

**THE EXCEPTIONS TO PATENT RIGHTS UNDER THE WTO-TRIPS AGREEMENT:
WHERE
IS THE RIGHT TO HEALTH GUARANTEED?**

A dissertation submitted in partial fulfilment of the requirements of the degree
LLM (Human Rights and Democratisation in Africa)

By

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October 2002

Declaration

I, Mugambe Lydia, declare that my work is original and has never been presented anywhere at the University of the Western Cape or at any other institution. I further declare that all the secondary information used has been duly acknowledged in this thesis.

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Dedication

To my parents Dr. and Mrs. Mugambe who have been there for me all the way

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i) **List of Abbreviations**

IP	Intellectual Property
IPRs	Intellectual Property rights
WTO	World Trade Organization
TRIPS	Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organization
NGOs	Non Governmental Organizations
ICESCR	International Convention on Economic, Social and Cultural Rights
CESCR	Committee on Economic Social and Cultural Rights
R&D	Research and Development
WIPO	World Intellectual Property Organization
GATT	General Agreement on Tariffs and Trade
PMA	Pharmaceutical Manufacturers Association (South Africa)
TAC	Treatment Action Campaign
MSF	Medecins Sans Frontieres
IFPMA	International Federation of Pharmaceutical Manufacturers Association (USA)
UNESCO	United Nations Economic, Social and Cultural Council
UDHR	Universal Declaration on Human Rights
UNGAS	United Nations General Assembly Special Session on HIV/AIDS

ii) Acknowledgement

I would like to express my gratitude to Riekie Wandrag for the supervision and guidance that was so valuable. Many thanks too to Mark Heywood, Jonathan Berger and Dr. David Padilla for their advice, intellectual discussion, support and encouragement and to all friends who have made valuable input towards my preparation and completion of this writing. In a special way I am grateful to the staff of the Community Law Centre, University of the Western Cape, particularly Prof. Steytler, and the staff of the Centre for Human Rights, University of Pretoria and the European Union which provided financial aid for my LLM course.

1. INTRODUCTION

1.1 Background to the study

“.... Governments promised leadership. The pharmaceutical industry must keep its promise to make AIDS drugs available to developing countries at affordable prices. Scientists to work where the real needs are, not just where the money and the glory lie. NGO leaders to be uncompromising advocates for all their constituencies, not just the elite. For sustained progress against the (AIDS) epidemic it is time to tackle the driving forces of global inequality. To put AIDS firmly on the political agenda that shapes the world order- a world beyond just science and classic public health. International trade negotiations may make as big a difference to AIDS treatment as any number of national treatment plans. Donor imposed caps on public sector spending must not fight inflation at the expense of sustained investment in AIDS....”¹

Health as the world affirmed in the Universal Declaration of Human Rights more than fifty years ago, is a fundamental human right and an indispensable component of development under any economic policy model.² Poverty in families and nations produces poor health and the links also go the other way, failure to invest in good health will undermine even the best-laid development plans. Protection of the right to health is important as a prerequisite for the right to life. It is therefore imperative that as the world turns into a global market and village, the essence of human existence is not forgotten. There is a need to strike a clear and meaningful balance between profit and human wellbeing with greater consideration for life without which, the profit motive is itself futile.

The scale of the AIDS crisis now outstrips even the worst-case scenarios of a decade ago.³ AIDS has reached pandemic proportions. Described by the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) as a “global emergency” on account of its sheer scale and impact, AIDS is recognised as a formidable threat to human life, dignity and the enjoyment of fundamental human rights.⁴ Dozens of countries are already in the grip of serious HIV/AIDS epidemics, and many more are on the brink. Around the world, an estimated five million people became infected in 2001, 800,000 of them children.⁵ Over the next decade, without effective treatment

¹ Piot, P. UNAIDS Executive Director, in a speech at the opening ceremony of the X1V International AIDS Conference, Barcelona, July 2002, available at (www.unaids.org), accessed on 1 August 2002.

²“Africa’s Right to Health”, available at (www.africaaction.org/action), accessed on 30 August 2002.

³“A global overview of the epidemic,” UNAIDS report on the Global HIV/AIDS epidemic-2002, available at (www.unaids.org/barcelona), accessed on 22 August 2002.

⁴ Declaration of Commitment on HIV/AIDS: “Global Crisis-Global Action”, U.N. G.A., 26 Special Session, Annex 1, Agenda Item 8, at 2, U.N. Doc. A/RES/S-26/2, (2001) (hereinafter referred to as UNGASS), available at (www.unaids.org/whatsnew/others/un_special), accessed on July 14, 2001.

