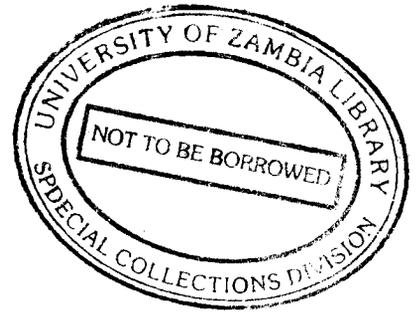


**THE TRIPS AGREEMENT AND ITS EFFECT ON
DEVELOPING COUNTRIES**



BY

JEAN COUNVARAS

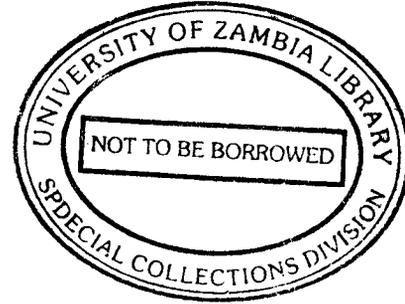
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2008

THE TRIPS AGREEMENT AND ITS EFFECT ON DEVELOPING COUNTRIES.

BY

JEAN COUVARAS



**A DIRECTED RESEARCH SUBMITTED TO THE FACULTY OF LAW OF THE
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**FACULTY OF LAW
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FEBRUARY, 2008.

THE UNIVERSITY OF ZAMBIA
SCHOOL OF LAW

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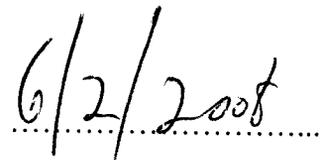
JEAN COUVARAS
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Be accepted for examination. I have checked it carefully and I am satisfied that it fulfils the requirements relating to the format as laid down in the regulations governing Directed Research.


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Supervisor

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DECLARATION

I, **JEAN COUVARAS**, Computer No. **21043779**, do declare that I am the author of this Directed Research Paper Entitled:

THE TRIPS AGREEMENT AND ITS EFFECT ON DEVELOPING COUNTRIES.

And that it is a product of my ingenuity and that due acknowledgment has been given where other scholars' work has been used or cited. I truly believe that this research has not been previously presented in the school for academic work.

Date... 01/02/08

Signed... 

DEDICATION

This work is dedicated unreservedly to the memory of my late father, Mr. Robert Couvaras.

Dad, it's been ten years now since you answered the Lord's call. We have all learnt to deal with our pain and loss, but you left such a big gap in our lives that we do not go a day without thinking about you. I know in my heart that you always look out for me from up there, and I know you also bask in my glory. I wish you were here to see me go through University and encourage me through all these hard years. I will always remember how you believed in my academic capabilities and how you always stood up for me all the time. I miss you so much dad, and I delight in the fact that when I smile at the heavens, you smile right back at me. Rest in peace dad, I know we shall meet someday and our family will be complete again.

ACKNOWLEDGMENTS

A work of this nature could never be the result of merely one mind. It is only through the help and guidance of others, and indeed their support that such a work could be accomplished. Firstly, I am indebted to **God** for all he has done for me in my life. The blessings are too numerous to even remember. Thank you Lord for everything.

I would also like to thank my supervisor for his support and guidance throughout my work. He made such an arduous task a lot easier with his patience and constructive criticism. Thank you so much **Mr. Kahn-Fogel**.

I would also love to express my thanks to my family who have been so supportive through out my stay at UNZA. **Mum**, you are the greatest, thank you for all the sacrifices and the support. **Joy, Cindy, Nancy, Hazy and the two Jimmys**: thanks for everything. I owe you guys so much.

Muzi and Themba. I wouldn't even know where to start. Themba sonny, you are the light of my life. Everyday I pray to God and thank him for you. This one is for you. Muzi, thanks for everything and for being there for me always. You are a *God-send* baby and I love you so much. For my many aunties and uncles, grannies, nieces, nephews and the others, thank you all for everything.

For my friends **Lwiindi, Eddie, Chile, Tiwo, Justina, Moono, Chabula** and the others. Life wouldn't be the same without you guys. When I want to laugh, I always know who to call. Thank you guys, you rock! Ba Lwiindi, lets finish this round and then we can have our hard-earned celebration. You know how we do it!

ABSTRACT

The TRIPS Agreement is an Agreement that came into force in 1995 and it regulates intellectual property rights with specific regard to trade in goods. This Agreement was argued for forcefully by developing countries in order to prevent piracy in goods as well as counterfeiting. This research will basically attempt to analyze the impact the Agreement has had so far on developing countries and their prospects for development. It will also attempt to analyze whether the alleged benefits of the TRIPS Agreement have so far been realized and the options available for developing countries to fulfil their development prospects.

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CHAPTER ONE

International Law is an area of the law in which countries and international institutions agree to relate to each other and co-operate with each other in certain aspects and with regard to a specific subject matter. This is usually done through treaties and custom and is essentially based on the consent of the parties to be bound by the terms of the Agreement or custom. In the area of intellectual property law, it is even more important for nations to co-operate especially as intellectual property rights have a large bearing on trade.

1.0 BACKGROUND TO THE TRIPS AGREEMENT

The Agreement on the Trade Related Aspects of Intellectual Property (hereinafter referred to as the TRIPS Agreement), was a result of seven years of negotiations – from September 1986 to December 1993, as part of the Uruguay Round of Multilateral Trade Negotiations of the General Agreement on Trade and Tariffs (hereinafter referred to as GATT). These negotiations were launched at Punta Del Este, Uruguay and formally concluded at Marrakech, Morocco, along with other negotiations of the Uruguay Round.

Interestingly, the link between trade negotiations and intellectual property rights (hereinafter referred to as IPRs) dates back to the nineteenth century¹. Prior to the TRIPS Agreement, there were other agreements which sought to protect IPRs on an international scale and with regard to trade.

¹ Watal, J (2000) : **intellectual property rights in the WTO and developing countries**

1.1 GATT And IPRs

Prior to the Uruguay Round, international trade rules, as incorporated in GATT, 1947, essentially governed trade in goods. Before the TRIPS Agreement, there were only limited and marginal references to IPRs in international trade law, in so far as they impinged on trade in goods.

Article XX of GATT deals with the circumstances under which contracting parties can legitimately make exceptions to the application of GATT rules. Article XX(d) permits GATT members to *'adopt or enforce measures necessary to secure compliances with laws or regulations which are not inconsistent with the provisions of this agreement, including those relating to the protection of patents, trademarks and copyrights, and the prevention of deceptive practices'*. Similarly, article IX of GATT encourages contracting parties to co-operate with each other with a view to preventing the use of trade names in such a manner as to misrepresent the true origin of the product.

Thus while GATT allowed the protection of IPRs as a legitimate exception to its rules and encouraged co-operation on trade names, it did not mandate such protection.

In 1973, with the increase in the production and international exchange of counterfeit goods, developed countries, representing the interests of famous brands, sought disciplines in this area. Preparations by developed countries for introducing an anti-counterfeiting code into GATT disciplines began in earnest during the latter part of the Tokyo Round of 1973. The objective was to agree on border measures for the interception and eventual destruction of such goods outside

the channels of commerce. However, no Agreement could be reached as only the US and the EC supported it².

1.12 WIPO AND ITS CONVENTIONS

The World Intellectual Property Organisation (hereinafter referred to as WIPO) is a specialized agency of the United Nation that deals with IPRs. It administers inter alia two of the oldest IPR treaties, the Paris Convention for the Protection of Industrial Property (hereinafter referred to as the Paris Convention) and the Berne Convention for the Protection of literary and Artistic Works (hereinafter referred to as Berne Convention). These cover two important branches of IPRs, which are, Industrial Property and Copyright.

At the time of the preparations for a new Round in GATT, the standards under the Berne Convention on Copyright were considered to be quite high by the US, which was still not a member of the convention³.

The Paris Convention, on the other hand was considered to be weak by the US. This convention principally mandates national treatment, meaning the same treatment for foreign and local applicants, and the recognition of a grace period, also called priority rights, for filing of industrial property applications. Otherwise, member countries are more or less free to determine standards of protection for industrial property, more particularly for patents, such as subject matter to be protected, term of protection or even exceptions with some limited restrictions on compulsory licenses. No WIPO treaty contained any effective dispute settlement provisions for challenging their non-implementation by member countries.

² Watal, J (2000): **intellectual property rights in the WTO and developing countries**

³ *ibid*

The reason for the long-standing interest in trans-border co-ordination of the legislation and enforcement of IPRs stemmed from the realization that patent protection or copyright protection restricted within national borders had little effect in preventing imitations or copying abroad, unless similar protection is offered by other countries.

