AN ANALYSIS OF THE CONFLICT BETWEEN INTELLECTUAL PROPERTY RIGHTS AND THE HUMAN RIGHT TO HEALTH IN RELATION TO THE HIV/AIDS GLOBAL CRISIS

by

DIANA BUNTING

Computer NO 97131865

submitted to the University of Zambia in partial fulfilment of the requirements of the Bachelor of Laws (LLB) Degree programme

School of Law
University of Zambia
Lusaka

November 2003
I recommend that the Obligatory essay prepared under my supervision by DIANA BUNTING

Entitled

AN ANALYSIS OF THE CONFLICT BETWEEN INTELLECTUAL PROPERTY RIGHTS AND THE HUMAN RIGHT TO HEALTH IN RELATION TO THE HIV/AIDS GLOBAL CRISIS.

be accepted for examination. I have checked it carefully and I am satisfied that it fulfills the requirements relating to format as laid down in the regulations governing Obligatory essays.

Prof/Dr/Mr/Ms..............................
(Supervisor)

...........................................
Date

28.11.88
<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedications</td>
<td>(i)</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>(ii)</td>
</tr>
<tr>
<td>Preface</td>
<td>(iii)</td>
</tr>
<tr>
<td>CHAPTER ONE: Introduction</td>
<td>1</td>
</tr>
<tr>
<td>1.1 IPRS and Growth</td>
<td>1</td>
</tr>
<tr>
<td>1.2 What is Intellectual Property</td>
<td>2</td>
</tr>
<tr>
<td>1.3 HIV/AIDS Crisis and obstacles to Access Essential Medicines</td>
<td>3</td>
</tr>
<tr>
<td>1.4 Protection of IPRS</td>
<td>6</td>
</tr>
<tr>
<td>CHAPTER TWO: The TRIPS Agreement</td>
<td>9</td>
</tr>
<tr>
<td>2.1 Introduction</td>
<td>9</td>
</tr>
<tr>
<td>2.2 BACKGROUND</td>
<td>9</td>
</tr>
<tr>
<td>2.3 Rights Conferred and Limitations</td>
<td>12</td>
</tr>
<tr>
<td>2.4 Compliance with TRIPS</td>
<td>14</td>
</tr>
<tr>
<td>2.5 Does TRIPS Protect Health</td>
<td>15</td>
</tr>
<tr>
<td>2.6 Options Available in TRIPS</td>
<td>17</td>
</tr>
<tr>
<td>2.6.1 Exclusions from Patent Admissibility</td>
<td>17</td>
</tr>
<tr>
<td>2.6.2 Exceptions to Patent Rights</td>
<td>18</td>
</tr>
<tr>
<td>2.6.3 Parallel Importing</td>
<td>18</td>
</tr>
<tr>
<td>2.6.4 Compulsory Licensing</td>
<td>19</td>
</tr>
</tbody>
</table>
DEDICATION

To my late mum. You preferred to respond to the Almighty's call than wait for the fruits of your investment. Mama I love you and always will. To my baby in utero, life seems ever so beautiful as I wait for your coming.
ACKNOWLEDGEMENTS

First and most importantly of all, making it possible for me to complete this work amidst the difficulties I have gone through, the Heavenly Father must be thanked earnestly.

I wish to thank, the Co-ordinator, Dr. Munalula for the timely guidance in the Research work.

I would also like to thank Mr. M. Kanja for his assistance and supervision in my research work.

My acknowledgements would be incomplete without recording the inspiration that I have drawn – and continue to draw – from Jonathan Berger, for his help, advice and material during the course of my research to him I extend my utmost gratitude.

Kaumbu Mwondela, for tirelessly helping me with materials for my research. God bless you.

Ismail, for being a faithful and honest friend, and indeed a friend for all seasons.

My friends, Sandra, Triphine, Namukale, Jackie, Chituwa, Shalin and Medndai, for being a source of encouragement.

My sister Lynn, and brothers John, Paul and Chris, thanks for being there for me.

To Precious Mweemba, I say thank you for typing my work and keeping your smile all the way.
PREFACE

The world today has been hit by the most deadly epidemic – HIV/AIDS. The growing depth of the HIV/AIDS tragedy carries alongside it lack of access to medicines for people with HIV. Even countries in Africa like South Africa, that has the best health infrastructure has almost no access to HIV drugs, a country that has the most people living with HIV or AIDS in Africa. The issue of access to medicines has become so critical because many people die every day.

It is worrying that whilst there is a wide awareness of the HIV/AIDS epidemic in Africa, the statistics are so mind numbing that it almost breeds paralysis about what should be done to save the lives of millions.

It is also amazing that amid the poverty of Africa, some people are able to purchase health and vigour. They live today because they can afford to pay for life itself. This seems an iniquity of very considerable proportions that, simply because of relative affluence, some should remain living when illness and death beset millions of others.

Admittedly the major reason for this imbalance is that the Agreement on Trade-Related Aspects of Intellectual property Rights (TRIPS Agreement) (1994), requires the member states to provide patent protection for virtually all areas of technology. Thus the owner of the patent shall have all exclusive rights that prevent third parties from making, using, selling the product etc. Ultimately, the
right to life and health becomes one for those who can afford to pay for expensive HIV drugs. This should not be so because access to treatment and to health care services has become the pivotal human rights and legal issue. It is the issue on which other areas of human rights will ultimately stand or fall in the AIDS epidemics. Therefore, there is need to interpret the TRIPS Agreement widely so that there is some degree of flexibility in its implementation in the pharmaceutical sector. Indeed the interest of the patent holder should be safeguarded, but to what degree should this be done so that the problem of access to drugs is overcome?

It is agreeable to a limited extent that the TRIPS Agreement takes into consideration the special situation of Developing countries as regards Health issues. However, the implementation of the provisions spelt out in the agreement are not easily implemented as they are met with fierce opposition from the developed countries.

In view of this, the question that follows is “Should the right to life and health care be only for those who can afford to pay for it or even for the poorest of the poor in Africa? This research therefore seeks to critically analyse the conflict between Intellectual Property Rights and the right to health in relation to the HIV/AIDS Global crisis. Chapter one is a general introduction of the subject and highlights the conflict between IPRS and the right to health.
Chapter two endeavours to discuss the TRIPS Agreement in detail and illustrates the extent to which the Agreement promotes the right to health and options found in it that developing countries can use to access cheap and affordable Medicines. Chapter three will emphasise the importance of the right to health as a human right. Making reference to international treaties that recognise it as a human right. This chapter will also offer an explanation as to why the right to health should be given preference over any other right. Furthermore, chapter four will illustrate and analyse the relationship between TRIPS and the right to health and examine ways in which conflicts between IPRS and the right to health could be resolved under international law.

Finally chapter five will be a conclusion chapter. In this chapter, suggestions and recommendations will be given. Being a conclusion chapter, a brief overview of the research as presented in this research will also be given.
CHAPTER 1

1. INTRODUCTION

1.1 IPRS AND GROWTH

Over the past fifteen years, substantial changes have occurred in the legal regimes in many developing countries with respect to intellectual property rights (IPRS). Moreover, beginning on 1 January 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights, administered by the World Trade Organisation, became the standard for protecting IPRS in those nations seeking to engage in international trade and enhance their prospects for economic growth. Countries that heretofore ignored IPRS subsequently adopted laws that at least provided the basic protection for innovators as outlined in TRIPS.¹

This respect for IPRS represents a challenge to access to health in many developing countries. Indeed access to health care is a major concern for people throughout the world. Even in some developed countries, there exist patient populations that may not have access to health care. However, the problems of access are often more severe among the developing countries. Admittedly, the Aids epidemic is a major factor contributing to the wide-wide problem of lack of access to essential drugs. Though there are other barriers responsible for access problems, it is fundamental to examine access to health care in terms of pharmaceuticals, especially as is related to the impact of the TRIPS Agreement.