⁵See n2 above.

and care, they will join the ranks of the more than twenty million people who have died of AIDS since the first clinical evidence of HIV/AIDS was reported in 1981.

It is equally clear that the vast majority of people including those living in countries with high national HIV prevalence have not yet acquired the virus. Enabling them to protect themselves against HIV and providing adequate and affordable treatment and care to those infected with the virus represent two of the biggest challenges facing human kind today.⁶ The even more onerous challenge is making this a reality.

Despite its global nature, not every region is equally threatened by the pandemic's potentially devastating consequences. Of the estimated 36.1 million people with HIV/AIDS globally,⁷ approximately 25.3 million or 70% live in sub Saharan Africa, a region with only 10% of the world's total population. Not only is sub Saharan Africa the most adversely affected, it is arguably also the region least able to deal with the consequences of such an epidemic.⁸ In this context it is not surprising that the UNGASS Declaration sees the African epidemic as a "state of emergency" threatening development, political security and the very fabric of society."⁹

Amidst all this, the right to health has become fiercely contested. In particular the degree to which the patents on medicines impede what the United Nations High Commissioner has described as the "human right" of access to essential medicines is under close scrutiny.¹⁰ The controversy generated by an article arguing, "*in Africa patents and patent law are not a major barrier to treatment access in and of themselves*" is indicative of the intensity of the debate.¹¹ More importantly advocacy for the human right to health and to treatment in particular is pitting developing country interests against those of the developed rich world and research based pharmaceutical companies. Advocacy for access to treatments is leading to careful moral and legal scrutiny of patents taken out on medicines, new attempts to define

⁶See n2 above.

⁷ Joint United Nations Programme on HIV/AIDS (UNAIDS), AIDS Epidemic update: December 2000 3, available at (www.unaids.org/wac/2000/wadoo/files/WAD_epidemic_report.htm) accessed on 17 July 2002.

⁸Berger, Jonathan, "Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity."(Spring 2002), 17 *Connecticut Journal of International Law*, No. 2, 157-248 at158.

⁹ UNGASS (n4 above) 8.

¹⁰ "The Impact of the Agreement on Trade Related Aspects of Intellectual Property on Human Rights" Report of the United Nations High Commissioner for Human Rights, 27, (June 2001), (E/CN.4/Sub.2/2001/13), para 42.

¹¹ Attaran, A and Gillespie-White, L "Do Patents for Anti-retroviral Drugs Constrain Access to AIDS Treatments in Africa?"(2001) *JAMA*, 286 15, For replies to the article by Attaran and Gillespie see Boelaert et al Letters, *JAMA* Vol. 287:7; E. Goemaere, Letters, *JAMA* Vol. 287:7; M.J Selgelid et al Letters *JAMA* Vol. 287:7.

the boundaries to intellectual property and calls for a re- negotiation of the world trade rules.

As human existence gets engulfed in the consequences of globalisation,¹² policy makers and ordinary people are turning to technology for solutions to the world socio-economic and developmental problems. Today's technological transformation is pushing forward the frontiers of medical research, communications, agriculture and energy, and is seen as a source of dynamic growth. Access to health care is today widely accepted as a core component of efforts to promote and protect the right to health.¹³ However there exist unacceptable inequalities in the health status of people particularly between developed and developing countries as well as within countries.¹⁴ Developments in medical research provide greater opportunities for realising the right to health. Yet the reality is that curable and preventable diseases continue to kill and maim millions in Africa and other developing regions of the world.¹⁵ It is therefore safe to conclude that globalisation has created new opportunities as well as challenges for the protection and promotion of human rights.¹⁶

Against this background, the central thesis of this study is the emphasis that the manoeuvre within the TRIPS regime is not the end in realising the right to health. Rather it is only a starting point for the realisation, which lies at the domestic level. The analysis of the exceptions to patent protection rights under TRIPS confirms the statement that it takes the commitment of the state and other actors concerned, in this case the pharmaceutical companies for the true realisation of the right to health and human rights in general.

¹² Globalisation is a much used word or concept often to refer to the opening up of the world economy through freer movement of goods, services, capital and persons. For an indication of problems of conceptualising and defining the concept, see R. J. Barry Jones, "Globalisation and Interdependence in the International Political Economy, Rhetoric and Reality" (1995) Pinter Publishers, London, especially chap. 1 and Phillip Cerny " Globalisation and the Changing Logic of Collective Action" (1995) 49,4.

¹³ B. Toebes "Towards an Improved Understanding of the International Human Right to Health" (1999), 21 Human Rights Quarterly 661,663.