Business interests in developed countries were concerned about the developing countries earlier attempts to weaken international protection of Industrial Property in WIPO. Since 1974, developing countries had been trying to further lower the standards of Industrial property applicable to them, albeit unsuccessfully. In the face of the rampant increase in counterfeiting and piracy, the developed countries felt the need to embrace an internationally stronger IPR regime. It is against this background that the Intellectual Property Committee (IPC) founded in March 1986, dominated by the US research-based Industry, forcefully engineered an agreement to that effect⁴.

An important goal on launching a new Round of trade negotiations was the effective integration of developing countries, which were becoming increasingly more competitive in both traditional and high technology products into the multilateral trading system⁵.

In all the seven years of the negotiations, the developing countries were split in their opinions, although most were reluctant to concede to most of the proposed terms.

⁴ Khor, M (2002): **Rethinking IPRs and TRIPS**

⁵ Khor, M (2005): **Intellectual property rights, competition and development.**

In spite of all these mixed ideas and opinions, the final text was drafted and concluded by 1994.

The arguments against TRIPS were dispelled by the alleged benefits that would accrue to developing countries if the Agreement was passed. These included technology transfer, furthering local Research and Development and the promotion foreign direct investment.

The TRIPS Agreement is the most comprehensive international agreement on intellectual property to date. This is not only because of the breadth of the subject matter covered but also on account of its near universal applicability. When fully implemented, the Agreement will unambiguously strengthen protection of IPRs almost worldwide, a feat not achieved by any single international treaty up to date⁶.

The TRIPS Agreement covers all major IPRs, including some new areas and rights not before addressed by international law. Its implementation will necessitate changes in the IPR laws of all WTO members⁷.

Undoubtedly, however, the more important changes are those in the relevant laws, regulations and procedures of developing countries, where many sectors of economic and social activity such as agriculture, health, education and culture may be affected⁸.

Some of the changes introduced by the TRIPS Agreement include the 20 year patent protection for inventions, availability of patents for all inventions in all fields of technology, granting of patents for life-forms and extending copyright protection to computer programs.

⁶ Watal, J (2002): **Implementing the TRIPS Agreement.**

⁷ E.g S 27 (3) (b) on patenting of life-forms

⁸ Correa, C (1998): **Options for implementing the TRIPS Agreement in developing countries.**

1.2 OBJECTIVES OF THE STUDY

The purpose of this study is to analyze the TRIPS Agreement in detail and relate it to the development prospects of the developing nations. The study will try to answer the following two questions:

1. Are the perceived benefits of the TRIPS agreement being realized?
2. Is the TRIPS Agreement at variance with other international instruments such as the Convention on Biological Diversity (CBD) and the International Covenant for Economic Social and Cultural Rights?

1.3 METHODOLOGY

This research involves the use of both primary and secondary sources of data.

Primary sources will include statutes (both national & international) as well as case law.

Secondary sources will include commentaries, text books and law journals.

In aspiring to be scientific, the research will cover data that may be verified by referring to texts of other authors.

The research will mostly involve desk research from written texts and references to the Agreement in question.

1.4 CHAPTER OUTLINE

Having discussed the background to the TRIPS Agreement, the second chapter will discuss how the TRIPS Agreement and its patent terms have affected the health sector in developing countries.

The third chapter will focus on the relationships between the TRIPS Agreement and the Convention on Biological diversity as well as traditional knowledge.

The fourth chapter will discuss the flexibilities in the TRIPS Agreement with emphasis on the Doha declaration of 2001 and its effect on the pharmaceutical and health sector.

Chapter five will discuss the conclusions reached from the research done, including lessons learnt by developing countries as well as the way forward viz a viz the TRIPS Agreement.

CHAPTER TWO

2.0 TRIPS AND THE HEALTH SECTOR

The TRIPS Agreement has introduced a new and important framework for IPRs, which in turn, has important implications for the health sector. In this regard, these implications will be analyzed under different headings in tying the link between the public's right to good health and intellectual property rights. Of utmost importance in this analysis is the role of pharmaceutical companies in the public health sector and as beneficiaries of IPRs.

2.1 TRIPS ON MEDICAL PATENTS

The TRIPS Agreement sets out detailed obligations in respect of the protection of inventions including⁹:

- To recognize patents for inventions in all fields of technology, with limited exceptions.¹⁰
- Not to discriminate with respect to the availability or enjoyment of patent rights.
- To grant patent rights for at least twenty years from the date of application.
- To limited the scope of exceptions to patent rights and to grant compulsory licenses only under certain conditions. And

⁹ Third World Network (2003): **Manual in good practices in public health sensitive policy measures and patent laws.**

¹⁰ Article 27 (1) of the TRIPS Agreement

- To effectively enforce patent rights.

The TRIPS Agreement, however, does not establish a uniform international law, or even uniform legal requirements. WTO member countries are merely obliged to comply with the minimum standards of the TRIPS Agreement. The tendency has naturally been for developed countries to set even higher standards than those imposed by the TRIPS agreement.¹¹

Literally interpreted, article 27 (1) of the agreement does not permit exclusion from patentability of medicines in general, or arguably, of specific groups thereof. Prior to this agreement, the national legislation in most developing countries did not provide patent protection for pharmaceutical products. This enabled developing countries like Argentina, China, India, Korea and Mexico to have a strong vertical integrated pharmaceutical industry. India's pharmaceutical industry, for instance, had grown by 20% before the change in patent laws¹².

However, this is no longer possible. In light of article 27, patents should be available for any invention, whether process or product, in all fields of technology, provided the standard criteria for patentability, namely novelty, non-obviousness and industrial applicability, are met.

This means that all these countries have now had to change their national legislation on patent in accordance with the TRIPS Agreement. This will have an impact in many developing countries which have depended on previously existing patent laws which were favourable to domestic producers, allowing free competition and thereby reducing the prices of essential drugs. With

¹¹ Correa, C (2002): **Integrating Public Health Concerns in Patent Legislation in Developing Countries**

¹² *ibid*

the TRIPS Agreement in place, such competitive opportunities will be restricted after the phase-in period. Developed countries argued that patent protection in all fields of technology as provided in article 27 would have three major effects in developing countries¹³:

- i. there would be more foreign-direct investment (FDI)
- ii. it would promote transfer of technology
- iii. patent protection would promote local Research and development (R&D)

Generally speaking, a patentee acquires the exclusive right, enforceable at law, to decide who shall, and who shall not, exploit his patented invention. Article 28 of the TRIPS agreement provides that where the subject matter of a patent is a product, the owner shall have the exclusive right *'to prevent third parties not having the owner's consent from acts of making, using, offering for sale, selling or importing'* that product. When the subject matter is a process, the owners is granted the exclusive right *'to prevent third parties not having the owner's consent from the acts of using, offering for sale, selling or importing products directly obtaining from that process.'*

In light of these provisions, one can clearly see that the patent holder has a monopoly over their invention till the patent expires. This entails that they can control the quantities of the product in the country, influence its price and thereby affect the economy of the country. This obviously leads to restrictive competition in the country due to the resultant monopolies.

¹³ Khor, M (2000): **Rethinking IPRs and TRIPS**

The patent system of intellectual property rights denies rights to local and indigenous knowledge, practices and innovations. It however, does allow the patenting of life-forms¹⁴. It has been argued by some authors especially of the Third World Network that this would lead to erosion of traditional knowledge (which is the subject of the next chapter). Inventors are now left free to patent genes, genes sequences, and basic techniques of recombinant DNA and plant varieties. There has been some outcry by some people who feel this is immoral. Torpuz¹⁵, for instance, reiterates a lot of writers' demand for the banning of patenting of life-forms. She alleges, *'nobody can own what exist in nature. We have created nothing and so we can in no way claim to be owners of what does not belong to...'*

In light of the TRIPS Agreement therefore, pharmaceutical companies can brand their products and patent them without any restrictions imposed. Patents on pharmaceuticals have been justified as a critical pre-condition for investment in pharmaceutical research and in the development of new drugs. The importance of patents in this sector is attributed to the high up-front costs of developing pharmaceutical products and the ease with which commercial quantities of products can be produced¹⁶. Proponents of stronger patent protection argue that a majority of innovations in the pharmaceutical industry would not have been available to consumers in a world without patents.

They argue that patents protection offers pharmaceutical companies a chance to recoup the vast amounts of money used in research and tests on the products or processes.

