual property protection “for the development of new medicines”. Unlike other preambular paragraphs, this one specifically refers to “medicines”. This statement – welcomed by the pharmaceutical



industry – is balanced by the second sentence, which recognizes one of the troubling effects of patent protection: its impact on prices. In this way the declaration tries to strike a balance between the need to encourage development and invention through patents while at the same time allowing the possibility of providing cheaper drugs.

The patent system is designed to enable patent holders to set prices higher than those that would be obtained in a competitive market. The Doha Declaration recognizes that the high prices of medicines caused by patent protection are part of the grave problems that afflict developing countries and LDCs and is a "concern" that needs to be addressed. The consensus achieved on patent protection's impact on drug prices may be considered one of the major political achievements of the developing countries in the Doha Ministerial Declaration.

### ***3.2.3 Analysis of paragraph 4 on Public health measures***

Paragraph 4 of the Doha Declaration was one of the most controversial provisions of the document and the subject of intense negotiations during the preparations for and at the Ministerial Conference in Doha. Developing countries' negotiating target was, as mentioned above, to obtain recognition that nothing in the TRIPS Agreement shall be interpreted as preventing Members from adopting measures necessary to protect public health.

Developing countries were essentially seeking a declaration recognizing their right to implement certain pro-competitive measures, notably compulsory licences and parallel imports, as needed to enhance access to health care. They were frustrated by the opposition and pressure exerted on some countries by the pharmaceutical industry and governments.

Moreover, some felt that the final proviso in Article 8.1 establishing that any measures adopted, *inter alia*, to protect public health should be consistent with the provisions of the TRIPS Agreement.

Developed countries did not view the TRIPS Agreement as representing a barrier to the achievement of public health objectives, and they were not prepared to undermine any of the obligations under the Agreement. In order to give meaning to paragraph 4, it is possible to interpret that the intention of the Members was to indicate that in cases where there is conflict between IPRs and public health, the former should not be an obstacle to the realization of the latter. A possible reading of this paragraph is that such a conflict may arise, and this is precisely why “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”.

As mentioned, a basic issue underlying the discussions leading to the Doha Declaration was the extent to which the final proviso of article 8.1 would mean that intellectual property could override public health. One possible interpretation of this proviso is that, unlike Article XX (b) of the GATT, under the TRIPS Agreement Public Health and other reasons enumerated in Article 8.1 permit Members to adopt measures, such as commercialization and price controls, but not to derogate obligations relating to the availability or enforcement of IPRs. However, in the light of paragraph 4 of the Doha Declaration, it may be argued that Article 8.1 would not prevent derogation from certain obligations under the TRIPS Agreement if necessary to address public health needs.

The realization of public health becomes, with the Doha Declaration, a clearly stated *purpose* of the Agreement. In affirming that the TRIPS Agreement, “can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all”, paragraph 4 gives guidance to panels and the Appellate Body for the interpretation of the Agreement’s provisions in cases involving public health issues. In doing so, Members have developed a specific *rule of interpretation* that gives content to the general interpretive provisions of the Vienna Convention on the Law of the Treaties (hereinafter “the Vienna Convention”) on which GATT/WTO jurisprudence has been built up. Therefore, in cases of ambiguity, or where more than one interpretation were possible, panels and the Appellate Body should opt for the interpretation that is effectively “supportive of WTO Members' right to protect public health”.

It also should be noted that paragraph 4 makes a specific reference to the issue of “access to medicines for all”, indicating that in the interpretation of the Agreement’s obligations, special attention should be given to the achievement of this goal.

Finally, paragraph 4 alludes to the *implementation* of the Agreement, and not only to its interpretation. Implementation takes place at the national level, but is influenced by actions taken by other governments, either in the context of bilateral dealings or in the multilateral framework. The important message of the Declaration in this regard is that the Agreement can be implemented in a manner supportive of WTO Members' right to protect public health. As a result, other Members should restrain from any action that hinders the exercise of such rights by Members, especially developing countries and LDCs.

According to this paragraph, however, Members not only *can* implement the TRIPS Agreement “in a manner supportive of WTO Members' right to protect public health”, but they *should* also implement it in that way. This means that all Member countries, including developed countries, are bound to contribute to the solution of the public health problems addressed by the Doha Declaration. One possible way of doing so would be, for instance, by adopting measures to allow the export of medicines needed in a country with no or insufficient manufacturing capacity, an issue which paragraph 6 of the Declaration requires Members to address.

#### ***Flexibility in TRIPS vis-à-vis Doha declaration***

The second part of paragraph 4 of the Doha Declaration reflects one of the main concerns of developing countries in the process leading to the Doha Ministerial.

The concept of “flexibility” as applied to the obligations imposed by the TRIPS Agreement, has been central to several analyses of the TRIPS Agreement and to the position of developing countries at the Council for TRIPS in the special sessions on TRIPS and health. Spelling out some of the available flexibility was the main objective of the Declaration.

The Declaration stresses the flexibility “for this purpose”, that is, for the purpose of adopting measures to protect public health. As indicated by the coverage of paragraph 5, Members, only specified, in a non-exhaustive manner, some of the aspects of the Agreement that provide for such a flexibility (“...we recognize that these flexibilities *include*...).