¹⁴ Bertrand A & Kalafatides L " The WTO and Public Health", (1999) The Ecologist, available at (http://www.aidc.org.za/archives/wtohealth_bertrandkalafatides.html), accessed on 15 March 2001, reported in Sisule F. Musungu (2001) "The Right to Health in the global economy, Reading Human Rights obligations into the Patent regime of the WTO-TRIPS Agreement" 8.

¹⁵ The Cable News Network (CNN) programme "CNN Perspectives" tactically summed up the paradox in a special feature on HIV/AIDS by titling it The Dream Differed. The ravages of disease have shattered the dream that the twenty first century would be the century for Africa, reported in Sisule (n14 above) 8.

¹⁶ R. Howse & Mutua " Trading in Human Rights: The Human Rights Obligations of the WTO" ICHRRD (April 2000), reported in Sisule (n14 above) 7.

Today, many nationals of member states of the World Trade Organisation (herein after referred to as WTO) watch as legislatures are drafting new intellectual property laws to meet the requirements under the WTO-TRIPS Agreement. The agreement is much criticised, especially for being retrogressive to the realisation of the right to health. Compared to civil and political rights, it is even more difficult to realise the right to health in an environment where the international and effectively national legal systems subject this and other socio-economic rights to progressive realisation within available resources.¹⁷ The proposition of this study is that there are opportunities to realise the right to health left under the TRIPS Agreement, and these must be positively exploited with full commitment at the national level. The study therefore is aimed at identifying opportunities within the WTO/TRIPS agreement for realising the right to health and proposing a medium in which this can be achieved.

1.2 Statement of Research Problem

Trade being the driving engine of globalisation, it is pertinent that at the very least, rules governing it do not violate human rights but rather promote them. The implementation of the TRIPS Agreement has resulted in a conflict between the obligations of states to promote and protect health and the achievement of economic goals under the WTO regime. The conflict between intellectual property (herein after referred to as IP) and the right to health arises partly from ensuring that the integration of economic rules and institutional operations in relation to intellectual property rights (herein after referred to as IPRs) coincide with states' obligations to promote and protect public health, but also from the question of willingness and commitment of political leaders to make health a reality for the people within their jurisdictions. In this context, protection of the right to health and other human rights is cardinal to the democratic concept of leaders being accountable to their people. If then it is true that leaders must be accountable to their people, it follows that if they

¹⁷ See "The nature of states parties obligations, (under the ICESCR) "General Comment No. 3 adopted 3-14 December 1990. U.N. Doc E/C. 12/1990/8 (1990) and South African constitutional court case no. 8/02 (unreported) Minister of Health and 8 others v The Treatment Action Campaign and 5 others. herein after referred to as TAC appeal. (This was an appeal from the decision in the Treatment Action Campaign and 5 others v Minister of Health and 8 others, in the High Court of South Africa, Transvaal Provincial Division, Pretoria, Case No. 21182/2001.) In this case the court gave a restricted interpretation of the right to health while relying on General Comment 3 to interpret progressive realisation within availability of resources.

fail to account and justify their leadership then they are voted out of power by the will of the people at the next election.¹⁸

1.3 Objective of the Study

This study centres on the debate on health and IPRs, and the politics that is eminently ostentatious to the realisation of the right to health. Specifically the study deals with the exceptions to the rights granted to patent holders under the TRIPS Agreement. A lot of criticism has been levelled against the TRIPS agreement for disregarding the availability of and accessibility to drugs and consequently the right to health. The study will evaluate whether the exceptions under the agreement provide any real opportunities for the protection of the right to health. Further to this is the question whether the TRIPS agreement is an end in itself for realising this right. The challenges posed by accessibility to drugs particularly in the fight against AIDS, especially in the developing and least developed countries will be analysed in view of the exceptions under the TRIPS Agreement. This is to determine whether a valuable balance is secured by the exceptions. In analysing the exceptions, a human rights paradigm shall be invoked by contextualising both the right to health and intellectual property rights in the standard of the International Covenant on Economic Social and Cultural Rights. (herein after referred to as ICESCR). The ICESCR was chosen for a number of reasons. First, the ICESCR recognises both the right to health and the right to the protection of inventions in clearer terms than any other human rights instrument. Secondly at least 111 of the state parties to the ICESCR are also members of the WTO, including a large number of developing and least developed countries.¹⁹ The rapid development of treatments for HIV and its prevalence in both the developed and developing worlds has arguably put it above other illnesses. This is supported by the argument that whilst treatments for HIV were designed in and for a profitable first world market, the greatest need for them is now in developing countries where they are largely unaffordable. This has suddenly created a new group of patented 'essential medicines' (particularly anti-retrovirals) that are still highly profitable in rich countries but desperately needed in poor countries.²⁰ The question of research and development as the main argument by the pharmaceutical

¹⁸ For a further discussion of the issue of accountability by leaders to their people, see Piot, P speech (n1 above).