¹⁴ Article 27 (3) (B)

¹⁵ Corpuz-Tauli (2003): **Bio-diversity, Traditional Knowledge and Rights of Indigenous People**

¹⁶ Kanja, G (2002): **Implications of the TRIPS Agreement**

2.20 IPRs AND THE HUMAN RIGHT TO HEALTH

The link between medical patents and the right to health has become a subject of central concern at the international level.

From a legal perspective, two main areas of law are relevant in this debate. First, the question of access to medicine is a central question in any consideration of the human right to health. Human right law, in particular through the Convention on Economic Social and Cultural rights (here-in after referred to as the ICESCR)¹⁷ has made a significant contribution to the codification of the human right to health and our understanding of its scope.

Secondly, debates on access to drugs are now strongly linked to the question 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 the law for the 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 the area related to basic needs such as health, and recent developments in the health sector itself, the links between the two fields are increasingly becoming obvious and direct, necessitating further consideration of the relationship between the right to health and patents in medicines, in particular, in the case of developing countries. While human rights documents have given some consideration to the position of IPRs in relation to human rights, there have been no similar efforts in the field of intellectual property.

¹⁷ UN (1966): ICESCR

2.21 THE HUMAN RIGHT TO HEALTH

The importance of a healthy life has generally been acknowledged at both international and national levels. One of the most detailed pronouncements of this right is to be found in the ICESCR which recognizes everyone's right to the enjoyment of the highest attainable standards of physical and mental health. The right to health implies, like other economic and social rights, obligations to respect protect and fulfill 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 realization of the right.

It is symptomatic that the Committee on economic social and cultural rights has indicated in its authoritative interpretation¹⁸ of the right to health that states have an obligation to facilitate access to essential health services when required. In the case of primary health care, this includes the promotion of a safe and adequate supply of water and basic sanitation, proper nutrition, immunization against the major infectious diseases, appropriate treatment of common diseases and injuries, and the provision of essential drugs.

Following the adoption of TRIPS, UN human rights bodies have progressively given more attention to the question of the impact of IPRs on the realization of the public's right to good health. Among other political organs, the sub-commission on human rights has adopted, for

¹⁸ General Comment 14

instance, a resolution in 2001 which recognizes the existence of potential conflicts between the implementation of TRIPS and the implementation of economic social and cultural rights¹⁹.

2.3 ACCESS TO DRUGS AND MEDICAL PATENTS

Access to drugs is one of the most fundamental components of the human right 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. This implies a strong link between lack of access to drugs and poverty. Since price is a major issue in access, it is significant that patented drugs are more expensive than generic drugs. The links among patents, the price of medicines and access to drugs, therefore, has to be taken into account by various countries in developing their legal and policy framework in the health sector²⁰.

2.4 THE TRIPS AGREEMENT AND ACCESS TO DRUGS

The TRIPS agreement has significant impacts beyond the trade and intellectual realm. However, the linkages among intellectual property, environmental management human rights have not taken much prominence in the WTO framework. TRIPS, as already noticed will inevitably have significant impact on the realization of fundamental human rights such as the right to food and

¹⁹ Resolution 2001/21: Intellectual Property Rights and Human Rights. UN Sub-commission on Human Rights. UNC Doc. E/CN. 4/Sub. 2/Res/2001/21 (2001).

²⁰ Phillip cullet (2001): **patents and medicines: the relationship between TRIPS and the human rights to health.**

health in developing countries. As far as health is concerned, TRIPS will be an important agent of change in the health sector, especially in countries which previously rejected product and/or process patents on drugs, indeed, the introduction of such patents in the pharmaceutical sector implies a fundamental change of orientation for countries like Brazil and India where no patents were available in this field prior to the Uruguay Round.

In most developing countries, the introduction of process and product patents for drugs is likely to influence access to drugs to a significant extent. There will be abrupt rises in prices, impacts on local pharmaceuticals and industries and a greater emphasis on private research and development. Further, these are likely to create a situation where drugs become less accessible and less affordable. There is therefore, a direct link between the patentability of drugs on one hand, and on the other hand, the availability of medicines, the realization of the health, ultimately, of the right to life²¹.

It ought to be stated here that some effects of the TRIPS Agreement are already being felt in most developing countries in the health sector. Striking a balance between the protection of pharmaceutical patents, on the one hand, and the supply of effective and affordable medicines and people's access to such medicines and treatment, on the other hand, has become controversial between developed countries and the developing countries, especially in the wake of the AIDS pandemic that has put the spotlight on the issue of affordability of essential medicines.

²¹ Cullet, P (2001): **patents and medicines. The relationship between TRIPS and the human right to health.**

A number of recent events have illustrated the effects the TRIPS agreement has had on health policies. In this respect, the landmark case of the Pharmaceutical Companies and the South African government is an outstanding example. In this case, the government of South Africa faced with an alarming increase of HIV cases among its population and the prohibitive prices of life-saving anti-retroviral drugs, tabled a bill in parliament in 1977 to amend the country's Medicines and Related Substances Control Act with a view to giving the country a new drug policy which would facilitate the availability of medicines to the majority of South Africans. By the year 2001, South Africa had over four million people infected with HIV/AIDS and more than 40,000 had already died of opportunity diseases²².

The move by the South African government was looked at with concern not only by leading pharmaceutical companies within and outside South Africa, but also the US and European governments who saw the Bill as a blatant violation of IPRs under both domestic law and international law. The Bill, in spite of the pressures put on the South African government was enacted into law on 25 November, 1997 after the assent of the then president, Nelson Mandela. The Bill substantially empowered the Minister of Health in certain circumstances so as to protect public health to prescribe conditions to increase accessibility of essential drugs. Such measures would include parallel importing and the granting of compulsory licenses. The issue of compensation was, however, not addressed by the amended Act. Inevitably, the pharmaceutical companies sued the government before the Act came into force alleging that the new Act violated provisions of the Patents Act, which was TRIPS compliant. The case was, however, withdrawn by the pharmaceutical companies before judgment could be passed. Scholars have

²² Kanja, G (2003): **implications of the TRIPS agreement on access to cheaper pharmaceutical drugs by developing countries.**

naturally speculated about what the outcome of the case would have been had the court passed judgment on the case. The DOHA Declaration does give an insight into the possible outcome of this case and this will be analyzed in a later Chapter.

A similar situation arose in Brazil earlier than the South Africa case. The Brazilian government also faced with a high death rate due to the AIDS pandemic revoked a patent for an anti-retroviral drug which was sold by the manufacturing pharmaceutical at a very high price. After failed negotiations with the pharmaceutical company on reducing the price of the drug, the government sought to have the drug manufactured by World Health Organization certified laboratories in India. Inevitably, there was an outcry from the pharmaceutical industries who were contending that the move by the Brazilian government would discourage investors from coming to the area. The government, however, justified its actions on public health grounds. Suffice to note that since then, the death rate in Brazil relating to HIV/AIDS infections has reduced by almost 50% and the price of drugs for HIV/AIDS have reduced by 72%²³.

These two cases illustrate the conflicts that would inevitably arise in balancing IPRs with public health concerns. As Yolanda Taylor²⁴ correctly points out, the impact of patents on access to drugs, especially anti-retroviral is a serious challenge to policy makers. The Universal Declaration on Human Rights (UDHR) affirms a people's right to health.

²³ Kanja, G (2002): Implication of the TRIPS agreement.

²⁴ Taylor, Y (2004): Battling HIV/AIDS

However, this right is difficult to achieve in light of these patents on drugs and their high prices. Millions of people are dying in developing countries due to the high cost of these medicines imposed by pharmaceutical companies. How, one may ask, would you reconcile the aims of intellectual property, which provide for incentives by restricting the use of protected products or processes, thereby, guaranteeing extra-ordinary gains, with society's interest in allowing the maximum use of knowledge through low prices, in ensuring diffusion and in facilitating continuous improvement of innovation?

It ought to be stated that health concerns affect all nation; developed and developing alike. In the South African case, for instance, South Africa was faced with the dilemma of which of the two interests should prevail: the egoistic and private interests of the pharmaceutical industry, or people's lives and public interest. When they chose the latter, they came under heavy criticism from the developed countries for not complying with the TRIPS agreement.

On the contrary, in the wake of the anthrax outbreak in the United States in October, 2001, the pharmaceutical protection came under threat from the US and Canada. The US government demanded 100 million tablets from the manufacturer, Bayer, at half the usual price. Otherwise, it had threatened to over-ride the patent²⁵.

From these cases, one can note that the TRIPS agreement would lead to conflicts of obligations on WTO member states as regards the ICESCR and the TRIPS itself.