The confirmation that the TRIPS Agreement has left room for flexibility at the national level has important political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement, especially in the light of the recognized “gravity of the problems” faced in the area of public health by developing countries and LDCs. In legal terms, such confirmation means that panels and the Appellate Body must interpret the Agreement and the laws and regulations adopted to implement it in light of the public health needs of individual Members States.

As can be observed, paragraph 4 of the Doha declaration was the most controversial in the drafting stages and remains the most challenging as the question of accessibility to drugs is analysed.

### ***3.2.4 Analysis of paragraph 5***

The objective of developing countries in proposing sub-paragraph 5(a) of the Doha Declaration was to stress the importance of TRIPS Articles 7 and 8 in the interpretation of the Agreement, particularly in the light of Article 31 of the Vienna Convention. They attained their objective without ignoring, however, that other provisions of the Agreement also contribute to the determination of its object and purpose.

That TRIPS purposes are elaborated in its Articles 7 and 8, but also in other provisions of the Agreement have, in fact, already been recognized in TRIPS/WTO jurisprudence. In fact, the Doha Declaration goes beyond merely confirming the relevance of Articles 7 and 8 for the interpretation of the TRIPS Agreement. It provides an *understanding* about the purpose of

the TRIPS Agreement in relation to public health issues, which should guide any future rulings by panels and the Appellate Body dealing with such issues.

***The Doha declaration further allows for Compulsory licences under paragraph 5(b)***

Developing countries have identified compulsory licensing as one of the key instruments that may limit the exclusive rights of the patent owner when needed to fulfill certain objectives of public policy, particularly in order to ensure the availability of alternative sources for the supply of medicines at lower prices.

Sub-paragraph 5 (b) of the Doha Declaration deals with an issue central to the interests of developing countries. It simply states what is apparent: Article 31 sets forth a number of *conditions* for the granting of compulsory licences (case-by-case determination; prior negotiation, in certain cases, with the patent owner; remuneration, etc.), but it does not limit the *grounds* on which such licences can be granted. Though Article 31 refers to some of the possible grounds (such as emergency and anti-competitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as non-working, public health or public interest.

Though sub-paragraph 5 (b) does not add anything substantively to the understanding of TRIPS, the Doha Declaration specifically employs the expression “compulsory licence”, which is not found in the TRIPS Agreement itself. The use of this terminology may help to create awareness, particularly among health ministries in developing countries and LDCs, about the possible utilization of compulsory licences to meet public health and

other objectives. Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (c) deals with the aspect of Emergency. This part is closer to developing countries in the light of the HIV/AIDS pandemic. For instance, it recognizes that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Zambia has declared HIV/AIDS a national disaster and therefore declared a period of emergency as provided for by paragraph 5.

Paragraph 5 (c) of the Doha Declaration states what is an unquestionable right of Members States: the right to determine “what constitutes a national emergency or other circumstances of extreme urgency”. Such determination may be relevant for the granting of compulsory licences, the establishment of exceptions under Article 30, or the adoption of other measures permitted under Article 8.1 of the Agreement.

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (d) provided for Exhaustion of rights. This issue was again left to each individual country to determine the question of exhaustion of rights. Although developed countries wanted a common position on the issue, the Doha declaration finally left it to individual jurisdictions.

The authorization of parallel imports under an international principle of exhaustion has also been regarded by developing countries, as a key component of a patent system sensitive to

public health needs. This was one of the key issues raised by pharmaceutical companies against South Africa in the famous pharmaceutical case.

Developing countries were keen to clarify in the Doha Declaration the Members' right to adopt an *international* principle of exhaustion of rights, in accordance with article 6 of the Agreement. Paragraph 5 (d) provides the sought-after clarification. It specifically states that "the effect of the provisions in the TRIPS Agreement... is to leave each Member free to establish its own regime for such exhaustion *without* challenge".

Though this paragraph does not add substantively to the TRIPS Agreement, it certainly reassures Members wishing to apply an international exhaustion principle that it would be legitimate and fully consistent with the Agreement to do so.

It is necessary to stress that in order to take advantage of this and other flexibilities allowed by the TRIPS Agreement – and confirmed by the Doha Declaration – national laws must incorporate the appropriate rules in the form of compulsory licences, exceptions and other relevant provisions. Such flexibilities do not automatically translate themselves into national regimes, and do not protect governments (or private parties) from legal actions based on national laws and regulations that fail to make use of the TRIPS Agreement's flexibilities. For example, specific legal provisions allowing for parallel imports would be normally necessary in order to benefit from the principle of international exhaustion of rights.

A survey of patent laws in developing countries shows that many of such countries have not or only partially used the flexibilities allowed by the TRIPS Agreement. The effective



implementation of the Doha Declaration in those countries, therefore, would call for an amendment to national laws so as to incorporate the exceptions and safeguards necessary to protect public health. One would have expected the Statutory Instrument passed by the Zambian government, after declaring HIV/AIDS a national disaster, to address not just the issue of manufacturing but also that of parallel imports. That aspect, it is argued provides a much cheaper option than developing a complex R & D pharmaceutical base, especially in the short term

### ***3.2.5 Analysis of paragraph 6***

Paragraph 6 of the Doha Declaration on TRIPS and Public Health deals with the issue of some Members having insufficient or no manufacturing capacities. In paragraph 6 the Doha Declaration instructs the Council for TRIPS to address a delicate issue of how Members lacking or with insufficient manufacturing capacities, can make effective use of compulsory licensing. The Declaration requests the Council for TRIPS “to find an expeditious solution to this problem and to report to the General Council before the end of 2002”. As discussed below, in order to be effective such a solution should be economically viable, and not only legally acceptable.