¹⁹ See UNHCHR report (n10 above).

²⁰ In early 2002, the World Health Organization issued a list of essential drugs including all anti-retrovirals. See World Health Organization, Essential Drugs and Medicines Policy, "Summary of Recommendations by the Expert Committee on the Selection and Use of Essential Medicines" 15-19

companies shall also be discussed. In the context of effective utilisation of the exceptions to patent protection under TRIPS, this thesis will attempt to illustrate how despite the acknowledgement of other factors named by WHO (such as reliable health infrastructures and supply systems) as influencing access to medicines for health, the content of a national patent regime and the commitment of government and pharmaceutical companies is very important. The thesis in the first place clearly recognises the weaknesses in respect to the right to health in built within TRIPS. As such the restrictions for example on compulsory licensing to the domestic market are of notable concern in respect to developing countries.

1.4 Significance of the Study

While technological advancements necessitate the protection of exclusive exploitation rights, which IPRs ensure, the maintenance and improvement of human health must be considered as a primary objective of states. As the World Health Organization (herein after referred to as WHO), the United Nations (herein after referred to as UN) and states manoeuvre to enhance the right to health within the TRIPS regime, it is pertinent that in the first place there is real commitment for the said realization. This study will therefore contribute to the post Doha debate intended to identify avenues for the right to health and whether the challenges for realizing the right to health lie only in the TRIPS regime.²¹ It is noteworthy that although the question of access to medicines and related issues are critical to human rights, many traditional human rights NGOs including Human Rights Watch (HRW) and Amnesty International (AI) continue to distinguish the right to health and other socio-economic rights from civil and political rights, giving them less attention.²² The study therefore will also enhance civil society understanding of the importance and need for socio-economic rights advocacy.

(April 2002), available at (www.who.int/medicines/organization/par/edl/procedures), accessed on 17th May 2002.

²¹ Doha, the capital of Qatar is where the WTO fourth ministerial conference took place from 9-14 November 2001.

²² See recent annual reports of Human Rights Watch and Amnesty International.

1.5 Hypothesis/Research Question

The thesis of this study is that the flexibility within the exceptions to patent rights protection under the TRIPS Agreement has not sufficiently been exploited at the national level. The study conceptualises the regimes for the protection of the right to health and IPRs not as mutually exclusive but as potentially reinforcing. The contention is therefore that the obligations in respect to the right to health limit the manner in which states can exercise the flexibility within the patent regime of the TRIPS Agreement. Eventually the study seeks to answer the question: Where does the guarantee for the right to health lie in light of the TRIPS regime?

1.6 Review of Chapters

The study is divided into three chapters preceded by an introduction. The introduction lays the background for the discussion. Chapter one deals with the definition of important concepts and provides the context in which the study is set. The chapter also discusses the background to the creation of the TRIPS Agreement, with an emphatic discussion on the involvement or lack thereof of African and other least developed and developing countries in this process.

Chapter two discusses the patent rights exceptions clause under the TRIPS agreement. Against this background, compulsory licensing, government use and parallel importing as means of making accessibility to drugs a reality under the TRIPS Agreement will be discussed.

Chapter three identifies other means of making drugs more accessible and identifying places where they have worked well. In this chapter, generic substitution, establishment of a pricing committee, therapeutic value pricing, pooled procurement, negotiated procurement and planned donations will be discussed. Finally a conclusion will be drawn from the discussion and recommendations will be advanced.

1.7 Research Methodology

UNAIDS will be utilised to develop the situation of AIDS and the availability of drugs. The Internet will be utilised to access web sites of the WTO, Amnesty International and Human Rights Watch as sites for evaluating the TRIPS agreement and responses of different groups to the agreement. The Internet is the main source because most of the discussion relating to the TRIPS Agreement and the WTO can be found on the Internet. From the onset it should be understood that even though there may be differences between developing and least developed countries, for purposes of the foregoing discussion, the two are not necessarily distinguished as they have similar circumstances apparent in the discussion.