²⁵ Kanja, G (2002): **Implications of the TRIPS Agreement on access to pharmaceutical drugs by developing countries.**

The protection of public health is one of the most pressing issues in developing countries.

A large part of the world population still lacks access to essential drugs; in the poorest parts of Africa, for instance, over 50% of the population lacks that access. An estimated 1.5 billion people are not expected to survive to the age of 60, and more than 880 million people lack access to health care. Of the 33 million HIV positive people in the world 95% live in developing countries, and most of them cannot afford the necessary medication. Issues of national health policy, pharmaceutical policy and patent policy are interlinked and none of these policies can be framed or implemented in isolation²⁶.

From this detailed analysis of the relationship between TRIPS and the right to health, one can clearly see that policy makers have to tread a thin line in balancing the two competing interests. Both interests have to be protected obviously, but the level of protection has to differ on a case by case basis and this will obviously reflect the government policy behind the decision. It has been noted that developed countries tend to have a stronger IPR regime than developing countries. However, in both types of states, the two interests clash at some point and the policy makers have to decide which interest will prevail over the other.

²⁶ Correa, C (2000): **integrated public health concerns into patent legislation in developing countries.**

CHAPTER THREE

The TRIPS Agreement has important ramifications for developing countries as regards its biological diversity as well as its traditional knowledge. This Chapter will attempt to analyze the TRIPS Agreement and its impact on the environment, especially regarding article 27 3 (b). Traditional knowledge is now widely recognized as having played and as still playing crucial roles in economic, social and cultural life and development, not only in traditional societies, but also in modern societies. Traditional knowledge is also strongly linked to the Convention on Biological Diversity.

3.0 TRADITIONAL KNOWLEDGE, GENETIC RESOURCES AND PATENTS

Traditional knowledge refers typically to practices in farming and agriculture that have been devised and refined over long periods of time and can be clearly attributed to human actions. Genetic resources, on the other hand, are not the product of human invention or creativity but are typically found in nature²⁷. The real importance of genetic resources lies in the encoded genetic information that is proving to be valuable in developing medicines and pharmaceutical products to cure human diseases and for raising agricultural productivity. Traditional knowledge is an expression of culture which represents living, functional traditions, rather than souvenirs of the past. It ought to be noted that it is not restricted to agriculture only, but extends to all practices and customs common to a people.

²⁷ Subramanian (2002): **Proprietary protection on Genetic resources and traditional knowledge**

Human communities have always generated, refined and passed on traditional knowledge from generation to generation. Such traditional knowledge is often an important part of a people's cultural identity. In developing countries, up to 80 percent of the population depends on traditional medicines to help meet their health care needs²⁸. The contributions of traditional knowledge to human development, especially in food production; crop yields and health care are widely recognized in developing countries and the world over.

The recent increase in awareness of the value of biological diversity (and the need for its conservation and sustainable use, for present and future agriculture and provision of health care) has highlighted the role and critical importance of traditional knowledge. There has been a huge outcry from environmentalists on the need to save the ozone layer, the need to preserve our forests and wild animals, and the all important need to preserve our soil fertility by avoiding the over-use of chemicals on it²⁹.

Biological diversity consists of our plants and animals naturally occurring in nature and it is these which are in danger of extinction should destructive methods continue to exist. It is only through the conservative use of the existing resources that the coming generations can be assured of a fulfilling life on earth. Traditional knowledge is generated from biological diversity. It is this biological diversity from which all the important traditional knowledge necessary for the very livelihood of the community is generated.

The knowledge of local communities, farmers and indigenous peoples on how to use the many forms and types of biological resources and for many functions, as well as on how to conserve

²⁸ WHO Fact Sheet No. 271. June, 2002

²⁹ Correa, CL: (2002): **Protection and promotion of traditional medicines**

these resources, is now recognized as being a precious resource that is critical to the future development, and even survival, of human kind. This knowledge is intricately tied to the very livelihood of the people and it is thus important to recognize these people's right to this knowledge, its use and the products arising from it. The misappropriation of their resources would not only violate their rights, but would also adversely affect the conservation and use of knowledge and of biological diversity.

The contribution of traditional knowledge to the modern economy, especially the agricultural sector, the innovation and development of new drugs, are large. According to a report by RAFI, 80 percent of the world's population relies on indigenous knowledge for their medical needs and about two thirds of the world's people depend on foods provided through indigenous knowledge of plants, animals, insects, microbes and farming system. More than two thirds of the world's plants species (of which at least 35,000 are estimated to have medicinal value) come from developing countries³⁰.

As Khor further observed, the developing countries are the most blessed in terms of biological diversity and traditional knowledge. South America is richly blessed with an expanse of forests and wild animals most of which have proved useful to cure some diseases. In Africa too, most nations are richly forested with fertile soils and expansive resources. The developed countries are however more technologically advanced and are in a better position to exploit any available resources³¹. Ironically, however, very few developed countries are rich in biological diversity.

³⁰ Martin Khor (2002): **Intellectual Property, Biological Diversity, and Sustainable Development**

³¹ Watal, J (2002): **Implementing the TRIPS agreement**

This has led to the phenomenon of bio-piracy which will be discussed in detail in the next few pages.

Due to the very nature of traditional knowledge and biological diversity, protection under patent law is impossible for the local communities. It is, however, widely accepted that traditional knowledge has to be protected from misappropriation. This is due to the many benefits that local communities derive from them. Biological diversity is said to have important ecological functions that sustain plant and human life. Biological diversity provides a variety of services: protecting watersheds, regulating local climates, maintaining atmospheric quality, absorbing pollutants and generating and maintaining soils, among others³².

Under patent law, for any product to qualify for patent protection, it must fulfill the following conditions:

- i. it must be novel
- ii. it must involve an inventive step (non-obviousness)
- iii. it must be capable of industrial application and
- iv. it must fall within patentable subject matter.

Traditional knowledge obviously falls short on the first requirement as it is of general knowledge in the community. Naturally occurring products are also usually not the subject matter of

³² CIPR (2002): *Integrating IPRs and development policy*.

patentability³³. Protection therefore, has to be sought elsewhere and not under patent law or TRIPS.

3.1 THE PHENOMENON OF BIO-PIRACY

The relationship between IPRs and biological diversity emanates from the concept of bio-prospecting. There is no accepted definition of 'bio-piracy' so far. The Action Group on Erosion, Technology and Concentration (ETC group) defines it as 'the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually plants or plant breeder's rights) over these resources and knowledge³⁴. Jayashree, on the other hand, defines it as the systematic search for, and the development of new sources of chemical compounds, genes, micro and macro organisms and other valuable biological products. Bio-prospecting is based on tradition knowledge³⁵.

Resource-based industries have found it profitable to screen natural resources such as soil samples, marine waters, insects, tropical plants and genes in developing countries. There have been a number of documented cases in which traditional knowledge is being patented after being obtained by institutions from developed countries whiles in developing countries.

These include:

³³ Kanja, G (2006): **Intellectual Property Law**

³⁴ CIPR (2002): **Integrating IPRs and development policy**

³⁵ Jayasree, W (2000): **Intellectual property rights in the WTO and developing countries.**

i. **The Turmeric case**³⁶

Turmeric is a plant of the ginger family which yields rhizomes used as a spice for flavoring Indian cooking. It also has medicinal properties and can be used in cosmetics and colour dyes. In 1995, two Indian studying at the University of Mississippi Medicinal Centre were granted patent number 5,401,504, on use of turmeric in wound healing. The Indian Council of Scientific and Industrial research requested the patent office to re-examine the patent on grounds of lack of novelty as it had been used since time immemorial within the Indian community, and they succeeded as this had all been documented. This was a landmark case as it was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged.

ii. **The Neem case**³⁷

Neem is a tree from India and other parts of Asia. It has medicinal pesticide and fertilizer properties. In 1994, a US corporation was granted a patent in Europe; No. 0436257. Neem extracts had been used in India over the years against hundreds of pests and fungal diseases that attack food crops; it had been used to treat colds and flues and even some skin diseases. The patent was revoked in 2000 by the European Patent Office after a challenge by some Non-governmental Organizations on grounds of lack of novelty.

iii. **The Ayahuasca case**³⁸

The Shamans of the Amazon basin has for generations been producing a ceremonial drink called ‘ayahuasca’ from the bark of *Banisteriopsis caapi*. They used it in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits and divine the future. In 1986, an American obtained a US patent No. 5,751 claiming it was a distinct version of the caapi species because of its flower color. Efforts to have the patent revoked on grounds of lack of novelty were however, unsuccessful.

iv. **The Hoodia Cactus**³⁹

The San from the Kalahari Desert in Botswana, have traditionally eaten the Hoodia Cactus to stave off hunger and thirst on long hunting trips. In 1995, CISR patented Hoodia’s appetite- suppressing element and licensed it to Phytopharm, and later to Pfizer. It was patented as a potential slimming drug. On hearing this, the San people threatened legal action for ‘theft’ of their traditional knowledge and that CISR had failed to comply with rules of the Convention on Biological Diversity. By 2002, an understanding had been reached between the San and CISR, by which the San were to receive a share of any future royalties.