A major limitation in compulsory licensing rules under Article 31 (f) of the TRIPS Agreement is the requirement that a product made under a compulsory licence be supplied predominantly to the licensee's domestic market<sup>29</sup>, unless the licence were issued to remedy anti-competitive practices (Article 31 (k) of the Agreement). This means, in practical terms,

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<sup>29</sup> TRIPS Article 31: “Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

...  
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”.

that Members with large markets, like India, the UK or the USA, typically could easily grant compulsory licences for the supply of patented medicines to meet public health needs. However, for Member countries with small markets, like Zambia where the AIDS crisis is most severe, it might be extremely difficult to establish economically viable production if the manufactured product has to be “predominantly” sold in the local market.

The basic problem underlying paragraph 6 is that many developing countries lack or have an insufficient capacity to manufacture medicines on their own. The manufacturing capacities in pharmaceuticals are distributed very unevenly in the world. Not many countries have the capacity to produce both active ingredients and formulations, and very few countries maintain significant research and development (R & D) capabilities.

Given that only a few developing countries have substantial manufacturing capacity in pharmaceuticals, once the TRIPS Agreement becomes fully operative (after 2005), many countries may face difficulties in acquiring medicines at affordable prices. Today, for example, some countries, such as India, do not provide patent protections for pharmaceutical products, and produce generic versions at a fraction of the price of the patented product. A Member country where the price of patented products is high has the option of issuing a compulsory licence to permit import from such countries. The problem is that, as countries fully comply with the TRIPS Agreement by 2005 at the latest, they will no longer be able to produce and export cheap generic copies of patented medicines. Consequently, the sources of affordable new medicines will dry up and countries without sufficient manufacturing capacity and market demand will not be able to grant a compulsory

licence either for the local production or for the importation of such medicines: they will become entirely dependent on the expensive patented versions<sup>30</sup>.

### ***3.2.6 Analysis of Paragraph 7 on Transfer of technology to LDCs***

Paragraph 7 of the Doha Declaration reaffirmed “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.”

LDCs have repeatedly raised concerns at the Council for TRIPS about the lack of effective action by developed countries to comply with Article 66.2 of the TRIPS Agreement. Though some developed countries provide different forms of technical assistance on IPR-related issues, LDCs have repeatedly noted that no or little action has been taken by developed countries to specifically implement their obligations under Article 66.2. It remains to be seen whether the reaffirmation in the Doha Declaration of such obligations has a practical impact on developed countries’ actions in this area.

Though the wording in paragraph 7 is broad, its inclusion in the Doha Declaration indicates that effective incentives should be granted in developed countries in order to specifically foster the transfer to LDCs of health-related technologies, including pharmaceutical technologies.

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<sup>30</sup> This was the argument by Oxfam in 2002.

## Extension of transitional period for LDCs

The Doha Declaration permits LDCs to opt for an extension of the transitional period provided for under Article 66.1 of the TRIPS Agreement. Paragraph 7 establishes the grounds for an extension of the transitional period for LDCs in relation to pharmaceutical patents only. It contains a “duly motivated request” – in the terms of Article 66.1 of the TRIPS Agreement – on the basis of which the Council for TRIPS must give effect to that extension. LDCs do not need to individually follow the procedure provided for under Article 66.1 to enjoy this period. The Declaration, however, explicitly preserves the right of LDCs to request extensions for other matters (not related to pharmaceutical patents) in accordance with Article 66.1's procedure<sup>31</sup>, without diminishing their right to request further extensions for pharmaceutical patents after 2016.

This extension applies to “pharmaceutical products”. However, the protection conferred to a patented process encompasses, according to Article 28.1 (b) of the TRIPS Agreement, the protection of the products directly obtained with such process. Hence, the extension of the transitional period should also be deemed to apply to process patents. Likewise, extension would apply to cases involving a *second indication* of a pharmaceutical product, since claims are generally drafted in these cases as product claims on the basis of the “Swiss-claims” formulation.

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<sup>31</sup> In fact, it would have seem more logical to extend the transitional period for all fields of technology since, unless individual extensions are accorded, LDCs would be required anyway to bear the costs of granting patents in other sectors.

The extension of the transitional period applies in relation to Sections 5 (patents) and 7 (undisclosed information) of Part II of the TRIPS Agreement, and to the enforcement of such rights.

An important practical aspect is to determine which are the LDCs that can effectively benefit from paragraph 7 of the Doha Declaration. Out of thirty African LDCs, only two, Angola and Eritrea, do not currently grant patents for pharmaceuticals. These would be, in principle, the only African LDCs that can benefit from this paragraph, unless they amend their legislation.