2. CHAPTER ONE

2.1 Understanding the Right to Health

At least at the level of rhetoric, the right to health is embedded in many International and regional human rights instruments as well as national bills of rights. However there remains widespread disagreement on the concise meaning of the right and its resultant obligations. In South Africa it is referred to as the right of access to health care²³ and in the ICESCR it is referred to as the right to the highest attainable standard of health and in other jurisdictions, it is called the right to health. The preamble of the WHO defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.²⁴ Both the ICESCR and the UDHR recognize and make provision for the right to health. Article 12.1 of the ICESCR in a more detailed model of the UDHR recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Subsection 2 provides a non-exhaustive list of steps that are necessary to achieve the full realization of the right. Other international instruments that recognize the right along similar lines include the Convention on the Elimination of all Forms of Discrimination against Women (CEDAW),²⁵ the Convention on the Elimination of all Forms of Racial Discrimination (CERD)²⁶ and the Convention on the Rights of the Child (CRC).²⁷ The right as set out in article 12.1²⁸ connotes functioning public health facilities and supporting relevant programs.

The WHO definition of health has been criticized as being inherently vague and capable of being devoid of any content. For example one may wonder what is meant by complete social wellbeing. That said however, the WHO definition remains the most comprehensive. In its broadness, it covers mental and physical wellbeing, the provision of services at primary, secondary and tertiary levels and fleshes out the kind of services it includes, that is preventive, curative, treatment and diagnostic which had never been clearly defined before. In addition to this, in moving away from the narrow focus on disease and infirmity, it obliges states to fulfill the prerequisites for the right to health like food, water and sanitation, moving away from the narrow

²³ See S. 27 of the South African Final Constitution Act 108 of 1996.

²⁴ The constitution of the World Health Organization, 14 U.N.T.S 186, reported in Basic Documents of WHO (1981).

²⁵ Articles 11.1(f) and 12.

²⁶ Article 5(e).

²⁷ Article 24.

²⁸ See Article 12.1 of the ICESCR.

biological definition of the right. Finally the WHO definition is endorsed by other UN instruments and committees. In understanding the right to health, one has to read the WHO definition positively so as to enhance the realization of the right to health.

2.2 Non Retrogressive Requirement

Member states to the different conventions providing the right to health are under obligation to fulfill the right. The ICESCR in particular obliges member states as primary duty bearers to take steps for the attainment of the highest level of socio economic rights. States are under obligation to adopt non-retrogressive measures²⁹ in respect to socio economic rights. Retrogressive measures refer to those measures that result in the overall level of protection falling below the level that existed at the time the state took on the obligation to progressively realize the right. The rule against retrogression is aimed at enhanced protection of the right to health.

2.3 Concept of Minimum Core

In General Comment 3, the CESCR developed the concept of minimum core obligation for socio economic rights. This serves as a minimum standard below which a state should not fall in realising socio economic rights. In the comment, the CESCR underscored states' obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights in the Covenant.³⁰ In respect of the right to health, the CESCR was of the view that under no circumstances including resource limitations can states justify its non-compliance with core obligations, which are non-derogable. By the same token, the CESCR noted that the assessment of whether a state has discharged its minimum core obligation, account must be taken of resource constraints applying within the country concerned.³¹ Further to this, article 2.1 obliges each state party to take the necessary steps to the maximum of its available resources.³² For a state to attribute its failure to meet at least the minimum core obligations to a lack of available resources, it must demonstrate that every effort has been made to use all resources that are available at its disposition in an effort to

²⁹ For a further discussion of retrogressive measures to be adopted, see CESCR, General Comment No. 14 on the right to the highest attainable standard of health, adopted on 25th April 2000, UN Doc E/CR/2000/4 (2000).

³⁰ See CESCR General Comment no. 12 (July 2000), See also details of General Comment No.3 (n17 above).

³¹ CESCR General Comment No.3 (n17 above) para 10.

³² Article 2 of the ICESCR.

satisfy, as a matter of priority, the minimum obligations.³³ In my view, the CESCR set down a very broad standard of the minimum core that a particular state can afford to avoid realisation of the embodied rights. Consequently, it is not surprising that in some jurisdictions, the minimum core is to a great extent disregarded even though the minimum core content as provided in General Comment 3 is invoked.³⁴ This impacts negatively on socio economic rights in general.

2.4 Duties in respect to the Right to Health

Pertinent to the foregoing debate is the issue of duties on the state in respect to the right to health as a socio economic right.³⁵ The South African constitutional court³⁶ has defined the following duties. The duty to respect is a negative duty not to interfere with an existing right. The duty to protect is a positive duty to adopt measures that ensure that the right is not being infringed. The duty to promote includes creation of awareness of what the rights are, the culture of having and realizing them. The duty to fulfill requires the state to adopt measures of direct assistance in realizing the right.