These are but some of the documented cases on misappropriation of traditional knowledge for private gain. Today, at least, a quarter of the known medicines are based upon or derived from plants, and about three quarters of these have the same or similar use by native cultures. The link to the IPRs arises from the fact that in many

³⁸ *ibid*

³⁹ *ibid*

instances, bio-prospectors or their licensees are granted patent rights over the final products, without any knowledge of the contribution of countries of origin or of the indigenous communities. The appropriation by companies or institutions of local communities' knowledge on biological diversity use transforms the rights of the communities (in most cases located in developing countries) into the private and monopoly rights of these institutions (in most cases located in the developed countries)⁴⁰.

The situation is made even more ironic if the patented process is even sold at high prices to the developing countries, including those very countries from which the traditional knowledge originated. This leads to a reverse form of technology transfer as opposed to the one envisaged by the TRIPS Agreement in articles 8 and 32.

It has thus been imperative that the traditional knowledge of local communities be protected against any misappropriation. Developing countries face a challenge in achieving this end as the realm of Intellectual property offers little, if any, help. It is thus left to the communities to be overly alert and be protective of their indigenous knowledge.

3.2 ARTICLE 27(3) (b) AND ITS IMPACT ON AGRICULTURE

The importance of agriculture the world over cannot be over emphasized. It is a source of income, employment and even foreign exchange for any agricultural country. A productive and sustainable agricultural sector is critical to achieving economic growth and poverty reduction in

⁴⁰ Khor, M (2002): **Intellectual Property, Bio-diversity and Sustainable Development.**

developing countries. Historically, IPRs did not apply to living things but this is no longer the case.

Article 27.3 (b) states: '*Members may also exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological processes.*' Thus it appears that WTO member countries have to allow patents for certain types of life-forms and living processes. Case law however, clearly indicates that patent extends to artificially produced life-forms, and not those that are naturally occurring. In the **Chakrabarty**⁴¹ case, the US Supreme Court allowed the patenting of an artificially created bacterium which was obtained by genetic alteration. This bacterium was also useful in clearing up oil spills. The Court in this case did observe the boundary line between the discovery of a naturally occurring life form which is not patentable (as was the case in the **Kalo Inoculant** case⁴²), and the creation of a new life-form.

Another illustrative case is the **Harvard Onco Mouse** case⁴³. This case involved the creation of a transgenic mouse which was particularly susceptible to cancer and was useful in helping to find the cure for cancer. The European Patent Office initially rejected the request for a patent on the ground that it was essentially a life-form and not the proper subject matter for patents. The Technical Board of Appeal reversed this decision and concluded that the mouse was not an animal variety as such, but a non-human mammal. The patent was thus granted.

447 US 303 (US Supreme Court): 1980 LEXIS 112 (1980)

333 US 127, 130 (1948)

T 19/90 (1990) O.JEPO 476, Tech Bd App.: (1990) E.P.O.R 525, EX. D.

is quiet clear from the cases above that patent protection will obviously extend to life-forms as long as they are artificially created. This is more especially where they are useful to humans and do not cause unnecessary pain to the animals involved. Artificially created plant varieties are also patented. Most countries that have established plant breeders ' rights have joined UPOV (International Union for the Protection of New Varieties of plants) which has a convention aimed at granting exclusive intellectual property rights to breeders of new plant varieties. If one patents a seed, it means farmers may buy that seed, but cannot save and use it. There is currently a great patent race for genes and other biological substances. As of November 2000, patents were pending or had been granted on more than 500,000 genes and partial gene sequences in living organisms in the US⁴⁴.

The development of the many varieties of the world's staple food crops has been carried out mostly by developing countries over the generations through cross-breeding. Most developed countries are now allowing the patenting of plant varieties and this will inevitably have harmful repercussions for farmers who would wish to use such plant varieties. Farmers have traditionally re-planted, exchanged or sold seed from the previous year's crop which means that breeders have difficulties in recouping the investment made in improved varieties through repeat sales. With the adoption of TRIPS however, developing countries have been obliged to adopt a protection of plant varieties, by patent or other means without any consideration as to the effects of this on the agricultural sectors of these poor countries.

Like other aspects of traditional knowledge, there has been bio-piracy even in the agricultural sector. Soybean, for instance has been patented by a biotechnology company, Agracetus. This is

⁴⁴ Khor, M (2002): **IP, Biodiv and Sustainable Development.**

in spite of the fact that this crop was first cultivated in China and is now widely used for food, oil and animal feed. The patent was challenged by Monsanto (a Company) on grounds of lack of novelty, which later dropped the challenge after buying up Agracetus. By December, 1999, cases were brought up against 475 farmers suspected by Monsanto to have saved and re-sowed the seeds⁴⁵.

There have also been patents on rice, maize, potato; wheat and other major crops⁴⁶. Most such patents are owned by companies in the United States and Japan. One can clearly note from the ongoing that patenting in agriculture will lead to serious problems for farmers in developing countries who will be incurring high costs in buying up new seeds after each season. As with medicines, a crucial issue is whether and how intellectual property protection can help promote research and innovation relevant to the needs of developing countries and poor people.

The patenting of life-forms also raises ethic and moral issues. It also raises the important issue of the need to protect the environment from harmful substances. TRIPS does not exclude from patentability products which may be harmful to the environment. For instance, in the **Genetic Systems Case**⁴⁷, although the technical board of appeal did accept in principal that protection of the environment fell within the real of public order, they still insisted that sufficient evidence had not been adduced to show damage to the environment as the challengers had only raised possible hazards.

It still remains a risk, therefore, that environmentally hazardous inventions could still be patented and these would lead further depletion of the ozone layer.

⁴⁵ CIPR (2002) : **Integrating IPRs and development policy**

⁴⁶ Khor (2002): IP Bio div

⁴⁷ (1995) E.P.O.R 357. Tech Bd App

3.30 THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity was agreed upon in 1992. The CBD was prompted by the growing concern about the rapid worldwide loss of biological diversity, recognition of the importance of traditional knowledge and the rights of local communities that developed and hold the knowledge, and the need to regulate access and the sharing of benefits deriving from the conservation and sustainable use of biological diversity. It therefore, grew out of concerns of the environment and development communities and the indigenous peoples who are organized as holders of the traditional knowledge.

Protection of the environment is at the heart of the CBD⁴⁸. It seeks to sustain the environment for future generations by promoting the conservative use of the earth's resources, discouraging destructive farming habits and the over-use of chemicals on soils, the loss of wildlife and even the consistent cutting of trees. This is all aimed at sustaining human, animal and plant life. It calls for the use of environmental friendly technology and discourages the emission of toxic substances in the environment which continually deplete the ozone layer and result in global warming, cause cancer in humans and animals and pollution in the environment. It seeks to promote the conservation of biological diversity and the equitable sharing of benefits arising out of the utilization of genetic resources. It asserts the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim of facilitating the sustainable use of these resources promoting access and their common use. It notes that access to genetic resources should be on the basis of prior informed consent, and on mutually agreed terms that provide fair and equitable sharing of the results of research and

Article 1 of the CBD

development and of the benefits of commercialization and utilization. It also calls for the fair and equitable sharing of the benefits derived from the use of traditional knowledge⁴⁹. This was the argument of the San in the Hoodia Cactus case. They claimed that CISR had not complied with the rules of the Convention on Biological Diversity which required the prior consent of all stakeholders, including the original discoverers and users. In the end, they did agree on sharing of mutual royalties with the San.

In respect of intellectual property, the CBD states in Article 16.5 that ‘contracting parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.’ This clause seems to indicate that the framers were aware of possible tensions with IPR enforcement and sought to ensure that they be supportive. The pre-condition was however, that they be consistent with international law as well as municipal law. Governments should put in place policies to ensure that access to genetic resources take place on mutually agreed resources.

The CBD views biological diversity as a heritage which is owned by everyone and should be used for the common benefit of all. It is thus not to be monopolized for individual interests without any benefits to the community at large. One of the CBD’s central aspects is the recognition of the need to regulate the behavior of private corporations and researchers and constrain their rights of access and benefits within a larger framework that stresses the goals of environmental protection and the rights of sovereign states to their resources and the rights of the

Article 15 of The CBD

local communities within them. International law, incidentally, also recognizes the sovereignty of nations within their boundaries and over their subjects and resources.