As analysis of the Doha declaration is made, it becomes pertinent that the statistics of patents in the region is brought to the fore. Twelve out of the 34 African LDCs are members of the Organisation Africaine de la Propriété Intellectuelle (OAPI) and 10 of the African Regional Industrial Property Organization (ARIPO).

There are 10 LDCs among ARIPO's members (see Table 2). Figure 2 illustrates the patents granted by ARIPO from 1985 to 1999. Notably, also indicated is the proportion of these patents classified under IPC classification mark A61K (preparations for medical, dental, or toilet purposes) or having a corresponding patent filed elsewhere classified under mark A61K

**Table 2**

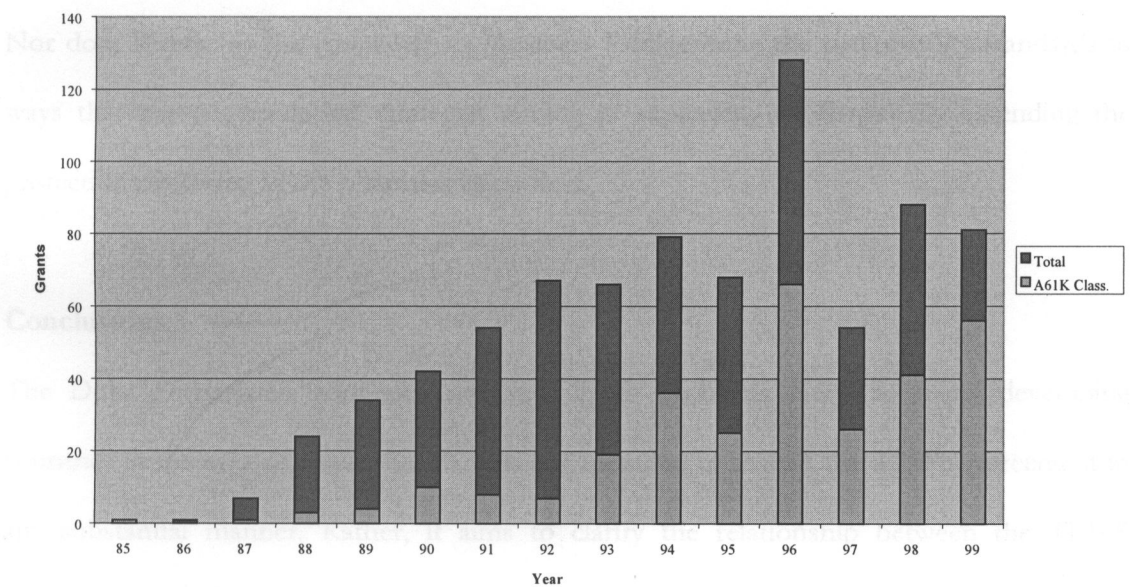
**Current Membership of ARIPO**

|                |               |                   |                                    |
|----------------|---------------|-------------------|------------------------------------|
| Botswana       | <i>Gambia</i> | Ghana             | Kenya                              |
| <i>Lesotho</i> | <i>Malawi</i> | <i>Mozambique</i> | <i>Sierra Leone</i>                |
| <i>Somalia</i> | <i>Sudan</i>  | Swaziland         | <i>United Republic of Tanzania</i> |
| <i>Uganda</i>  | <i>Zambia</i> | Zimbabwe          |                                    |

[Countries in italics are United Nations designated Least Developed Countries (LDCs)]

LDCs that already grant pharmaceutical patents could, however, amend their legislation and not grant product patents until 2016, since they are not constrained by the "freezing clause" of Article 65.5 of the TRIPS Agreement.

Figure 2 Patents Granted by ARIPO



Source: WHO official publications

Moreover, the Declaration can be regarded as a “subsequent agreement” between the parties regarding the interpretation of a treaty or the application of its provisions, under Article 31.3 (a) of the Vienna Convention on the Law of the Treaties.

It should be stressed, however, as mentioned above, that the Doha Declaration is not self-executing and both developed and developing countries should adopt the legal amendments necessary to implement it. Developing countries, in particular, should ensure that they are using to the full extent possible the flexibilities allowed by the TRIPS Agreement to protect public health and facilitate access to health care by all.

### **Issues not covered in the Doha Declaration**

The Doha Declaration does not cover all the areas where flexibility of the TRIPS Agreement exists, such as the exceptions to patent rights (Article 30) and the protection of data submitted for the registration of pharmaceutical (and agrochemical) products (Article 39.3). Nor does it refer to the room left to Members to determine the patentability standards in ways that prevent patenting strategies aiming at expanding or temporally extending the protection conferred in the pharmaceutical field.

### **Conclusions**

The Doha Declaration addresses real and urgent problems faced by many developing countries in the area of public health. It is not intended to amend the TRIPS Agreement in any substantial manner. Rather, it aims to clarify the relationship between the TRIPS Agreement and Public Health policies of Member countries, and confirm the rights that Members have retained under the Agreement, particularly by defining the flexibility allowed in certain key areas.

The Declaration addresses most of the concerns of developing countries on the issue of public health. The ambiguous wording used in some paragraphs – particularly in paragraph 4 – was the obvious price paid to build a consensus for the adoption of the Declaration. Despite such wording, the Declaration makes it clear that a conflict may exist between TRIPS standards and public health, and has reaffirmed the right of Members, particularly developing countries, to take measures necessary to protect public health. The Declaration has set the ground for a differentiation of intellectual property policies when necessary to protect health.