This paper seeks to critically analyse and determine the efficacy of the TRIPS Agreement in relation to the existing conflict between the Intellectual Property Rights and the Right to Health. In this respect the paper will give an overview of the impact of the world wide epidemic HIV/AIDS on people’s lives due to the problem of lack of access to essential drugs. This will be followed by a discussion of the TRIPS Agreement, pointing out the relevant provisions that protect IPRS and or promote the right to health. An exposition of the salient provisions (as they relate to the right to health) in the UDHR, 1948; UN Charter, 1945; ICESCR, 1966; and the African Charter on Human and People’s Rights, 1981; will be highlighted. Thereafter, an analysis of whether or not the TRIPS Agreement makes it possible to realise the right to health will be made. Finally, a conclusion will be drawn and recommendations will be given.

This chapter will begin by giving a definition of Intellectual Property and of a patent. It will also give an overview of the HIV/AIDS crisis faced by many developing countries especially African countries and obstacles to access essential medicines. Thereafter, a general picture of the requirement of protection of IPRS through the TRIPS Agreement will be outlined.

1.2 WHAT IS INTELLECTUAL PROPERTY

According to Osborn’s concise Law Dictionary, the form describes those rights which protect the product of one person’s work by hand or brain against
unauthorised use or exploitation by another. Those rights protected are what are known as intellectual property rights (IPRS).²

Intellectual property according to Phillips and Firth has two descriptions, the colloquial and legal description. The colloquial description is that it simply comprises all those things which emanate from the exercise of the human brain such as ideas, inventions, poems, designs and microcomputers. The legal description focuses upon the rights which are enjoyed in the produce of the mind, rather than upon the produce itself.³

Richard Gerster defines a patent as a statutory grant which confer on the inventor the right to exclude others from using the invention.⁴ IPRS are therefore rights given to a person or a corporation over creations, such as, an author’s mental creation, an author’s copyright in their book or the rights of musicians in their recordings; a company’s distinctive trademark on products; or a patent on a technological invention.⁵

1.3 HIV/AIDS CRISIS AND OBSTACLES TO ACCESS ESSENTIAL MEDICINES.

The great majority of the world's population lives in developing countries and these people have limited access to any type of medicines they need. More than 85% of the world's population that lives in developing countries have no access to drugs that have saved and extended the lives of people in richer,
developed countries. In the developing world, where 95% of the people living with HIV/AIDS are found, 20 million people have already died of AIDS\textsuperscript{6}. Every day, over 8,000 more people die and another 15,000 are infected with HIV.\textsuperscript{7} This global epidemic is devastating entire countries and regions.

In Africa, millions and millions of people die every year of communicable diseases such as Aids, tuberculosis, malaria and many others. In many cases, treatments exist but very few people have access to them. For instance an estimated 4.5 million South Africans are infected with HIV-the highest number than any other country in the world.\textsuperscript{8} The problem of lack of access to drugs is real and it has increased over the years. This actually poses a serious threat because epidemics like the HIV/AIDS are growing rather than being eradicated, for a number of reasons.

The statistics above indicate that the rules on individual patent rights in drugs set out in domestic laws and international trade agreements affect the availability and affordability of both anti-retroviral drugs and medicines to treat opportunistic infections or communicable diseases that can harm or kill people with HIV/AIDS and other neglected diseases. On the premises, it is imperative to understand the connection between patent rights issues and access to affordable drugs. Drug patents have a lot to do with access to medicines. Depending on the patent laws in place, conditions will be created to favour improved access to medicines or not.

\textsuperscript{6} Richard Elliot, Canadian HIV/AIDS Legal Network.
\textsuperscript{7} Michael Blakeney, page 28.
\textsuperscript{8} Times of Zambia. Tuesday August 5, 2003.
However, there are many obstacles to access essential medicines. To name the main ones: the price of medicines; the concentration of the global pharmaceutical industry; the monopolistic control the pharmaceutical industry has over markets through the patent system; the very fact that research and the development of medicines is primarily determined by market profitability – and the fact that governments are increasingly adopting the same kind of reasoning as the pharmaceutical industry\(^9\)(which leads to the investment of public money only into what corresponds to this "logic" of profit). Although access depends on numerous factors, high prices of drugs constitute a key obstacle that cannot be addressed in a comprehensive and sustainable manner through foreign aid and drug donations alone. This key obstacle, has in recent years, largely as a result of the global HIV/AIDS crisis, increased attention on the issue of access to affordable medicines in many of the world's poor and developing countries. It cannot be disputed that making medicines accessible to those who need them requires action on many fronts. And given the evidence marshalled by human rights and humanitarian organisations, there can no longer be any doubt that, in some cases, the aggressive interpretation and assertion of private intellectual property rights in medicines pose key barriers to sustainable and guaranteed access to vital medicines at affordable prices. In particular, considerable attention has been drawn in the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement).

1.4 PROTECTION OF IPRS

The TRIPS Agreement has for the first time changed the way the member countries implemented their obligations under the international conventions on intellectual property. For instance under the Paris and Berne Conventions, Member countries were bound by the international obligations to the extent they wished to be bound. Under the TRIPS Agreement, this freedom was done away with. Members either have to take the Agreement in its entirety or leave it.

Developed countries argued that protecting IPRS was of prime importance as it would benefit developing countries in three main ways:

- There would be more foreign direct investment (FDI).
- It would promote transfer of technology.
- Patent protection would promote local Research and Development (R & D).

On the contrary, developing countries were reluctant to extend patent protection to pharmaceuticals. They realised that pharmaceutical production was highly concentrated in developed countries and more importantly, innovation – the development of new chemical entities – was almost exclusively undertaken in industrialised countries.

However, though developing countries were opposed to the protection of IPRS through the TRIPS Agreement, it was absolutely impossible for them to avoid the Agreement totally. Today, many developing countries are in the

---

10 Dr. Harrison Mwakyembe, George Mpundu Kanja p.3.
11 Ibid. p.4.
process of revising their patent laws to provide protection to pharmaceutical process and products pursuant to the TRIPS Agreement. However, the issue as to conciliation of the right to health and IPRS is still at the centre of debates and posed challenges not only to developing countries but even developed countries, especially on the access to cheap and affordable drugs by millions of people infected with HIV/AIDS. An illustration is the South African case against the pharmaceutical companies,\textsuperscript{12} in which South Africa was faced with the dilemma of which of the two interest would prevail; the egoistic and private interests of the pharmaceutical industry, or people’s lives and public interest. When she chose the later interest, she was heavily criticised by developed countries for not complying with the TRIPS Agreement and was consequently threatened with sanctions by the United States of America.

It is well understood that states are required by international (and often domestic) law to take all appropriate measures, including legislative measures, to realise every person’s right to enjoyment of the highest attainable standard of health. Therefore, the implications of the TRIPS Agreement for state’s freedom to act through legislation and policy in order to realise this human right are of particular concern. In particular, do the provisions of the TRIPS Agreement, both as written and as interpreted and applied, allow WTO member countries the flexibility to take measures to protect and promote the health individual and collective, of those under their jurisdiction? Numerous countries and commentators have claimed that the necessary flexibility is already to be found in the TRIPS Agreement, although

\textsuperscript{12} Details of the case will be discussed in Chapter four.
in practice, the experience to date gives some reason to question whether this is sufficient.

CONCLUSION

This chapter has given a general introduction of the subject. Apart from this, the chapter has endeavoured to show the extent of the seriousness of the HIV/AIDS epidemic. It is against this global crisis that the chapter has tried to highlight the conflict that exists between promoting the right to health and the protection of IPRS in developing and developed countries respectively.
CHAPTER 2

2. THE TRIPS AGREEMENT IN DETAIL

2.1 INTRODUCTION

The previous chapter generally gave an introduction of the subject and briefly highlighted the present conflict between the right to health and intellectual property rights. However, this chapter will concern itself to the specific provisions of the TRIPS Agreement that illustrate to what extent the Agreement promotes the right to health and the options found in the Agreement that developing countries have to access cheap and affordable drugs.