2.5 The Concept of Patents and Patent Rights

Patent law is a “rather artificial, highly complex and somewhat refined subject.”³⁷ A patent is a legal title granted by the state in a specific country that gives exclusive rights over the manufacture and use of an invention to the owner of this invention in that country, in exchange for the full disclosure of the invention to the public.³⁸ Effectively patent rights result in monopoly rights over a process or product for a

³³ CESCR General Comment 3 (n17 above) para 10.

³⁴ See for example the discussion by the constitutional court on the minimum core in S. 27 (1) of the South African constitution in the TAC appeal case (n.17 above). Effectively the constitutional court disregarded the minimum core content of the right to health in S. 27 (1) of the constitution setting a rather retrogressive precedent for the realisation of socio economic rights.

³⁵ For a further discussion of the duties on the state in respect to the right to health, see CESCR General Comment 14, (n26 above).

³⁶ *Government of the Republic of South Africa and others v Grootboom and others* 2000 (11) BCLR 1169, at par 34.

³⁷ *Commissioner of Patents v The Wellcome Foundation* (1983) NZLR 385 at 395.

³⁸ “Patent Situation of HIV/AIDS-related drugs in 80 countries”, Joint UNAIDS/WHO publication, (January 2000), Geneva.

given period. The exclusive rights run for a specified number of years.³⁹ In the words of the CESCR the legal recognition given to intellectual property is a ‘social product’ that has a “social function” namely to provide incentives for the inventiveness and creativity from which society benefits.⁴⁰ A patent is national and applications for patents must be filed in every country (or regional offices where they exist) where protection is desired for a specific invention.⁴¹ There is no international patent. Patents provide the patent owner with the legal means to prevent others from making, using or selling the new invention for the specified period of time, subject to a number of exceptions.⁴² A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether it can be supplied. The criterion for a patent to be granted is that the invention must be new, involve an inventive step and be capable of industrial application.⁴³ The novelty criterion implies that the invention should not be part of the “state of the art” world wide, but be a genuine innovation. Patented pharmaceuticals like other patents still have to go through rigorous testing and approval before they can be put on the market.⁴⁴ Patent rights are those rights accruing to a patent holder.

2.6 Legal Basis for Intellectual Property Rights

The theoretical justification for intangible property has traditionally been founded on two main theories of property. The first is John Locke’s labour theory of property. The other is the utilitarian doctrine. The modern patent system in particular is predominantly based on the utilitarian theory.⁴⁵ This traditional western view of property emphasizes private property and its importance in development.⁴⁶ The justification of the patent system based on this approach is that the inventor and

³⁹ Duckett M “Compulsory licensing and parallel importing. What do they mean? Will they improve access to essential drugs for the people living with HIV/AIDS?” Background paper, International Council of AIDS Service Organisations (ICASO), (July 1999), available at (<http://www.icaso>), accessed on 15 August 2002.

⁴⁰ Human Rights and Intellectual Property, Statement by the Committee on Economic, Social and Cultural Rights, United Nations Economic and Social Council, 14 December 2001 (E/C.12/2001/15) paras 4 and 6.

⁴¹ See Duckett M (n38 above).

⁴² “What is the basic patent right?” available at (www.wto.org), see also articles 27, 28, 29 and 30 of the TRIPS Agreement.

⁴³ See HIV/AIDS report in 80 countries (n37 above) 3 &4.

⁴⁴ “A patent is not a permit to put a product on the market”, available at (www.wto.org), accessed on 23 August 2002.

⁴⁵ The details given are required to be sufficiently comprehensive so that a person skilled in the particular art would be able to make practical use of the invention. Disclosure is a central prerequisite for the grant of a patent. See Grove, J in Young Vs Rosenthal, reported in Sisule (n14 above) 22-23.

investors are rewarded for their time, work and risk of capital by the grant of a limited but strong monopoly of exploiting the invention. In return for the inventor's disclosure of the details of the invention, a limited exclusive term is guaranteed.⁴⁷ The approach is seen as benefiting society by stimulating investments, creating employment and ensuring supply of technology based goods and services as well as ensuring a continuous process of knowledge creation and data building which is crucial for technological advancement.