Though an important political document, the Doha Declaration also has legal effects, equivalent to those of an authoritative interpretation under WTO rules.

As the mandate given in paragraphs 6 and 7 illustrates, the Doha Declaration represents, rather than the end of a process, the initial step for rethinking the TRIPS Agreement in light of the public interest.

Paragraph 6 aims at addressing a problem created by the extension of patent protection for pharmaceutical products to all WTO Members, irrespective of their level of development and of their pharmaceutical manufacturing capacity. While many different legal approaches may be developed, an effective solution must create the right economic conditions for countries with no or insufficient manufacturing capacity to obtain pharmaceutical products at low cost. Likewise, the TRIPS Agreement will continue to create tensions in the public health area, if the case of countries where no patent protection exists is not also a part of viable legal and economic solution.



All WTO Members are expected, in due time, to take necessary steps, as, to implement the Doha Declaration. A number of members are yet to make amendments to national laws in order to facilitate exports of needed pharmaceuticals under paragraph 6 of the Declaration. Developing countries should be encouraged (and the relevant technical assistance provided) to review their legislation in order to ensure that the flexibilities, as clarified in the Declaration, as well as other flexibilities allowed by the TRIPS Agreement, are incorporated in national laws and effectively used to address public health concerns. This is true of the Zambian situation where the country has not exploited the flexibilities provided in the TRIPS agreement.

### **3.3 *TRIPS AGREEMENT***

The WTO/TRIPS agreement has brought a new era to the intellectual property market. Prior to the TRIPS agreement of 1995, countries failed to provide patent protection for pharmaceutical companies except for process or product patents.

The TRIPS Agreement says the monopoly rights created by patents need to be balanced against other important interests. It says that protecting and enforcing intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology. Furthermore, TRIPS says that this should be to the benefit of both producers and users of technological knowledge, and should occur “in a manner conducive to social and economic welfare, and to a balance of rights and obligations” (Article 7). The TRIPS Agreement also sets out some basic principles that should guide how it gets interpreted (Article 8). It says that, in shaping their own laws; countries “may take

measures necessary to protect public health.” It also recognizes that countries may need to take “appropriate measures” to prevent the “abuse” of patent rights by patent-holders or to prevent practices which “unreasonably” restrain trade or negatively affect the international transfer of technology. These measures, however, must be “consistent” with the provisions of TRIPS. These provisions in TRIPS support the argument that countries are entitled to flexibility in how they meet their obligations to protect patent rights.

The fact that patent protection is territorial further complicated matters for most pharmaceutical companies, who had to make applications at great cost in a number of jurisdictions in which they sought protection. The weaknesses of the international intellectual property laws that lacked enforcement rules further complicated the scenario for pharmaceutical companies. However under the WTO/TRIPS agreement, a dispute resolution procedure is provided for that has also meant that big pharmaceutical companies in the world have been able to create a sustainable essential drug cartel, which monopolies disadvantage developing countries like Zambia.

The TRIPS agreement has however provided for flexibilities and windows of hope for a country that can be exploited by a country faced with a public health crisis. Article 31 of the TRIPS agreement provides for compulsory licences, while article 4 provides for dealing with parallel imports.

The TRIPS agreement public health provisions as enshrined in the Doha declaration on the TRIPS agreement and Public Health adopted on November 14, 2001 allows developing countries, who are members of WTO to protect public health and in particular to promote

access to drugs for all, by ensuring that intellectual property does not become a fetter to access to drugs. The last WTO Ministerial Conference (Doha, November 2001), member countries issued a *Declaration on the TRIPS Agreement and Public Health* stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all." However, there are still areas of uncertainty in the interpretation of the TRIPS Agreement. Whether the Doha Declaration will have any positive, concrete effect remains to be seen, and there are still problems in the TRIPS Agreement that have not been addressed. Advocacy is still needed to ensure the maximum flexibility in interpreting and implementing the agreement. If the necessary flexibility cannot be found, it may be necessary to amend the Agreement to ensure that countries can protect the health and human rights of their people. But formally renegotiating the text of the agreement is a process that may take years before yielding unknown outcomes, while there is an urgent need for access to medicines now.

Another window of hope under the TRIPS agreement is Parallel Importing. Parallel importing implies a situation where Manufacturers charge lower prices for a drug in one country than in another. This means a country with limited resources can sometimes afford more of a patented drug by purchasing it abroad and importing it, rather than buying it directly at home from the manufacturer at a higher price. Patent laws in most countries say that once a patent-holder sells its goods, it has no right to control the resale of those goods. In other words, the patent-holder has "exhausted" its property rights in that sold product. (The patent-holder still has the exclusive right to make the product in the first place, preserving its monopoly on the "know-how" behind the invention.) So an intermediary could buy a patented drug in one country at the lower price being charged by the

manufacturer, and then resell that drug in another country at a price lower than what the manufacturer is charging for its product in that other country. This is called "parallel importing". The TRIPS Agreement (Article 6) says that nothing in it prevents a country from allowing parallel imports.