The discussion shall include the historical background of the TRIPS Agreement which shall be followed by the identification of the salient provisions of the Agreement with regard to the discussion at hand.

2.2 BACKGROUND

Over the years, it was noted that the development of international trade could be adversely affected if the standards adopted by countries to protect intellectual property rights (IPRs) varied widely from country to country. Furthermore, the lax or ineffective enforcement of such rights could encourage trade in counterfeit and pirated goods, thereby damaging the legitimate commercial interests of manufacturers who held or had acquired these rights.13 Following this, proposals were made by the developed countries that action should be taken in the General

---

Agreement on Tariffs and Trade (GATT) to control the trade in counterfeit and pirated goods as early as the Tokyo Round of negotiations. When the Uruguay Round was being launched, these countries proposed that the negotiations should not only cover trade in counterfeit goods but also aim at developing minimum standards of protection of intellectual property rights IPRS for adoption by member countries. While the developing countries were in general not opposed to the proposals for action on counterfeit goods, they initially resisted discussion on minimum standards protecting IPRS. They were apprehensive that such negotiations would require them to change their policies. For development and social reasons, their policies excluded certain products from patentability or provided shorter protection periods than the 20 years for which patent protection was generally granted by developed countries for inventions relating to such products as pharmaceuticals, chemicals, fertilizers, insecticides and pesticides. They were also fearful that the adoption of minimum standards would lead to increased royalty payments for the use of patented technology under licence and thus to higher prices for the products so manufactured.

These views, however, did not prevail and pressures from developed countries ultimately resulted in the negotiations focusing to a greater extent on the establishment of substantive and uniform standards providing for a higher level of protection for intellectual property rights. It is important to note in this context that the attitude of both developed and developing countries evolved as the negotiations proceeded. It was thus possible to reach a consensus on the

---

14 International Economic Relations page 118.
Agreement on Trade – Related Aspects of Intellectual Property Rights which, inter alia, lays down minimum standards for the protection of all the main categories of intellectual property rights.

It is worth of mention that the TRIPS Agreement is a shorthand way of referring to the Agreement on Trade – Related Aspects of Intellectual Property Rights. The TRIPS Agreement builds on the main international conventions on intellectual property rights by incorporating (by reference) most of their provisions. It further provides that countries may in pursuance of these conventions guarantee higher protection than is required by the TRIPS Agreement’s provisions as long as it does not contravene the Agreement’s provisions\(^{15}\). The TRIPS Agreement is also one of a series of trade agreements administered by the World Trade Organisation (WTO). It sets out rules for intellectual property rights that all countries that are WTO members must reflect in their own domestic laws as a condition of belonging to the WTO.

The TRIPS Agreement has numerous provisions that states have to abide to. However, it offers for a degree of deference particularly in the case of “least developed countries” towards states’ legislative choices in implementing their obligations under the Agreement.

All “developed” countries were required to bring their domestic laws into line with TRIPS rules no later than January 1, 1996. “Developing” countries had until January 1, 2000 to comply—although they have until 2005 for patents on

\(^{15}\) TRIPS Agreement Article 1.
pharmaceutical products if they did not previously recognize these. Those countries considered “least developed” have until January 1, 2006 to change their laws, and may ask for extensions of time, if they so wish.\textsuperscript{16}

2.3 RIGHTS CONFERED AND LIMITATIONS

Further more the \textit{preamble} and Article 1 of the TRIPS Agreement, have “recognized...the special needs of the least developed country members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base”. Article 1, regarding the nature and scope of the WTO members’ obligations under the treaty, states that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”. In essence, this entails that the interpretation of the TRIPS Agreement should be in a fashion that is consistent with states obligations under their domestic law and ultimately international human rights law.

The TRIPS Agreement contains a number of requirements that WTO member countries must satisfy in their national laws. Before the TRIPS Agreement, most industrialized countries granted patents on drugs, but many developing countries did not. In some cases, countries only granted patents for the process of producing an invention, for example, the method of producing a drug, but not for

\textsuperscript{16} Patents – International Trade Law and Access to Essential Medicines, TRIPS Agreement Article 65.
the product, that is the drug itself. Because in some countries pharmaceutical products could not be patented, generic copies of these drugs could be made or imported into those countries without first getting permission from the inventor (that is, the firm or individual that had been granted a patent in some other country that recognized drug patents). This meant that there was no transnational market monopoly for the patent holder, so prices of medicines were often lower because of the generic competition against the patented drugs. With the coming into force of the TRIPS Agreement, all this was ended. Thus the TRIPS Agreement breeds Exclusive Patent rights. Under Article 28 of the TRIPS Agreement, governments are required to recognize patents on products and processes in all fields of technology, and to give the patent holder the exclusive right to make, use, sell or import the product in their country for a given period of time. During this time, a patent holder may choose to authorize another individual or corporation the right to do these things. This authorization is called "voluntary license".

The minimum patent term is 20 years. All WTO member countries are now required to grant patents on pharmaceutical inventions for at least 20 years. (Article 33). This prevents someone other than the patent-holder from making, using, selling or importing a drug during the period that the drug is still under patent. TRIPS creates a trans-national market monopoly where none existed before, by allowing the patent owners to keep generic drugs off the national market in every WTO member country. The Patent owner's monopoly often
results in significantly higher prices for patented medicines than in a situation of market competition.

Given the exclusive patent rights, the TRIPS Agreement under Article 27 also requires countries to make patents, and all patent rights, available without discrimination on certain grounds. Under TRIPS, countries are not allowed to treat national and foreign inventions differently, nor are they allowed to discriminate between types of products, for example pharmaceuticals versus computers (Article 3) The TRIPS Agreement further provides that countries patent laws cannot discriminate based on whether a product is imported or locally produced. (Article 4).

2.4 COMPLIANCE WITH TRIPS PROVISIONS

All member countries have to comply with the provisions of the TRIPS Agreement. If a country does not comply with the provisions of the Agreement, other countries can take it before a trade tribunal (Article 64). One of the primary functions of the WTO is to provide a forum for countries to settle trade disputes. One of the WTO agreements, the Dispute settlement understanding (DSU), sets out a procedure to be followed when a country wishes to challenge laws or practices of another country. If a WTO tribunal rules that a country has breached a trade agreement, it “shall recommend” that a country bring its laws or policies into line and may suggest ways to do this. The country then has three choices. It can comply with the “recommendations” by changing its laws or policies. Or, it
can decide not to comply with the ruling, and pay "satisfactory compensation" to the country that brought the complaint, presumably on an ongoing basis. Finally, if it does not receive satisfactory compensation, the country with the complaint can request WTO authorization to impose trade sanctions in retaliation. Again by default, the WTO will accept this request unless every country (other than the ones involved in the dispute) rejects it. The country facing sanctions may have an arbitrator decide whether the sanctions are fair.