Will Kymlicka suggests that utilitarianism conforms to our inner sense of social responsibility; that is, the idea that the well being of humans matters, and moral rules must be subjected to tests for their consequences to human beings.⁴⁸

Although the inventor's rights must be recognized in the IPRs scheme, the rights must be juxtaposed with the interests of society.⁴⁹ One must therefore ask if the institution of IPRs is just when it provides benefits to a select few. In the global economy, access to advantages produced by the IP protection is based on financial resources, which one would expect in a competitive economy.⁵⁰ Such a system is satisfactory when one is concerned about the distribution of nonessential items, that is objects that do not affect peoples' well being.⁵¹ However the system is not justified for essential goods such as medicines. There is a need to distinguish medicines from other goods in a patent regime.

2.7 Legal Protection of IPRs

Article 27.1 of the UDHR provides that,

"Everyone has the right to the material protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author."

Article 15 of the ICESCR agrees with the UDHR but is more detailed. First it recognizes the right of everyone to take part in cultural life, to enjoy the benefits of scientific progress and its application and to benefit from the protection of the moral

⁴⁶ See Sisule (n 14 above) 24.

⁴⁷ *ibid* 23.

⁴⁸ R.L Ostergard, "Intellectual property: A Universal Human Right?" (1999), 21 Human Rights Quarterly 156, 157. reported in Sisule (n14 above) 22.

⁴⁹ See Sisule (n14 above) 24.

⁵⁰ *Ibid*.

⁵¹ *ibid*.

and material interests resulting from any scientific, literary or artistic production of which he is the author. The intellectual property regime under these two instruments requires a balance to be struck between the promotion of public interests in accessing technology and in protecting the interests of inventors. On the whole there is no justification for protection of IPRs at the expense of public interest or human rights.

2.8 The Question of Drug Patents

The debate over the consequences of patenting essential products including medicines is not new. Historically some inventors and courts have deemed certain discoveries in the fields of medicine and surgery too valuable to be subject to a patent, recognizing the inherent inconsistency between monopoly rights over goods that might have a significant impact upon health. This is true of the effect of surgery, of penicillin, medical applications of radium and the polio vaccine. In the recent case of Bristol-Myers Squibb v FH Faulding, Justice Finkelstein stated that “the important question: ‘is it ethical to patent a pharmaceutical substance or a method of medical treatment?’ admits of no satisfactory answer.” He noted that Dr. Squibb is reported to have said, “I do not myself think that anything should be patented by either physician or pharmacist.”⁵² This dilemma led to the development of divergent approaches, with some countries choosing to exempt medicines from all or parts of patent law. In countries like Canada and Australia patent regimes were moderated by mechanisms to control prices, or to facilitate local production under compulsory licenses.⁵³ In countries such as India, Thailand and Brazil other legal means were found to allow competitors to circumvent the negative effects of patents by allowing the patenting of medical products but not processes or vice versa. For example in Brazil, Bermudez et al note how “Pharmaceutical products and processes were patent-protected until 1945, when a change in legislation excluded inventions that contained food or

⁵² Bristol-Myers Squibb Co v F H Faulding & Co Ltd (2000) FCA 316, available at (www.ipcr.gov.au/SUBMIS/doc2/Sub11AttA.pdf), accessed on 17 May 2002.

⁵³ In an affidavit filed in support of the Treatment Action Campaign Professor Collen Flood of the University of Toronto mapped how patent law in Canada evolved since 1923 with the “expressly stated goal of making food and medicine affordable to the public.” (at para 4) To facilitate this various legal devices including compulsory licensing and administrative mechanisms (a Patented Medicines Prices Review Board) were established. However, in common with developing countries, Canada has been pressured to strengthen intellectual property protection. In Australia, the government negotiates with industry as a monopolist purchaser and is thus able to provide drugs to the community at greatly reduced prices under a ‘Pharmaceutical Benefits Scheme.’

pharmaceutical substances obtained by chemical means or processes.” Eventually another change in 1969 excluded patent protection completely for pharmaceuticals.⁵⁴

Before the TRIPS regime, the question of intellectual property was not really addressed by the General Agreement on Tariffs and Trade (herein after referred to as GATT) and Member States had adopted various approaches towards drug patents. While some used to grant patents for pharmaceutical products and process inventions, others allowed patent protection only for process inventions. The objective of the latter was to make it possible for companies with limited financial resources to develop new processes for the same active principle as an original drug but more cheaply. Other countries did not grant any form of protection for inventions in the pharmaceutical sector. Moreover, the term of protection conferred by patent rights varied greatly between countries.