TRIPS also provides for Compulsory licensing under which a country's laws may allow the state or the courts to issue a "compulsory license,"<sup>32</sup> which permits either the government, an individual or a company to use a drug (i.e. produce or import a generic drug) without the authorization of the patent owner. Compulsory licenses are usually granted on grounds of general interest such as public health, economic development, national defence and the absence of working (i.e. when the holder is not "exploiting" its patent). The TRIPS Agreement does not limit the grounds on which governments or courts may issue compulsory licences. But there are restrictions on the use of compulsory licenses: Usually there must be an effort to negotiate a voluntary license with the patent owner "on reasonable commercial terms" within a "reasonable period of time." Importantly however, this attempt at negotiation with the patent holder is not required if the drug is to be used for "public non-commercial use," if there is a "national emergency" or other situation of "extreme urgency," or if a legal process has determined that the patent owner has engaged in "anti-competitive" practices. Further more if a compulsory license is issued, the patent owner is entitled to be paid "adequate remuneration" (e.g. either a symbolic fee acknowledging the inventor or a proper royalty in lieu of financial compensation for lost sales). The competent authority may also decide that the license should be granted free of charge. The TRIPS Agreement does

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<sup>32</sup> Patents, International Trade Law And Access To Essential Medicines By Richard Elliot

[www.icad-cisd.com](http://www.icad-cisd.com) Retrieved

27/09/2004

not say how "adequate remuneration" should be determined. Furthermore, the license must be used "predominantly" for supplying the domestic market in the country issuing the license (unless the license is issued to remedy "anti-competitive" practices by the patent owner). This presents a likely barrier to accessing affordable drugs in that many developing countries do not have the ability to produce their own generic drugs and would need to import them from other countries that do. But those countries that do have a generic drug industry are not permitted under TRIPS to issue a compulsory license authorizing someone to make a patent-protected drug primarily for export to other countries. The WTO is currently debating proposals for solving this restriction on exports of quality generic drugs to countries that need cheaper medicines but must import them because they cannot make their own. Zambia does not have the capacity to make all relevant drugs and therefore needs to lobby through WTO to allow importation of these generic drugs by developing countries, to ameliorate the crisis.

### ***Weaknesses of TRIPS vis-à-vis Drug availability***

The current problem is that the existing TRIPS (intellectual property) provisions of the World Trade Organization treaty require every country to have U.S./European style patent laws in force by 2006. It is not surprising that the Patents section of the TRIPS agreement has brought so much controversy compared to other aspects of intellectual property. This provision, adopted with no thought for its effect on access to health care, could be a disaster for poor countries, because pharmaceutical companies, price their drugs for rich-country markets, and have incentives to write off the poor who do not count financially, instead of having greatly varying prices which might lead to public-relations problems in rich countries.

But at the same time, some intellectual-property advocates hope that the new patentability of drugs for developing-country diseases might lead to medical research and drug development on diseases which are largely limited to poor countries, diseases largely neglected until now. Medicines could be sold profitably in poor countries, but they would have to be developed and marketed differently than in rich countries.

### **Striking a Balance: Patents and Access to Drugs and Health Care<sup>33</sup>**

#### ***WIPO (World Intellectual Property Organization)***

The debate over patents, pharmaceuticals (drugs), and fair and affordable access to health care for all is increasingly in the news today, even more so as worldwide attention focuses on the growing HIV/AIDS crisis. As a specialized agency of the United Nations mandated with managing intellectual property issues and standards on an international level, the World Intellectual Property Organization (WIPO) participates in that debate.

Unfortunately, some of the discussion involving the relation between the intellectual property system and access to health care has been based on misunderstanding or misconceptions of the patent system. This part discusses various issues relating to access to drugs and health care and helps clarify the role of the patent system.

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<sup>33</sup> Striking a Balance: Patents and Access to Drugs and Health Care

<http://www.worldrevolution.org/Projects/Webguide/GuideArticle.asp?ID=1141> Retrieved 13/05/2004

Patents perform an essential role in stimulating the development of essential drugs, including Anti-AIDS drugs, by offering incentives for investing in expensive and long-term research and development of new drugs. Without patents, existing anti-AIDS drugs would not have been produced. Without patents, new and better drugs that are needed to overcome the increasing resistance of the AIDS virus would not be developed.

At the same time, the patent system also contributes to society as a whole by accumulating and making available human knowledge to fight against the AIDS crisis. The patent system requires significant disclosure of the information leading to the invention of new drugs. Without the patent system, such key technical information would remain unavailable or even secret. Many health care researchers and drug manufacturers, who depend heavily on such information for their work, would have to reinvent the wheel. Given the severity of the crisis, no one can afford to spare such resources and time.

WIPO considers it important to strike a proper balance between public health concerns and the interest of the patent owner. This balance exists within the patent system. It is important to note that a number of Member States of the World Trade Organization (WTO) agree that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered by the WTO, also provides the necessary flexibility to achieve that balance, and to accommodate the needs of countries deeply affected by HIV/AIDS. Some of the common misconceptions, or myths, surrounding the patent system and access to drugs and health care are examined and clarified below.