3.31 **TENSIONS BETWEEN THE CBD AND TRIPS**

These two international instruments differ in terms of rationale, background, objectives and even the overall framework. The possible tensions do naturally make it difficult for nations to fulfill their obligations at international level.

The TRIPS Agreement is an international agreement which aims at encouraging and supporting large corporations to promote their technological dominance and gain additional margins of profit through obtaining private monopolies. The IPR models contained in TRIPS is tilted highly in favor of the rights and benefits of IPR holders. TRIPS are largely a commercial treaty with commercial objectives that largely benefit trans-national companies. The CBD, on the other hand, was prompted mainly to raise environmental awareness in the communities the world over. The CBD merely exists to ensure equitable and sustainable use of the earth's resources for human, animal and plant fulfillment.

The CBD also asserts a nation's sovereignty over its natural resources as reiterated in article 3. The TRIPS agreement, on the other hand does allow the patenting of life-forms from third countries. The product or process does not necessarily have to lie in your country for one to be eligible as a patentee; it could be anywhere as long as they were the producers of it. TRIPS facilitates the conditions for the appropriation (or misappropriation) of ownership or rights over living things knowledge and

processes of diversity. The CBD was actually aimed at countering the possibility of misappropriation or bio-piracy, whilst one of the effects of the TRIPS agreement is to foster bio-piracy.

Furthermore, in the preamble to the TRIPS agreement, and under article 28, the exclusive rights of the patentee are recognized as to *'sell, make, import and to prevent third parties not having their authority from so doing'*. The CBD on the other hand, has several provisions that indicate that traditional knowledge is to be owned communally for the common benefit of all⁵⁰. Article 8 (j) clearly states that each contracting party shall 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and to promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits from the utilization of such knowledge, innovation and practices.' While TRIPS clearly aims at creating commercial monopolies for IPR holders, the CBD actually aims at guaranteeing that there is mutual benefit for everyone involved in the utilization and exploitation of the fruits and resources of the earth. This is a clear conflict of interest which leaves a lot of countries in a dilemma in trying to fulfill their obligations at international level.

Another important difference is the Agreements' treatment of the environment. The CBD has a profound concern for the environment where as the TRIPS agreement does not even refer to any environmental concerns. This is obviously unsatisfactory as it may lead to a situation where

⁵⁰ E.g Article 15

toxic and environmentally hazardous substances are being patented without any regard to their effects on the community.

The noticeable tensions between the CBD and TRIPS have challenging effects on WTO members who are parties to the Convention. It is trite to note here that the US is not a party to the Convention as it has wanted to hang on to its advantages in bio-technology, particularly genetic engineering⁵¹. We however, still have a lot of WTO member countries which are party to the Convention and this dilemma has to be resolved if they are to fulfill their international obligations to both international instruments.

⁵¹ Khor M (2002): IP, Bodiv

CHAPTER FOUR

4.0 FLEXIBILITIES IN THE TRIPS AGREEMENT

Thus far, a grim picture of the TRIPS Agreement and its effects on least developed countries has been painted. It ought to be acknowledged, however, that in reality, the Agreement does contain certain measures that could be adopted to lessen its impact on fragile economies. Most of these flexibilities relate to public health demands, which were the subject matter of Chapter Two. These flexibilities include compulsory licenses, parallel importing and transition periods. The Doha Declaration, though not a flexibility in the strict sense, reaffirms the use of these flexibilities for developing countries to meet their public health demands.

4.1 THE DOHA DECLARATION

The Doha Declaration is a major step in the campaign to ensure access to medicines for all. The 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 a legal challenge from the patent holders. 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 TRIPS¹. It states the *purpose* of the TRIPS Agreement in the area of public health, *interprets* the TRIPS Agreement with regard to some important

¹ Musungu, F(2006): The use of flexibilities in TRIPS by developing countries.

aspects, *instructs* the Council for TRIPS to take action, and *decides* on the implementation of the transitional provisions for least developed countries².

The main points of the Doha Declaration are laid out as below:

THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH³: Adopted on 14 November, 2001.

1. We recognize the gravity of the public health problems affecting 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 the Trade Related Aspects of Intellectual Property (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 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

² *ibid*

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

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

5. Accordingly, and in the light of paragraph 4 above, while maintaining our commitment in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) 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 licenses and the freedom to determine the grounds upon which such licenses are to be granted.
 - (c) Each member has the right to determine what constitutes 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 manufacturing sector could face difficulties in making effective use of compulsory licenses 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 to, with regard 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 countries 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.

After TRIPS, problems arose in large measure due to the prohibitive cost of patented ARV medicines as well as for medicines used in the treatment of opportunistic infections. The high prices of these medicines seriously compromised the ability of governments, communities and other stakeholders in the health sector in developing countries effectively to manage the HIV/AIDS pandemic⁴. The international debate on the implications of the TRIPS Agreement on access to essential medicines came into the limelight in 1997 with the attempt by the US government to force revision of South Africa's Medicines and

⁴ Khor, M(2001): **Rethinking TRIPS and IPRs**

Related Substances Amendment Act and the filing of a legal challenge against that law by the South African pharmaceutical association⁵.

The Doha declaration, adopted at the fourth session of the WTO Ministerial Conference in Doha, represents a final agreement between developed countries and developing countries, that, public health considerations condition the extent to which rules in patent protection should be implemented. The declaration marked a significant achievement for developing countries. As regards paragraph 6 concerning countries with inability to make effective use of compulsory licenses, the expedient solution reached in August, 2003 was to allow countries to import generic medicines from a foreign generic producer.

The Doha declaration clarified that each member is free to determine the grounds upon which compulsory licenses are to be granted and to establish its own regime on parallel imports. It also extended the transition periods for LDCs with respect of pharmaceutical products by ten years to 2016⁶.

The Doha Ministerial Declaration that launched the Doha development Agenda calls for review of the provisions on biotechnological inventions, the relationship between the Convention on Biological Diversity and the TRIPS Agreement, and traditional knowledge and folklore⁷.

⁵ This case was discussed in chapter two

⁶ Paragraph 7 of the Doha declaration

⁷ Watal, J (2002): Implementing the TRIPS Agreement.

4.2 COMPULSORY LICENSES

A compulsory license, also referred to as non-voluntary license, is a license granted by an administrative or judicial body to a third party to exploit a patented invention, without the consent of the patent holder⁸. The TRIPS Agreement allows for such licenses⁹. Although the TRIPS Agreement does not prescribe or limit the grounds upon which compulsory licenses may be granted by member states, it does provide elaborate conditions which the member countries should adhere to when granting these compulsory licenses. These include the requirement that consideration of each grant should be on a case by case basis on individual merit, the limiting of the scope and duration of each grant to the authorized purpose and period, the grant should be predominantly for the supply of the domestic market, the patent holder should be paid adequate remuneration and the license must be non-exclusive¹⁰.

The granting of patent rights enables the patent holder to prevent third parties from exploiting their inventions. However, when reasons of public interest justify it, national authorities may allow for exploitation of the patent by a third party without the patent holder's consent or authorization. In such cases, the public interest of ensuring broader access to the patented invention is deemed to be more important than the interest of the patent holder in retaining his exclusive right. Compulsory licenses, therefore, play a crucial role in ensuring that patent laws are able to meet public health needs, and that patent rights

⁸ Musungu, F (2004): **Utilizing TRIPS flexibilities to protect public health.**

⁹ Article 31 of the TRIPS Agreement.

¹⁰ *ibid*

do not unnecessarily hinder or prevent access to essential medicines¹¹. Compulsory licenses may be granted to enable the production of generic versions of patented medicines, or their importation from foreign producers.

Compulsory licenses as a policy mechanism can be used to address a number of situations, including¹²:

- i. The high prices of medicines
- ii. Anti-competitive practices by pharmaceutical companies
- iii. Failure by pharmaceutical patent holders sufficiently to supply the market with essential medicines.
- iv. Emergency public health situations.
- v. The need for establishing a pharmaceutical industrial base.

In light of the Doha Declaration, members are free to determine the circumstances under which they can grant compulsory license. However, the conditions prescribed under the TRIPS Agreement which each member has to adhere to when granting licenses may still make it difficult for member countries to implement these compulsory licenses. For instance, a developing country may fail to pay the adequate remuneration to the patent holder and to this extent, would be in breach of their obligations under the TRIPS Agreement.