2.5 DOES TRIPS PROTECT HEALTH

The TRIPS Agreement is not silent about protecting health. The Agreement itself says that 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.\textsuperscript{17} 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). Under Article 8, the TRIPS Agreement sets out some basic principles that should guide how it should be interpreted. It states 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

\textsuperscript{17} TRIPS Agreement Article 7.
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 should be entitled to flexibility in meeting their obligations. This was in fact the argument that was defended by Canada in the Generic Medicines Case.\textsuperscript{18} In 1997, the European Union (EU) challenged a section of Canada’s Patent Act intended to make it easier for cheaper, generic drugs to come to market as soon as possible. The section in no way limited an original drug company’s market monopoly during its 20-year patent term, but simply allowed generic drug companies to stockpile their versions of a drug for sale as soon as the patent expired. Among other things, Canada argued that public interest in earlier access to more affordable drugs was a legitimate basis for this limited exception to exclusive patent rights. Theoretically, these exceptions are allowed under Article 30 of TRIPS. The EU dismissed these arguments complaining of “discrimination” against the pharmaceutical industry. The WTO panel hearing this dispute ignored Canada’s public interest argument and took a very narrow approach to deciding what were acceptable limitations on patent rights, looking only at the private patent owner’s expectation of profits and not considering what other social benefits were to be gained by limiting this monopoly. Article 8 of the TRIPS Agreement is of particular significance and a WTO panel acknowledged that Article 8 must be applied in interpreting other terms in the TRIPS Agreement.\textsuperscript{19} This is consistent

\textsuperscript{19} Ibid at page 154 (Para 7.2b).
with the general principle of effectiveness in international law – that is, the duty to interpret the treaty as a whole, giving effect to all of its terms.²⁰

2.6 OPTIONS AVAILABLE IN TRIPS

Having highlighted Canada’s Generic Medicines case, a question of paramount importance is; Does TRIPS leave options for developing countries to increase access to affordable medicines? The answer is yes and no. There are some parts of TRIPS that countries can use to promote access to affordable medicines for people living with HIV/AIDS. However there are still many areas of uncertainty in the interpretation of the TRIPS Agreement. Advocacy is still needed to ensure the maximum flexibility in interpreting the agreement. Some argue that such flexibility not be formally acknowledged, it might be necessary to amend the Agreement to ensure that countries can protect the health and human rights of their people. But renegotiating the text of the agreement is a risky process that may take years before yielding unknown outcomes.

There are however four main aspects of TRIPS that may be useful for African countries to promote access to affordable drugs.

2.6.1. EXCLUSIONS FROM PATENT ADMISSIBILITY

A country may prevent the commercial exploitation of some inventions if necessary in order to protect human life and health, by refusing to recognize

---

their patent admissibility (Article 27(2)). How to determine whether this is necessary, and who decides, are not clear.

2.6.2. EXCEPTIONS TO PATENT RIGHTS

Under Article 30, a country may include in its patent laws limited exceptions to the rights of a patent owner to exclude others from making, using, importing or selling an invention, taking into account the legitimate interests of others. But these exceptions must not unreasonably conflict with the normal exploitation of the patent, and may not unreasonably prejudice the patent owner's legitimate interests. There has only been one WTO ruling interpreting this Article, the Generic Medicines case involving Canada's patent laws which seems not a conclusive decision.

2.6.3 PARALLEL IMPORTING

Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder.21 The underlying concept for parallel imports is based on the principle of exhaustion of rights, which is premised on the fact that where the patent holder has been rewarded through the first sale or distribution of the product, he no longer has the right to control the use or resale of the product.22

---

21 Dr. Harrison Mwakyembe, George Mpundu Kanja pg. 15.
22 IPRS, the WTO and developing countries – The TRIPS Agreement and Policy Options, Third World Network, Malaysia.
Thus manufacturers sometimes 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 the higher price. So an intermediary could buy a patented drug in one country at the lower price being charged by the manufacturer, and then resell those drugs in another country at a higher price, but one that is still lower than what the manufacturer is charging for its patented drug in that country.

Parallel imports are of particular importance for public health interests, since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines. Parallel imports would prevent market segmentation and price discrimination by patent holders on regional or international sale.23

The TRIPS Agreement, Article 6, explicitly says that nothing in it can be used to prevent a country from allowing parallel imports. Thus it allows member countries the freedom to incorporate the principle of international exhaustion of rights.

2.6.4 COMPULSORY LICENSING

A compulsory license is the licence issued by a government to a third party, whether a private company or government agency, for the right to use or exploit a patent without the patent holder's consent. Under Article 31 of TRIPS, a

country's laws may allow the government or courts to issue a “compulsory licence”, which permits either the government, an individual or a company to use a drug (produce or import a generic drug) without the authorization of the patent owner. Article 31 of the Agreement makes specific mention of five possible grounds for the granting of compulsory licences;

- Refusal to deal
- Emergency and extreme urgency
- Public non-commercial use
- Anti-Competitive practices
- Dependent patents

The TRIPS Agreement does not limit the grounds on which governments are allowed to issue compulsory licenses. But there are restrictions to the use of compulsory licenses:

(i) Usually there must be an effort to negotiate a voluntary license with the patent owner “on reasonable commercial terms”. Within a “reasonable” period of term”. Importantly however, this attempt at negotiation with the patent holder is not required if the drug is to be used for public noncommercial 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.
(ii) If a compulsory license is issued, the patent owner is entitled to be paid "adequate remuneration". The competent authority may also decide that the license should be granted free of charge. TRIPS does not say how this should be determined.

(iii) Further, the license must be used "predominantly" for supplying the domestic market in a country issuing the licence. This presents a likely barrier to accessing affordable drugs: 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 may not be allowed under TRIIPS to issue a compulsory license for the manufacture of a patent-protected drug primarily for export to other countries. This restriction in TRIIPS may need to be amended to make it easier for developing countries to access affordable medicines.

CONCLUSION

This chapter has pointed out the salient provisions of TRIPS that confer rights on Intellectual Property and the limitations to these rights. It has also made reference to the importance given to the right to health through the provision of TRIPS. Included in this are options available to developing country to accessing essential health care. This therefore demonstrates that Intellectual Property is not an obstacle to access to affordable medicines in developing countries. Thus Intellectual property protection should not be seen as a barrier to appropriate
measures in response to public health concerns. A member's right to pursue public health objectives and policies is unaffected by the TRIPS Agreement. Member countries can actually use provisions in TRIPS in a positive way to opt for a system that matches their public health objectives. However, whether these provisions of TRIPS are practical or merely a matter of theory that can never be achieved are of primary concern. The later chapters will discuss whether these provisions can be used in practice by developing countries to overcome the present health care problem due to lack of access to essential drugs.
CHAPTER 3

3.0 INTRODUCTION

This chapter shall discuss the right to health in detail by identifying international treaties or instruments that recognise it as a fundamental human right. This will include an explanation as to why the right to health should be given preference over any other right.

3.1 WHAT IS THE RIGHT TO HEALTH

The importance of a right to healthy has generally been acknowledged at both national and international levels. Health as a human right has been included in a number of international instruments but, like other economic and social rights, it remains subject to frequent criticism for being vague in content and intersecting with too many other rights.24 The right to health has mainly been described and given detailed pronouncements. Thus the right to health implies, like other economic and social rights, obligations to respect, protect and fulfil that right. States are to refrain from interfering directly or indirectly with the enjoyment of the right; they should take measures to prevent third parties from interfering with the guarantees provided; and they should adopt appropriate legislative, administrative and other measures towards the full realisation of the right.25 One of the most detailed pronouncements of this right is found in the International Covenant on Economic, Social and Cultural Rights (ICESCR) which recognises everyone's right to the enjoyment of the highest attainable standard of physical and mental health.26

26 General Comment 14.
There is no standard definition of the right to health. The right to health merely places an obligation on states to respect, protect and provide adequate health care for their people.

As expounded by the ESCR committee, the core obligations of the right to health include the imperative to ensure the right of access of health facilities, especially for vulnerable or marginalized groups.\textsuperscript{27} In the case of HIV/AIDS more specific elaborations of these obligations have been given. The World Health Assembly has, for instance, called on its member states to increase access to treatment and prevention of HIV-related illnesses through measures such as ensuring provision and affordability of drugs.\textsuperscript{28} The UN Human Rights Commission has taken the same direction with its resolution on HIV/AIDS stating that access to medication in this context is one fundamental element for achieving the full realisation of the right to the enjoyment of the highest attainable standard of physical and mental health.\textsuperscript{29}

\section*{3.2 RIGHT TO HEALTH AS A HUMAN RIGHT}

The most serious human right violation is the violation that denies a person the right to dignity. One can take away a person's job, or can deny a child the right to go to school, both of which are unpleasant, but when sick people are refused the medicine that, by watching British Broadcasting corporation (BBC), they know is easily available on the other side of the world, is the most profound of human rights violations.