Myth: "Problems in access to health care and the availability of life-saving drugs are primarily due to the patent system." Patents are only one of many factors that influence access to

health care and drugs. Many governmental and non-governmental organizations involved in the fight against HIV/AIDS cite socio-economic factors as barriers to access to drugs. Indeed, the United Nations Declaration of Commitment on HIV/AIDS from the recent Special Session on HIV/AIDS notes the importance of strengthening national health and social infrastructures as a key means to prevent the spread of the epidemic. Many drugs do not even fall under patent protection in some countries. In many African countries where the AIDS crisis is most acute, for example, a variety of protease inhibitors - a crucial treatment that helps stop the spread of the HIV virus from cell to cell within a patient - do not enjoy patent protection. Still, they are prohibitively expensive for most patients. In fact, some 95 percent of the pharmaceutical products on the World Health Organization's Essential Drug List - which includes many drugs used to treat various aspects and side effects of HIV/AIDS - are now "off patent", that is, no longer protected by patents, which generally last for 20 years counted from the time that an application is filed. Because of the time taken to process patent applications, the actual period of protection is often several years shorter. Yet many of these "off patent" drugs remain unavailable or unaffordable to most of those suffering from the virus. One can only wonder why? The reasons are not to be found in the patent system. The reasons are due to socio-economic factors. In many cases, patents are irrelevant, or only one of many factors that influence access to health care and drugs. As noted in the UN Declaration, a concerted, cooperative effort by governments, the business community and civil society groups is needed to successfully prevent the spread of HIV/AIDS and to make health care and drugs available and affordable to those already affected by the disease. Myth: "High drug costs are primarily due to the patent system, which allows companies to keep prices artificially inflated." A patent is not necessarily the determining factor in the price of drugs. The price of drugs depends on a wide variety of



factors, including the cost of research and development, production, distribution and marketing. Still, the actual market price is often marginal to the problem of access to drugs. Even reducing the price of HIV/AIDS treatments to cover the costs of basic manufacturing and distribution alone - as was recently done in a number of countries hardest hit by the crisis - still keeps the cost of annual treatments at between \$350 and \$600 per year. These prices, which are similar to the cost of generic versions of the same drugs and make no provision for recouping the cost of research and development, are still above the annual per capita incomes of some countries with high levels of HIV/AIDS.

Myth: "The patent system favors corporate interests over the greater social good." The patent system exists to protect the work of any inventor, whether an individual, a research institution, or an enterprise - ranging from a small operation employing a few persons to a large multinational conglomerate - in both developing and developed countries. It provides key incentives to inventive work and its related investment cost, by ensuring that the inventor derives certain economic benefits from his or her work for a fixed period of time, generally 20 years. An inventor must prove that the invention (such as a new drug) is new, is inventive, and is of practical use. In return for patent protection, the patent system requires adequate disclosure of information about new inventions which would otherwise remain secret as proprietary information, without being shared with society. Through this quid-pro-quo agreement between society and the inventor, key information on the invention is made available to the public and to other researchers, thus adding to the general body of accessible technical knowledge in the world. This form of technology transfer is of prime importance in promoting and aiding further research and development in every country, especially in the case of health care products. Medical researchers rely heavily on previous work in developing better drugs to treat diseases.

Myth: "The patent system deters sound competition." The

patent system can be viewed as a form of social contract, administered by the government, that balances the interests of the inventor - whether an individual or company - with the broader interests of society at large. In granting a patent, the government gives exclusive rights to the inventor or patent owner for a limited period of time to decide who may - or may not - use the patented invention. The patent owner may give permission to, or license, other parties to use, produce, license, or sell the invention, or may do so himself. During the patent period, anyone can obtain a patent on an improved invention on the basis of the patent of others. When the patent expires the protection ends, and the invention enters into the public domain, meaning that anyone can freely use or reproduce it without having to ask for permission or make payments. The patent system is designed this way to allow new entrants to compete against existing patent holders. At the same time, in most countries of the world providing patent protection, the relevant laws stipulate circumstances under which patent rights could be curtailed or limited, for example, by way of granting non-voluntary (compulsory) licenses, subject to certain conditions. Myth: "The patent system is especially unfair to developing countries, which face difficult social and economic circumstances and should be exempt from international intellectual property requirements, especially in the case of patent protection for certain drugs." A robust patent system providing for adequate patent protection is an indispensable incentive to creative and inventive work and is 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. It helps attract foreign investment. An adequate patent system can also help countries develop and strengthen their own research infrastructures and capacities, seen by the UN and other organizations as a key factor in fighting AIDs in the countries that are hardest hit. In general, adequate intellectual property systems are a key

factor in sustained economic development, which ultimately helps break the cycle of poverty and leads to better education, higher living standards, and better healthcare for the people. An adequate patent system also provides a proper balance between the public interest and the interest of the inventor. For example, it should be able to work effectively and equitably whenever the patent owner abuses the exclusive right, or if specific circumstances require an adjustment to the patent owner's rights.

Myth: "International treaties concerning patent protection interfere with the basic human right to life-saving drugs." Both the right of any individual to enjoy the material and moral benefits as a creator of intellectual property, and the right of all human beings to a standard of living that affords adequate health and medical care, are set forth in the United Nations Universal Declaration of Human Rights (Articles 25 and 27). They are not contradictory but should be seen as complimentary because the former rights afford the enjoyment of the latter rights through progress and innovation in science. International intellectual property treaties, including those relating to patents, fully comply with the Declaration.