¹¹ Kanja, G (2006): **Intellectual Property Law**

¹² Musungu, F (2004): **Utilizing TRIPS flexibilities to protect public health**

However, the guiding principle under the Doha Declaration remains clear, public health concerns should be the guiding force in any patent legislation.

4.3 PARALLEL IMPORTS

Parallel importation refers to a situation where a third party, without the authorization of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder, his licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licensee¹³. The practice is based on the principle that the patent holder has been remunerated through the first sale of the product and his further control over the resale of the product would unreasonably restrain trade and stifle competition. In other words, having been remunerated, the right holders are said to have exhausted their rights¹⁴.

Parallel imports are goods brought into a country without the authorization of the patent, trademark or copyright owner after those goods were placed legitimately in circulation elsewhere¹⁵. These are recognized in article 6 of the TRIPS Agreement where member countries have the prerogative to set their own regulations and rules as regards parallel imports. This has also been reaffirmed in the Doha Declaration.

Parallel importation is used as a measure to prevent market division and price discrimination on a regional and international scale¹⁶. Since pharmaceutical companies set prices for the same products at different levels in different countries, parallel importation

¹³ibid

¹⁴ibid

¹⁵Maskus, E (2002): **benefiting from IP protection**

¹⁶ibid

enables consumers to gain access to the product without affecting the right of the patent holder to receive remuneration in the country where the product is first sold.

According to Musungu¹⁷, developing countries have three options open to them as regards the implementation of parallel imports, namely:

1. Members may adopt the principle of international exhaustion of patent rights. Adoption of this principle in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party.
2. Members may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility importing into the national territory a patented product originating from any other member state of a regional trade agreement.
3. The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patents in one country to only those put on the market by the patent owner or his authorized agents in that same country. In this case, there can be no parallel importation.

4.4 TRANSITION PERIODS

The TRIPS Agreement provides for three transition periods for the implementation of its minimum standards. The first two sets of transition periods, that is those relating to developed and developing countries were initially supposed to expire in 2000 and 2006

¹⁷ In *The use of flexibilities in TRIPS by developing countries*

respectively. These have, however, been extended to 2013¹⁸. As regard pharmaceutical products, the transition period has been extended for least developed countries to 2016.

The end of the 1995 to 2000 transition period obliged developing countries to implement the TRIPS Agreement and to put into place patent legislation that complied with the minimum standards of intellectual property protection prescribed by the TRIPS Agreement¹⁹.

The 2000-2005 transition period could be used by those countries which had not provided patent protection for pharmaceutical or agro chemical products at the entry into force of the Agreement.

After the expiry of the transition periods, all WTO member countries are supposed to comply with the minimum standards imposed by the TRIPS Agreement.

4.5 THE USE OF FLEXIBILITIES BY DEVELOPING COUNTRIES

Documentation and research suggest that most developing countries have incorporated TRIPS flexibilities in their national patent laws to meet their public health demands.

As regards transition periods, records seem to indicate Cambodia is the only country to be taking full advantage of its extension on pharmaceutical products. Article 13 of Cambodia's law on the Patents, Utility, model Certificate and Industrial design, 2003, states:

¹⁸ <http://www.wto.org>

¹⁹ Article 62.2 of TRIPS

“The pharmaceutical products mentioned in Article 4 of this law shall be excluded from patent protection until January, 2016, according to the declaration of the Ministerial Conference in Doha on the TRIPS Agreement and public health dated November, 14, 2001.”

As regard compulsory licenses, it is noteworthy that most developing countries make detailed provisions for their use. However, the grounds on which such licenses could be granted varies between countries. A general public interest ground features in most patent legislations²⁰. Zimbabwe, for instance, in 2002, issued the following declaration for a period of emergency on HIV/AIDS for the purpose of enabling

“The state or a person authorized in writing by the Minister to make or use any patented drug, including any anti-retroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drugs used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions”²¹

This empowered the minister to issue compulsory licenses and is similar to the South African case which was discussed in chapter two.

In Zambia, the Pharmaceutical act²² also empowers the government to issue compulsory licenses.. Its main purpose is to regulate, and to control the manufacture, importation, exportation, possession, storage, distribution, supply and use of medicines.

²⁰ Musungu, F (2004): **Utilizing TRIPS flexibilities to protect public health.**

²¹ Declaration of period of emergency (HIV/AIDS) Notice 2002,

²² Act No. 14 of 2004

The Patents (Manufacture of patented Anti-retroviral drugs) (Authorization) Regulation, 2004²³ in section 3 provides that

'The Minister may, in writing, authorize any government department or person to manufacture, use or vend, any patented anti-retroviral drug during the period of emergency.'

Argentina has provided for parallel importation in its laws. Its patent laws provide for a broad interpretation of the international exhaustion principle by stating that patent rights are exhausted where *'the said product has been lawfully placed on the market in any country'*.²⁴

Kenya has also incorporated the international exhaustion regime regarding parallel imports. Section 58 of Kenya's 2001 Act²⁵ states that *'the right under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya'*

These are but some of the examples by developing countries of the use of flexibilities in TRIPS to meet their public health demands.

²³ Statutory Instrument No. 83 of 2004

²⁴ Musungu, F (2006): **the use of flexibilities in TRIPS by developing countries.**

²⁵ Intellectual Property Act, Chapter 509 of the laws of Kenya

CHAPTER FIVE

CONCLUSIONS

During the round up to the formulation of the TRIPS Agreement, a lot of developing countries were uneasy about most of the provisions contained in TRIPS and what they entailed. In spite of all this indecision, the TRIPS Agreement was still passed and some of the unease was dispelled by the alleged benefits that would accrue to developing countries. These benefits included technology transfer to developing countries, increased research and development (R&D) and increased foreign direct investment (FDI)¹.

It has been twelve years since the TRIPS Agreement came into force and a serious appraisal of the TRIPS agreement has to be done to analyze its relevance to developing countries. It is an undisputed fact that every government wishes to develop and improve the living standards of its citizens. Development in every country should cover all sectors of the livelihoods of its citizens including health, economic, cultural, social and education. Development will be measured by a country's ability to control its mortality rate, its food production, its technical expertise, its exportation and so on. It is thus of critical importance for any country, developing or otherwise, to be able to fashion its laws in such a way that its prospects for development can be realized². Each country has the interests of its citizens at heart and therefore desires to better their living standards in all aspects of life.

¹ Watal, J (2000): **Intellectual property rights in the WTO and developing countries.**

² Toldaro, M (1981): **Economic Development**

Article 66.2 of the TRIPS Agreement provides that ‘developed country members shall provide incentives to enterprises and institutions within their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technology base’. This Article obviously entails more foreign direct investment and technology transfer to the developing countries. While conceding that this would very much hasten development for LDCs, it still remains doubtful whether TRIPS can achieve this. As Correa³ concluded, ‘the strengthening and expansion of intellectual property rights are likely to adversely affect the conditions for access to and use of technology, and thereby the prospects for industrial and technological development in developing countries..... under the TRIPS Agreement, reverse engineering and other methods of imitative innovation -that industrialized countries extensively used during their own process of industrialization- shall be increasingly restricted, thereby making technological catch-up more difficult than before’.

Historically, technology transfer has played a key role in industrialization, and a large part of this transfer took place by firms imitating or copying the technologies used by others. Producers in developing countries will find it difficult to copy technology which is IPR protected when TRIPS and associated national legislation takes effect. As Gerster⁴ observes, when most of the now developed countries established their patent and other IPR laws in the nineteenth century, all of these IPR regimes were highly deficient by

³ Correa, C (2000): **Intellectual property rights, the WTO and developing countries.**

⁴ Gerster, R (1999): **Patents and development**

today's standards. If at their stage of development the developed countries had had to adhere to the minimum standards set by TRIPS, it is doubtful many of them would have obtained the levels of technology and industrialization they have achieved.

As earlier alluded to, it has been twelve years since the TRIPS Agreement came into force, and to date, the alleged benefits have not yet materialized. As regards the promotion of R&D, most patents in developing countries are held by foreigners, thereby stifling competition for local researchers⁵.

One can thus tentatively submit that the TRIPS Agreement is a protectionist device designed not only to advance the monopoly privileges of the large corporations, but also to prevent developing countries from being successful competitors to the developed countries. Much as one can agree that it is important to have some international IPR regime to prevent problems of counterfeiting and piracy, setting equal standards for both developed and developing countries does hinder to some extent the development prospects of developing countries especially in so far as technology transfer is concerned.