\textsuperscript{27} General Comment 14.
\textsuperscript{28} World Health Assembly, 'HIV/AIDS: Confronting the epidemic', (WHO, 2000).
\textsuperscript{29} Commission on Human Rights (Resolution 2001/53(23\textsuperscript{rd} April 2001).}
To address such issues, there is need to reassess human rights, to rediscover the values that underlie these rights. The "enjoyment of the highest standard of health" has been recognised as a "fundamental right" by the international community since the adoption of the constitution of the World Health Organisation (WHO) in 1946.\textsuperscript{30} The preamble of the WHO constitution sets out various principles which the states parties’ declare in conformity with the charter of the United Nations, ‘...to be basic to the happiness, harmonious relations and security of all peoples’. It states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being" and that "the health of all peoples is fundamental to the attainment of peace and security". This recognition indicates that the right to health is indeed an inalienable right which cannot be taken away from any human being. As such other international instruments illustrate the importance of the right to health through their provisions.

3.3 INTERNATIONAL INSTRUMENTS AND THE RIGHT TO HEALTH

The United Nations Charter\textsuperscript{31} makes no specific reference to a right to health, but obliges UN member countries to “take action” to achieve universal respect for, and observance, of human rights. The contents of those rights, and the nature of states’ obligations in realising those rights, is set out in more detail elsewhere in international law. The right to health, for example, was already recognised in the WHO constitution and enunciated in UN human rights conventions. While the UN Charter does not specify the content of human

\textsuperscript{30} 14 UNTS 185. The Constitution of the WHO was adopted by the International Health Conference, New York, 19 – 22 June, 1945; Opened for signature on 22 July 1946 by the representatives of 61 states and entered into force on 7 April 1948.

\textsuperscript{31} Charter of the United Nations, 26 June 1945 (entered into force 24 October 1945), TS 67 (1946).
rights norms, it leaves no doubt as to the legally binding nature of member
states' obligations to realise human rights. By way of the charter, UN member
states have agreed to support and fulfil the purposes of the UN. Two of the
UN's four purposes stated in Article 1 of the Charter are:

➢ To achieve international Co-operation in solving international problems of
an economic, social, cultural, or humanitarian character, and in promoting
and encouraging respect for human rights and fundamental freedoms for
all without distinction as to race, sex, language or religion; and
➢ To be a centre for harmonizing the actions of nations in the attainment of
these common ends.

By way of this treaty, UN member states also agreed that they "shall act" in
accordance with a number of principles, including the principle that all
members "shall fulfil in good faith the obligations assumed by them in
accordance with the present charter." The specific legally binding obligations
most relevant to the current discussion regarding the human right to health
are to be found in chapter IX of the Charter: Article 55 state that with a view to
the creation of conditions of stability and well-being which are necessary for
peaceful and friendly relations among nations based on respect for the
principle of equal rights and self-determination of peoples, the UN shall
promote;

---

"32 Un Charter, Article 2."
a. higher standard of living, full employment and conditions of economic and social progress and development;

b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation;

and

c. universal respect for, and observance of human rights and fundamental freedoms for all without distinction as to race, sex, language or religion.

Article 56 states that all members pledge themselves to take joint and separate action in cooperation with the organisation for the achievement of the purposes set forth in Article 55. Thus the references to human rights in both Articles 1 and 55 of the charter establish as legally binding states' obligations to fulfil those rights.33

The Universal Declaration of Human Rights (UDHR), adopted by the UN General Assembly several months after the WTO Constitution came into force, contains three provisions particularly relevant to the current discussion regarding the importance of the right to health in international law: Article 25(1) provides, Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment, sickness, disability,

widowhood, old age or other lack of livelihood in circumstances beyond his control.

(2) motherhood and childhood are entitled to special care and assistance.

All children, whether born in or out of wedlock, shall enjoy the same social protection.

Article 27(1) states that everyone has the **right**...to **share in** scientific advancement and its benefits. In reference to the right to health, this provision entails that every individual should benefit from new inventions that promote living standards for the health and well-being of people rather than the invention being premised on private profit. Further Sub Article (2) provides that everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. Thus there ought to be a meeting point between the patent holder and the public at large so that every person’s rights are fully realised. Article 28 provides that everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realised. Article 28 provides that everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realised.

As a Declaration of the UN General Assembly, the UDHR is not legally binding on states as a treaty.\textsuperscript{34} However, it is now accepted that the UDHR forms part of customary international law, namely those general practices recognised, with substantial uniformity, by states as being required by

\textsuperscript{34} Brownlie, Principles of Public International Law (5\textsuperscript{th} ed, 1998), at pp.14 – 15.
prevailing international law (the existence of an opinio juris). As part of customary international law, the UDHR is legally binding upon all the world's states. Indeed, the Preamble to the Declaration identifies it as "a common standard of achievement for all people and all nations, to the end that every individual and every organ of society....shall strive to secure their universal and effective recognition and observance. As one of its pre-eminent drafters has observed: "Today the bill is binding on all countries, including those which did not approve it in the first place in 1988".  

This is for a simple reason that all human rights are universal, indivisible, interdependent and interrelated. The international community thus must treat human rights globally in a fair and equal manner, on the same footing and with the same emphasis.

Aside from the binding commitment in the UN Charter to promote solutions for international health problems and to achieve the realisation of human rights, and the status of the UNDHR as part of customary international law, the right to health appears, in one form or another, in numerous other international treaties adopted within the UN system. In particular, the International Covenant on Economic, Social and Cultural Rights (ICESCR) elaborates on the general rights stated in the UDHR, including broadly defining a human right to health.

The objective of the ICESCR and the accompanying International Covenant on Civil and Political Rights (ICCPR) was to transform the rights set out in

---

general terms in the UDHR into binding treaty obligations. The ICESCR represents the clearest, fullest articulation, in a legally binding international treaty, of the right to health and the obligations on states to realise that right. The key provision of the ICESCR establishing the human right to health is Article 12: Article 12(1) The states parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

(2) The steps to be taken by the states parties to the present covenant to achieve the full realisation of this right shall include those necessary for:

(a) the provision for the reduction of the still birth – rate and of infant mortality and for the health development of the child;

(b) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

This article shows that the binding nature of the covenant and how important the right to health is to every human being.

However, the binding nature of the ICESCR remains for too remote to be adhered to by many developing countries. The realisation of the right to health under this convention has been undermined as most developing countries treat the rights found in the ICESCR as second generation rights.

and are not guaranteed in their constitutions. In Zambia for instance, the right to health is found in Part 9 of the constitution merely as a directive and is not justiciable. Thus a person who claims the right to health cannot enforce his rights compared with another person claiming civil and political rights.

The African human rights system, under the 1981 African Charter on Human and Peoples' Rights, the states parties have agreed by treaty that "every individual shall have the right to enjoy the best attainable standard of physical and mental health", and that states "shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.\textsuperscript{37} Arguably, this provision entails that it is the duty of every state to come up with laws and other means to ensure that their people have adequate health protection since the right to health is placed at the apex of the pyramid, no law, can stop a nation from protecting the right of health.

The aforementioned international treaties illustrate that they are binding and call on all states parties to promote the human right to health. Furthermore, the UN Charter explicitly and unambiguously states under Article 103 that, "In the event of a conflict between the obligations of the members of the UN under the present charter and their obligations under any other international agreement, their obligations under the present charter shall prevail.

The International Court of Justice has also confirmed that, pursuant to Article 103 of the UN Charter, a state’s obligations under the charter supersede any conflicting obligation under any other international agreement. In the Aerial Incident over Lockerbie Case\(^{38}\) the state of Libya claimed that, under the Montreal Convention for the Suppression of unlawful Acts Against the Safety of Civil Aviation, it was entitled to choose domestic prosecution over extradition of those accused of the airplane bombing in question. However, the ICJ ruled that the UN Charter (Article 25) requires UN member states to carry out the decisions of the Security Council, and this charter obligation prevailed over the provisions of the Montreal Convention. As a result, Libya was legally required to comply with the UN Security Council’s resolution requiring extradition of the accused. This case has nothing to do with the right to health but merely illustrates that the ICJ is in agreement with the provision of the UN Charter (103) that all international laws should comply with the UN Charter.