WIPO's Contribution WIPO has a wide range of programs for establishing international legal and administrative norms and standards which help promote and ensure a well-balanced international intellectual property system, including for patents. WIPO supports the initiatives taken by the Secretary-General of the United Nations, and is cooperating with the World Health Organization, UNAIDS, and the World Trade Organization in areas where it can offer its experience and expertise regarding the question of patents and health care.

WIPO has no mandate to interpret provisions of the TRIPS Agreement, which is administered by the WTO. However, within its mandate, WIPO continues to provide legal and technical assistance to countries on the implementation of the TRIPS Agreement. WIPO has been providing a wide range of technical and legal assistance for developing countries and least-developed countries for the last three decades. This

includes assistance for the establishment, modernization and automation of intellectual property offices, human resources development programs, the provision of legal advice on compatibility of legislation with relevant international treaties, and assistance in strengthening capacities to enforce intellectual property rules. Following the WIPO-WTO cooperation agreement concluded in 1995 and as part of technical assistance programs for developing countries launched in 1998, WIPO has provided more than 100 developing countries with a wide range of assistance regarding the TRIPS implementation. WIPO and WTO recently launched another joint initiative to assist least developed countries in implementing the TRIPS Agreement and in using intellectual property as a tool for technological advancement, economic growth, and knowledge and wealth creation. WIPO is convinced that all developing countries, through effective use of the patent system, should be able to stimulate local research activities and make joint efforts to develop and produce anti-AIDS drugs. In providing such support, WIPO's aim is to help all countries to fully utilize the intellectual property system and patent system as a dynamic tool for wealth creation and cultural development. An adequate intellectual property system, respecting both the needs of creators of intellectual property as well as consumers, is especially important in the field of health care. Promoting human creativity, and the use and protection of inventions and creations, is a key means to ensuring a better and more enriching life for everyone.

#### **4.0 CHAPTER FOUR**

#### **4.1 CONCLUSIONS AND RECOMMENDATIONS**

From the discussion outlined in this paper, it becomes relevant to apply the Doha Declaration more towards easier accessibility to drugs. The Doha Declaration affirmed the primacy of states' public health obligations, and the right to promote access to medicines for all, over intellectual property rights. Advocates should use this to push for the wider recognition that states' obligations to protect and promote human rights (including the realization of the highest attainable standard of health for all) take precedence over trade agreements. People concerned about access to medicines in developing countries need to ensure that the promise of the Doha Declaration is realized in good faith. Advocates must work toward a solution that deals quickly and fairly with the issue of authorizing production of quality generic drugs for export to developing countries, and that does not impose restrictive conditions that will lead to more preventable deaths by denying access to more affordable medicines. Advocates also need to ensure that the gains reflected in the Doha Declaration are not undermined by political pressure on developing countries if they pursue the measures allowed under the TRIPS Agreement to promote access to medicines. Other regional or bilateral trade agreements dealing with patents must also include these safeguards, and should not go beyond TRIPS in strengthening private patent rights at the expense of poor people who need medicines.

There is a need to revisit key legislation in the Zambian Jurisdiction especially the Pharmaceutical Act of 2004, which has failed to even reconcile the fact that the TRIPS agreement, to which Zambia is a party will have to be complied with, by ensuring that local legislation is in line with the objectives of the TRIPS agreement.

- 9) Developing countries, including Zambia, need to pursue the option of parallel imports as an alternative to manufacturing some essential drugs. This will involve applying paragraph 4 of the Doha declaration in a careful calculated way that will not also hinder the developed countries from exploiting their legitimate interest in the patented drugs.

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# APPENDIX 1

Supplement to the Republic of Zambia Government  
Gazette dated Friday, 10th September, 2004

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## GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 83 OF 2004

### **The Patents Act** (Laws, Volume 22, Cap. 400)

#### **The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004**

IN EXERCISE of the powers contained in section *forty* of the Patents Act, the following Regulations are hereby made:

- |                                                                                                                                                                                         |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 1. These Regulations may be cited as the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004.                                                      | Title                                         |
| 2. In these Regulations unless the context otherwise requires—                                                                                                                          | Interpretation                                |
| “ antiretroviral drug ” includes any generic drug used in the treatment of persons suffering from HIV/AIDS or an HIV/AIDS related condition;                                            |                                               |
| “ patented antiretroviral drug ” means any antiretroviral drug in respect of which a patent has been granted and is for the time being in force; and                                    |                                               |
| “ period of emergency ” means the period commencing on 1st August, 2004 and ending on 31st July, 2009.                                                                                  |                                               |
| 3. The Minister may, in writing, authorise any Government department or person to manufacture, use or vend, in Zambia, any patented antiretroviral drug during the period of emergency. | Authority to manufacture antiretroviral drugs |
| 4. Antiretroviral drugs that are manufactured pursuant to regulation 3 shall not be exported to any place outside Zambia.                                                               | Antiretroviral drugs not to be exported       |

LUSAKA

2nd September, 2004

[MCTL104/1/1c]

D. K. A. PATEL,  
*Minister of Commerce,  
Trade and Industry*