TRIPS has unfortunately led to some reverse form of technology transfer through bio-prospecting⁶ in which large corporations are patenting the traditional knowledge of indigenous communities of the gene-rich South. Examples of bio-prospecting have included the Neem extracts of India patented in the US, the Turmeric plant of India patented in the US, and the Hoodia Cactus of the Kalahari Desert in Botswana patented by a US-based Corporation.

⁵ Khor, M (2003): **Rethinking TRIPS and IPRs**.

⁶ As discussed in Chapter three

This was obviously not the kind of technology transfer envisaged by the TRIPS Agreement, but this is one of the effects of the Agreement. The TRIPS Agreement offers no protection whatsoever to the traditional knowledge of indigenous communities. Traditional knowledge is knowledge in the public domain of indigenous communities and can academically not be the subject matter of a patent as it is not novel. It has however, been the trend that the bio-prospectors misappropriate this knowledge and patent it in their countries without even the consent of the indigenous communities.

Before the Doha declaration, the TRIPS Agreement was at variance with major international instruments such as the UDHR and the ICESCR. However, with the Doha Declaration, much of this controversy has been resolved especially as regards the health sector. It is now universally accepted that public health concerns override any patent and are the guiding force in policy implementation. Doha reaffirms the use of TRIPS flexibilities to meet public health demands. However, the problem of branding still remains a challenge as regards other essential products. It is widely acknowledged that most patented products are sold at high prices⁷. The agricultural sector is one area in which patents are likely to adversely affect the crop yield as farmers will not be allowed to re-use their seeds if they are patented.

The above discussion shows that the alleged benefits of having a stronger IPR regime to developing countries – namely, technology transfer, increased R&D, and increased FDI – are likely to be marginal at best. The problem with TRIPS is not only that it does not bring much benefit to developing countries, but that it imposes substantial costs on them.

⁷ Khor, M (2003): Rethinking TRIPS and IPRs.

Firstly, due to TRIPS, there is need to increase royalty payments to patent holders, there is also a widespread monopoly pricing and other restrictive behavior by the transnational companies, and the problems of bio-prospecting. Developing countries cannot hope to develop their own technological capabilities under TRIPS. There are severe limitations on opportunities to imitate and make minor improvements – and these are routes critical to the development of technological capabilities in any country.

The TRIPS Agreement also seems to be at variance with the Convention on Biological Diversity (CBD). While the CBD acknowledges and reaffirms the sovereignty of nations over their traditional knowledge and biological diversity, the TRIPS Agreement does not even recognize it. Where as the CBD promotes national and communal rights over resources, and advocates for their sustainable use, the TRIPS Agreement encourages private monopolies and ownership of such rights.

There is therefore some obvious need to harmonize the two international instruments to prevent conflicts of obligations on contracting states. Furthermore, one of the fundamental principles of international law is that it should be based on the consent of states to be bound⁸. The TRIPS Agreement, however, is binding on all WTO member states without exception. The only option members who do not wish to adhere to TRIPS have, is to cease to be WTO members. This obviously brings into question the whole essence of having a law which contracting states do not seem to have much choice about.

⁸ Shaw, M (2004): **International Law**.

RECOMMENDATIONS

It is unquestionably acknowledged that intellectual property rights should be protected on an international scale and to some extent. The obvious controversy is the degree to which these IPRs should be protected. These are the recommendations that the author submits regarding IPR protection on the international arena and as regard the TRIPS Agreement:

1. Developing countries should make full use of the flexibilities under the TRIPS Agreement to meet their public health needs and other essential needs. They should incorporate the flexibilities in their national patent laws and utilize them to their fullest extent. Where a country is still not able to meet their essential needs, they should request for an extension of their transition period to enable them to take certain actions that might otherwise be considered to be contrary to the TRIPS Agreement.
2. The TRIPS Agreement should not be binding on all WTO member states. Members should be given the option of ratifying and entering reservations in so far as controversial articles are concerned. This is in line with the fundamental principle of international law which requires that members should only be bound if they have consented to be bound. It should not be automatic for every WTO member to be TRIPS compliant. This even lends more legitimacy to the instrument and encourages compliance. It is no wonder there are so many calls for reform to the TRIPS Agreement considering its nature. For instance, countries should be able to determine on their own what to exclude from patentability as opposed to the TRIPS Agreement which requires the granting of patents in all fields of human endeavor.

3. The patenting of life-forms should be subjected to very stringent measures and there should be a deliberate article banning the patenting of substances that are not environmentally safe. The rules outlined in the case of the Harvard Onco Mouse⁹ as regards the patenting of life-forms should be incorporated in TRIPS.
4. Even if the TRIPS Agreement were still applicable to developing countries, the standards applicable to them should be lowered to enable them improve their technological and industrial base. It is strongly recommended that there be created a Monitoring Body under the auspices of WIPO to determine what IPR standards should be applicable in a country depending on its level of development and the standards of living of its citizens.
5. The TRIPS Agreement should also offer some protection to traditional knowledge to prevent the phenomenon of bio-piracy. There should be an international protection of traditional knowledge through an international register which will recognize the indigenous communities as the owners of such knowledge. Since this may be difficult, it is submitted that each country should be responsible for preparing and submitting such a register in order to identify what it is the nation wishes to protect and in whom the proprietary interests lie.
6. The TRIPS Agreement should be harmonized with the Convention on Biological Diversity. The easiest way for this to be done is by the TRIPS Agreement expressly acknowledging that traditional knowledge shall not be the subject matter of patent law and that it shall be owned communally for the benefit of all.

⁹ T 19/90 (1990) O.J EPO 476. tech. Bd. App.: (1990) E.P.O.R 525 , Ex. D.

REFERENCES

BOOKS

1. Corpuz-Tauli, V (2003): **Biodiversity, traditional knowledge and rights of indigenous peoples**. Third World Network. Malaysia: Jutaprint.
2. Correa, C (1998): **Options for implementing the TRIPS Agreement in developing countries**. Switzerland: SADAG.
3. Correa, C (2002): **Protection and promotion of traditional knowledge**. Switzerland: SADAG.
4. Correa, C (2002): **Integrating public health concerns in patent legislation in developing countries**. Switzerland: SADAG.
5. CIPR (2002): **Integrating IPRs and development policy**.
6. Gerster, R (1999): **Patents and development**. Third World Network. Malasia: Jutaprint.
7. Kanja, G (2006): **Intellectual Property Law**. UNZA PRESS: LUSAKA.
8. Khor, M (2002): **Rethinking IPRs and the TRIPS Agreement**, Third World Network. Malaysia: Jutaprint.
9. Khor, M (2004): **Intellectual property, biodiversity and sustainable development**. Third World Network. Malasia: Jutaprint.
10. Khor, (2005): **Intellectual property rights, competition and development**. Third World Network. Malaysia: Jutaprint.
11. Maskus, E (2002): **Benefiting from Intellectual property protection**. Ed. Bernard Hoekman. World Bank: Washington.

12. Musungu, F (2004): **Utilizing TRIPS flexibilities to protect public health.**
Switzerland: South Centre.
13. Musungu, F and Cecilia Oh (2006): **The use of flexibilities in TRIPS by developing countries.** Switzerland: South Centre.
14. Shaw, M (2004): **International Law.** Universal Law Publishers: India.
15. Subramanian (2002): **Proprietary protection of Genetic resources and traditional knowledge.** Ed. Bernard Hoekman. World Bank: Washington.
16. Taylor, Y (2004): **Battling HIV/AIDS.** The World Bank: Washington.
17. Third World Network (2003): **Manual in good practices in public health sensitive policy measures and patent laws.** Malaysia: Jutaprint.
18. Watal, J (2001): **Intellectual property rights in the WTO and developing countries.** Oxford University Press: New Delhi.
19. Watal, J (2002): **Implementing the TRIPS Agreement.** Ed. Bernard Hoekmen.
World Bank: Washington.

LAW JOURNALS

Kanja, G (2003): Zambia Law Journal. Vol.34. **Implications of the TRIPS Agreement on access to cheaper pharmaceutical drugs by developing countries.** UNZA PRESS: LUSAKA.

CASES

Chakrabarty, Re. 447 303 US Supreme Court: 1980 LEXIS. 112 1980. T 19/90 0. JEPO 476. tech

The Harvard Onco Mouse Board of Appeal.: 1990) E.P.O.R. 525, Ex. D

Genetic systems case (1995): E.P.O.R. 357 Tech Bd. Appeal

The Kalo Inoculants case 333 US 127, 130 (1948)

INTERNATIONAL AGREEMENTS

The Convention on Biological Diversity

The Agreement on the Trade-Related Aspects of Intellectual Property

The Universal Declaration on Human Rights

The International Covenant on Economic Social and Cultural Rights,