Furthermore, in the Namibia Case the ICJ further ruled that state action which constitutes a denial of fundamental human rights is a flagrant violation of the purposes and principles of the charter.\(^{39}\)

As has been pointed out, the charter’s preamble is clear about the principal mission that the international community has agreed to uphold. This mission is explicitly based on the respect of the dignity and value of the individual and on the equality of people and nations. The protection, promotion and


\(^{39}\) Namibia Opinion, at 57 (para 131).
fulfilment of human rights and the rights of peoples constitute the primary means of reaching this objective.

The right to health is ultimately the right to life and the right to life sparks the beginning of any given right. Thus a person cannot have a patent right if he or she has no right to life. This in itself is explicit to demonstrate that the right to health is very cardinal and should be given priority over any other right as it is both a core foundation and a lever of any other right that can be imagined in this world.
CHAPTER 4

4.0 INTRODUCTION

This chapter shall illustrate and analyse the relationship between TRIPS and the human right to health. It will also show whether the TRIPS Agreement has made it possible to realise the right to health and to what extent. The chapter will also examine developing countries; options within the TRIPS framework as they are understood after the Doha health Declaration. It then goes to examine ways in which conflicts between intellectual property rights and the human right to health could be resolved under international law.

4.1 TRIPS AND RIGHT TO HEALTH

The link between medical patents and the human right to health has become a subject of central concern at the international level, as exemplified by the debates at the 2001 WTO ministerial conference.\textsuperscript{40} International attention to the issue has focused in large part on the HIV/AIDS crisis and the question of access to drugs for patients in developing countries, which are the most severely affected by the epidemic; over 95% of people living with HIV/AIDS are in developing countries.\textsuperscript{41}

From a legal perspective, two main areas of law are relevant in current debates. First, the question of access to medicines is a central issue in any consideration of the human right to health. Human rights law, in particular through the ICESCR, has made a significant contribution to the codification of the human right to health. Second, debates on access to drugs are now

\textsuperscript{40} Declaration on the TRIPS Agreement and Public Health 2001 (hereafter Dona Health Declaration).

strongly linked to the questions of whether drugs can, and should be patentable. The increasing scope of patentability in the health sector, codified in the TRIPS Agreement, constitutes one of the most significant changes in law for developing countries that are WTO members.

Intellectual Property Law and human rights law have largely evolved independently. However, with the broadening scope of patents in areas related to basic needs such as health, and recent developments in the health sector itself, the links between the two fields are becoming increasingly obvious and direct, necessitating further consideration of the relationship between the right to health and patents on medicines, in particular in the case of developing countries.\textsuperscript{42}

4.2 ACCESS TO DRUGS AND IPRS REGIME

Intellectual Property rights, in particular patents, are deemed to provide the necessary incentives for research and technological development. Patents are time-bound monopoly rights. They constitute a derogation from the principle of free trade by offering exclusive rights to an inventor to exploit the invention and stop others from using it without his/her consent. The rationale for granting patents is the need to reward an inventor. In practice, this translates mainly into a right to commercialise the invention and simultaneously to stop others from doing so. The exception to the free trade rule is balanced by limiting the duration of the right and by forcing the inventor

to disclose the invention so that society at large benefits from scientific advancement.\textsuperscript{43}

Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings. This is in direct contrast to property rights, which can always be ceded in voluntary transactions.\textsuperscript{44} As codified in the two UN covenants and other relevant instruments human rights constitute the basic framework guiding state actions at the domestic and international levels. As a result, states must bear in mind their human rights obligations when they negotiate and implement international rules on intellectual property rights or trade liberalisation.

Access to drugs is one of the fundamental components of the human rights to health. It is of specific importance in the context of the introduction of patents on drugs, because patents have the potential both to improve access, by providing incentives for the development of new drugs, and to restrict access, because of the comparatively higher prices of patented drugs. Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them.\textsuperscript{45} This implies a strong link between lack of access to drugs and poverty. About one-third of the world's population does not have access to basic drugs, a proportion

\textsuperscript{43} Ibid p.140.
which rises above one-half in the most affected regions of Africa and Asia.\textsuperscript{46} The sheer scale of the problem of access to drugs is only too clear in the context of HIV/AIDS. A consortium of international organisations has estimated that fewer that 10 per cent of the people living with HIV/AIDS in developing countries have access to antiretroviral therapy. This proportion goes down to about 0.1 per cent in Africa.\textsuperscript{47}

The TRIPS Agreement that protects IPRS is seen as a hindrance to access to drugs. The TRIPS Agreement is, as its name implies, concerned mainly with the interests of intellectual property rights holders.

Thus in most developing countries, the introduction of process and product patents on drugs through the TRIPS Agreement influences access to drugs to a significant extent. There are abrupt rises in price, impacts on pharmaceutical industries and a greater emphasis on private sector research and development. Together these create a situation where drugs are both less accessible and less affordable. There is therefore a direct link between the patentability of drugs on the one hand and, on the other the availability of medicines, the realisation of the right to health and ultimately the right to life. In other words, it is necessary to analyse closely the relationship between intellectual property rights and the human right to health.

It is also necessary to examine whether intellectual property rights qualify as human rights. The debates of 1948 and 1957 indicate that basic human rights

\textsuperscript{46} Ibid p.7.

\textsuperscript{47} Drug Price Report.
treaties did not intend to recognise the interests of the authors or inventors as fundamental human rights.\textsuperscript{48} Both the UDHR and the ICSECR recognise as a basic claim everyone's right to enjoy the fruits of cultural life and scientific development; the right of the individual author is subsidiary in the balancing of priorities. The implication is that human rights put the emphasis on societal benefits. This approach is opposed to that of intellectual property rights instruments, which focus mainly on the rights of the authors, inventors and other legal entities to claim exclusive rights over an intellectual creation. The question of the balance of rights and obligations is addressed by the TRIPS Agreement, but here the interests of society at large figure more as an addition to – or even an exclusion from the rights provided than as an integral part of the treaty. Human rights treaties require the balance to be attempted from the perspective of society at large.

Overall, there appears to be a substantive difference between intellectual property rights, and the fundamental and universal entitlements called human rights. The former are temporary rights granted by the state that can be revoked and transferred, while the latter are inalienable and timeless.

This show that Intellectual property rights were created for a purpose, and this purpose has however been abused. This abuse leaves the struggle for access to medicine remain a pertinent issue because at least two million people die of AIDS – related illness every year in third world countries.\textsuperscript{49} Of course medicines are not a cure, but medicines prolong life, improve life,


\textsuperscript{49} Justice Cameron's remarks in Durban at a Satellite Conference on Critical Legal Issues and HIV/AIDS.
allow people to work, and allow people to maintain dignity. The greatest tragedy is that whilst there has been a globalisation of medical science, there has not been globalisation in access to medicine. A poor person sitting in a township in Zambia can read about effective medicines on the internet, but has not got a hope of obtaining them. This is a disparity and tragedy of enormous proportions.

In view of the above, the issue of patent protection in the health sector has proved increasingly divisive. This is in part attributable to the fact that there is a significant conflict or tension between the pharmaceutical industry's aim to recoup its investments and governments' interest in containing the costs of health care. On the premise Controversies at the theoretical and practical levels concerning patents on drugs have led to the search for alternatives.

In its search for alternative, South Africa, faced with an alarming increase of HIV cases among its population and prohibitive prices of life saving anti-retroviral drugs, she tabled a Bill in parliament in 1997 to amend the country's Medicines and Related Substances Control Act of 1965 (referred to as Medicines Act)\textsuperscript{50} with a view to giving the country a new drug policy which would facilitate availability of affordable medicines to the majority of south Africans.

The South African government's move was probably inspired by the Brazilian case in which Brazil succeeded in making ant-HIV treatment available to a

\textsuperscript{50} Act No. 1 of 1965.
significant population of HIV-infected people through the use of cheaper generic or non-branded drugs.\textsuperscript{51} Brazil invoked the “national emergency” clause under Article 31 of the TRIPS Agreement of 1994 and managed to manufacture its own antiretroviral drugs. Brazil was challenged by the America government but later America withdrew the case and Brazil continued to provide the population with cheap and affordable antiretrovirals.

Motivated with the Brazilian Spirit, South Africa went ahead with amending her medicines Act. This was met with a lot of aggression and criticism from the leading pharmaceutical companies in South Africa, the US and European governments which saw the amendment of the Bill as a violation of IPRS under the TRIPS Agreement. The South African government was then pressurised to do away with the amended Act.

However the South African government remained firm on its ground and on 31\textsuperscript{st} October, 1997, parliament passed the Bill which was on the 25\textsuperscript{th} of November, 1997, assented to and signed by the then President, Nelson Mandela.\textsuperscript{52} Despite this, the Pharmaceuticals manufacturers’ Association of South Africa (PMA) and 41 pharmaceutical companies placed a law suit to demand the court to invalidate the amendments on account of being unconstitutional and ultra vires the patents Act of South Africa of 1978.

The lawsuit was however withdrawn and to date, it is not known whether the pharmaceuticals companies will ever revive the case.

\textsuperscript{51} Dr. Harrison Mwakyembe, George Mpundu Kanja p.21.
\textsuperscript{52} Ibid p.22.
The South African case is an illustration of the conflict that exists between IPRS and the right to health is reality. There is a serious debate as to which rights should be given priority over the other. Seemingly, the pharmaceutical companies in the first world tend to interpret the TRIPS Agreement strictly in order to give priority to IPRS. On the other hand, developing countries, that mostly do not have pharmaceutical companies demand for a more flexible interpretation of the TRIPS Agreement in order to give priority to the fundamental human right to health. From the point of view of human rights instruments, the relationship between the intellectual property rights system and the realisation of human rights has been given only limited consideration. To date, only scant attention has been given to the relationship between TRIPS and the human right to health. This is due in part to the sectoral nature of international law but also to the unresolved issues raised by potential conflicts between different areas of international law. The general principle remains that developing countries should do their utmost to implement both the human right to health and TRIPS in such a way as to minimise conflicts. However there are situations where conflicts may remain.

4.3 DOHA HEALTH DECLARATION

The conflicts that persisted between IPRS and the right to health led to negotiations for better and flexible interpretation of the TRIPS Agreement. As a result, on 14 November 2001, the Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health (herein after referred to as Doha Health Declaration) was adopted. The value of the
Declaration lies in its clarification of the relationship between the TRIPS Agreement and Public health policies of WTO members and its definition of the flexibility of several relevant provisions of the TRIPS Agreement, in particular with regard to patents.\textsuperscript{53} In addition, the Declaration is evidence that the TRIPS Agreement is not a static instrument laying down international minimum standards of protection exclusively for the benefit of right holders based in the developed countries, but one capable of reconciling intellectual property with national policies, such as in the area of public health, in particular in developing countries.\textsuperscript{54}

In more deeper understanding, the Declaration was designed to foster access to drugs through the intellectual property system. Some of the avenues that developing countries can use within the TRIPS context to foster better access to drugs and the realisation of the right to health in general have been outlined in chapter two. So far, the emphasis has been on finding acceptable interpretations of TRIPS from the point of view of access to drugs rather than the broader relationship between TRIPS and the right to health. This latter line of inquiry must, however, be pursued given that developing countries are obliged to implement TRIPS taking into account the existence of ICESCR and other international treaties.

A number of recent developments at the international level indicate that developing countries can explore different possible interpretations of the TRIPS provisions and decide to act on the margin of TRIPS. This situation

\textsuperscript{54} Ibid p.5.
has been brought about largely by the scale of the HIV/AIDS crisis and the extremely high price of existing medicines used to alleviate the disease. In fact the extent of the crisis has been sufficient to trigger some developing countries like South Africa and Brazil to introduce laws that promote access to HIV/AIDS medicines. Thus the failed challenges to the South African and Brazilian Acts indicate that even if the measures adopted are not strictly complaint with TRIPS, they are unlikely to be challenged again in the near future.

The question of manoeuvre that countries have in implementing TRIPS can be approached first from the perspective of the Doha Declaration. In effect, the Doha Declaration restates and increases the mechanisms that states can use within TRIPS context to foster public health goals. The declaration confirms for instance that member states can interpret their TRIPS obligations in such a way that they contribute to and do not work against their health policies. In other words, it reaffirms the importance of articles 7 and 8 in so far as they provide member states with a clear legal basis in TRIPS for taking measures that may diverge from generally acceptable interpretations of the agreement.

The declaration is important for developing countries in that it strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. The declaration does not open new avenues within TRIPS, but confirms the legitimacy of measures seeking to use to the largest extent

55 Ibid.p.4.
possible, the flexibility already built into the agreement. In other words, it constitutes a confirmation of the position of countries like South Africa and Brazil which sought to go beyond a narrow interpretation of TRIPS in their search for ways to tackle health crises.

While the Doha Declaration has contributed to softening of the tone of international debates concerning access to medicines in the context of TRIPS, it stops short of addressing the most significant issues in this field. Recent debates have focused mainly on the extent to which developing countries should be able to adopt the intellectual property rights situations where major problems have arisen. This does address the question of whether the introduction of process and product patents in all WTO member states is generally reconcilable with the measures states must take to foster the realisation of the right to health.

The declaration also fails to provide answers to more practical questions, such as the prohibition on a country such as India compulsorily licensing a drug mainly to export it to other countries that do not have a manufacturing base of their own. If exports are not permitted in this context, most Sub-Saharan African countries will not be able to take advantage of alternative sources of medicines.\(^\text{57}\) This problem points to one of the major challenges developing countries will face in future. If existing manufacturing capacity in countries like India were to be substantially reduced, this would have an impact not only on India but also on a number of other developing countries.

\(^{57}\) The Journal of World Intellectual Property p.35.
which do not have the capacity to manufacture drugs themselves and would therefore become totally dependent on supplies from developed country manufacturers.\textsuperscript{58}

Since the Doha meeting, there seems to be an international consensus that countries trying to deal with health emergencies will not be questioned in terms of their obligations under TRIPS. This however leaves completely open a number of other issues. As far as Brazil is concerned, while the United States halted the dispute settlement proceedings, it is not all clear whether there is an international consensus that Brazil is free to grant compulsory licences for any reasons related to public health, nutrition, protection of the environment or to the technological or social and economic development of the country.\textsuperscript{59} In the case of South Africa, article 15(a) of the medicines Act provides that patent rights can be overruled in some circumstances.\textsuperscript{60} While the Act entered into force as adopted, it is unclear whether it will be fully implemented and, if so, whether implementation will go unchallenged. The theoretical acceptability of the Brazilian and South African Laws thus does not indicate that all countries are entitled to deviate to such an extent from TRIPS.

From a broader perspective, even if deviation from TRIPS is allowed as an exception in the case of some health emergencies, this remains an unsatisfactory response from the perspective of human rights. It is not possible to distinguish the realisation of the right to health from the eradication

\textsuperscript{58} The Doha Health Declaration has not tackled this problem but required the TRIPS Council to provide a solution within a Limited time frame (Para. 6 of the declaration).
\textsuperscript{59} Yale Journal of International Law, 27 2002 p.365.
of poverty in general or the realisation of the right to food and water. If exemptions are warranted in the case of health, they should be extended to all sectors related to the fulfilment of basic needs.

In other words, the fact developing countries can use loopholes or unclear language in TRIPS to pursue the realisation of the right to health is unsatisfactory in so far as the central concern of health is consistently framed as an exception to a property right. Thus the Doha Declaration on health is inadequate and does not amend the TRIPS Agreement.

From the perspective of the right to health and access to drugs, the TRIPS Agreement needs to be revised to include principles in favour of access to drugs in the main provisions of the agreement rather than as exceptions. Over emphasising the flexibility of interpretation of the TRIPS Agreement does not cure the problems faced with regard to the right to health. Developed countries can still choose to interpret TRIPS narrowly without having regard to developing countries that do not have the manufacturing base. There is, therefore, a need to analyse TRIPS in its present form and examine the extent to which states can fully implement their TRIPS Obligations together with their human rights commitments.
4.4 REDUCING CONFLICTS BETWEEN IPRS AND THE HUMAN RIGHT TO HEALTH

As noted above, there are potential tensions between IPRs and the right to health. In trying to find solutions to the conflicts, it is of paramount importance to set the overall framework that should guide more technical legal analysis. From the narrow perspective of access to medicines, the challenge is to find ways to make sure that existing drugs are available at little or no cost to people who need them. More generally, the central concern that should guide the implementation of all international treaties concerning health directly or indirectly, is the promotion of better health care.

From the standpoint of TRIPS, the question of health can be tackled through some of the exceptions provided in section 5 of the agreement or through the two general qualificatory clauses of articles 7 and 8. This, however, falls short of an adequate resolution of the relationship between TRIPS and human rights. From the point of view of human rights, the interests of the community at large should generally prevail over those of, say, individual authors. This does not imply a rejection of the interests of the author but rather their subordination to broader goals.61

A human rights perspective on health neither entails a rejection of all intellectual property rights in the field of health nor provides another avenue for developing countries to claim preferential treatment. While there is a general divide between developed and developing countries with regard to the

---

61 Philippe Cullet p.156.
issue of drug prices and the development of medicines directly related to developing country diseases, a human rights approach to health is not strictly concerned with the level of economic development of countries. What is more fundamental from a human rights perspective is a focus on the most disadvantaged and marginalized individuals and communities. While human rights are universal entitlement, their effective realisation is to be judged against the level of implementation among the most disadvantaged. The issue is therefore not whether developing countries can afford patent rights in general, but whether the majority of their poor population will benefit. One of the first steps in tackling the problems faced by the most disadvantaged sections of society would be to make sure that all essential medicines remain free from patent protection.

From a practical point of view, patents on medicines in developing countries are fraught with other difficulties. In a number of countries, most people pay for their own health care. Since a large part of the population does not have access to existing drugs today, any price rise tends to limit access for more people.

Therefore, if compliance with TRIPS leads to reduced access to drugs, this might mean a substantive violation of the human right to health as provided for under the ICESCR. States have to take positive measures towards the fulfilment of the right to health.62 The introduction of product patents would be

62 ICESCR (art. 2. para 1.).
construed as a deliberately retrogressive step if no measures are taken to limit the impacts of TRIPS compliance on access to medicines.

In conclusion, the conflicts between IPRS and the human right to health could be resolved by giving preference to public good rather than private profit without totally disregarding the important role play by intellectual property. On the premise intellectual property should not be seen as a barrier to appropriate measures in response to public health concerns.
CHAPTER 5

5.1 SUMMARY

This paper has examined the relationship and conflict that exists between intellectual property rights and the human right to health. The conflict that exists between the two cannot be over emphasised. However the major problem seems to lie on whether either of the rights should be more protected and of so, which one should be more protected than the other. The paper has pointed out that both rights are important but when a conflict arises as there is one at the moment, the human right to health should be given preference over IPRS. Reference has been made to the TRIPS Agreement which purport to promote the right to health. Practical evidence has shown that the purported protection of the right to health is merely theoretical. The provisions of the TRIPS Agreement are interpreted strictly including the general provisions, articles 7 and 8 which allow flexibility in TRIPS implementation. This was exhibited in Canada’s Generic case in which the ICJ rejected a more flexible interpretation of articles 7 and 8 in order to give priority to public interest.

In this paper there has been an emphasis of the human right to health being a fundamental inalienable right which is timeless. To substantiate this, international instruments such as the UN Charter, UDHR and ICESCR have been used to exemplify the importance of the right to health. This therefore, was an indication that IPRS protected by TRIPS are not inalienable rights; they can be taken away from an individual at any time. On the premise, IPRS found in TRIPS should not be over protected so as to deny access to
medicines to a large part of society that needs them. They should be protected up to a point where they do not infringe a person’s right to health.

Having noted that the conflict between the two rights had persisted, the international community sought to minimise this conflict by restating how flexible the TRIPS Agreement is through the Doha Health Declarations which mainly focuses on the general provisions of articles 7 and 8 which developing countries can use side by side with options given in the TRIPS Agreement to realise the right to health. However, the declaration does not do much to resolve the conflict that exists between the human right to health and IPRS. Implicitly, the TRIPS Agreement in its present form does not make it possible to realise the right health at least in practical terms. However, theoretically, the TRIPS Agreement does have beautiful provisions which developing countries can use as options to the realisation of the right to health. But these provisions remain far fetched and remote as long as developed countries do not allow a more flexible interpretation and amendment of certain TRIPS provisions.

5.2 CONCLUSION

TRIPS is without doubt one of the most significant treaties of the late twentieth century. In the field of health, it has had and will have sweeping impacts in most developing countries. One of the complications from an international law point of view is that TRIPS is being applied not in a vacuum but in a context where the right to health is a well-established human right codified in main international human rights treaties.
The introduction of patents on drugs has provoked a significant outcry in a number of developing countries where access to medicines is already abysmally low. The justification offered for the existence of patents as incentives to innovation often do not appear convincing to patents in developing countries, who see that hardly any Research and Development is being invested in diseases specific to those countries. In other cases, such as HIV/AIDS, where drugs to alleviate the condition exist, the prices for these – for all practical purposes, life-saving – drugs have been so high as to render unaffordable for all but the wealthiest in developing countries.

The legal argument concerning the relationship between human right and intellectual property rights, and the practical debates concerning access to drugs in developing countries, both point towards the existence of potential conflicts between the introduction of patents in developing countries and the realisation of the right to health. While states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPS directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health. This appears to be unacceptable under international treaties such as ICESCR, and countries in this situation would be expected to give priority to their human rights obligations. This solution which gives primacy to human rights, is unlikely to meet with the approval of all states and would probably not stand if it came for adjudication in WTO context. It nevertheless seems adequate from a legal and ethical point of view.
5.1 RECOMMENDATIONS

In case of conflict, states should first refer to treaty law, which provides broad rules of interpretation and reviews the question of conflicts between different treaties. At a general level, states must attempt to the maximum extent possible to reconcile all their international obligations, or at least to minimise conflicts, to comply with their duty to implement all their obligations under international law. Thus all provisions in the TRIPS Agreement must be interpreted in the light of its Article 7 and 8, as well as relevant obligations of WTO members under international human rights law.

In other words, simultaneously meeting the different 'commitments under TRIPS and international human rights treaties seems feasible only if states are allowed to adopt broad interpretations of TRIPS. Further, when interpreting the TRIPS Agreement (or any other WTO agreement), the Dispute Settlement Body (including Panels and the Appellate Body) must prefer any reasonable interpretation of the agreement that is consistent with states obligations under international human rights (including their obligation to realise the right to health) over any alternative interpretation that is inconsistent with their obligations.

International law is to a large extent based on the principle that there is no hierarchy between sources of law and different areas of law. However, international law is not free from all forms of hierarchy. First the UN Charter states that it prevails over any other treaty signed by its member states. It is
REFERENCE

BOOKS


JOURNALS


REPORTS/NEWSPAPERS


INTERNET

TREATIES