Under the TRIPS Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness.⁵⁵ These standards were derived from those of the industrialized countries and are not necessarily appropriate for all countries' levels of development. Public health concerns should therefore be considered when implementing the Agreement. As soon as the Agreement comes into force in a Member State, unauthorized copies of patented drugs are prohibited, and countries breaking this rule, will incur trade sanctions authorized by the WTO.⁵⁶

In the four centuries of its application, patent law has evoked its fair share of controversy and criticism- but perhaps none as fierce as that which now rages around the patenting of new medicines, particularly those used for the treatment of AIDS. The target of much of this criticism is the TRIPS agreement. TRIPS is criticized because of the manner in which from the mid 1990s, it has made the extension of US standards of patent law to pharmaceutical products and processes a condition for membership of the WTO. Understanding how this happened and where patent law has been perverted, if indeed it has, is assisted by recapturing some of its history. In 1850, Charles Dickens wrote, “*A Poor Man’s Tale of a Patent*” in which the imaginary author, Old John, lamented the difficulty encountered by poor people in obtaining a patent for an invention. Old John saw a patent as a right, as a means to protect and

⁵⁴ Bermudez et al, “Access to Drugs, the WTO TRIPS Agreement, and Patent Protection in Brazil: Trends, Perspectives, and Recommendations to help find our way.” Paper presented for the Medecins Sans Frontieres, Drugs for Neglected Diseases working group, Feb 2002, available at (<http://www.neglecteddiseases.org>), accessed on 24 August 2002.

⁵⁵ See article 33 of the TRIPS Agreement, available at (www.wto.org), accessed on 22 August 2002.

⁵⁶ See WTO-TRIPS impact report(n16 above).

exploit his invention- a protection against other innovators with more resources, prone to stealing, exploiting and profiting from poor people's intellectual property. He complains, *"is it reasonable to make a man feel as if, in inventing an ingenious improvement meant to do good he has done something wrong?"*⁵⁷ This reference points to the manner in which even in the nineteenth century, the ability to obtain a patent had become an art, vulnerable to abuse and horizontal collaboration between a powerful state and powerful monopolies. At the end of the piece he complains that *"the whole gang of hanapers and chaffwaxes (administrative bureaucrats responsible for the onerous filing of patents) must be done away with..... England has been chaffed and waxed sufficient."*

From the point of view of the WTO, the TRIPS Agreement attempts to strike a balance between the long-term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing people to use existing inventions and creations.⁵⁸ In the same vein, the multinational pharmaceutical companies justify the need for their patent protection based on the high research costs incurred in the process of making the patents and inventions.⁵⁹ This is also in line with the profit motive for any form of trade, and squarely falls within the WTO general push for opening up markets for trade and profit. The consumer perspective on the other hand is that price should not be the sole determining factor for access to any drug. Most of the civil society that has been critical of the TRIPS agreement confirms this same point of view.⁶⁰ In this context, effective patent legislation should balance the interests of all concerned parties.

2.9 Background to and the Establishment of the WTO-TRIPS Agreement

The Uruguay Round of multi-lateral trade negotiations was launched in September 1986 in Punta del Este, Uruguay. The Round officially concluded in December 1993, but the legal instruments incorporating the results and establishing the WTO were signed on 15th April 1994 in Marrakesh, Morocco.⁶¹ The agreement instituting the WTO came into force on the 1st of January 1995. In deciding to become a member of

⁵⁷ Charles Dickens, (1850) "A Poor Man's Tale of a patent" Household Words, available at (www.underthesun.cc/classics/dickens/reprintedpieces), accessed on 4 October 2002, also reported in Heywood M "Chaffed and waxed sufficient": Drug access, patents and global health 10.

⁵⁸ "TRIPS and the pharmaceutical patents: fact sheet." (April 2001), available at (www.wto.org), accessed on 23 August 2002.

⁵⁹ Swarns Rachel, "AIDS Drug Battle Deepens in Africa", The New York Times, 8 March 2001, available at (www.nytimes.com), accessed on 9 March 2002.

⁶⁰ See for example Duckket M (n38 above).

the WTO, states also undertake to abide by its rules. A number of treaties on trade in goods and services are annexed to the WTO convention and the TRIPS Agreement is Annex 1C thereof.⁶² A total of 123 participating countries signed the TRIPS agreement, it entered into force in January 1995 and it is scheduled to take 11 years to be fully implemented.⁶³

The agreement establishes minimum standards in the field of intellectual property. All member states have to comply with these standards by modifying their national laws to accord with the rules of the agreement.⁶⁴ The main change with respect to pharmaceuticals is the obligation to grant patent protection to pharmaceutical products and process inventions.

2.10 The Drafting Process

Notwithstanding the existence of a number of international conventions and the specialized role of organizations like the World Intellectual Property Organization (herein after referred to as WIPO) and the United Nations Economic Social and Cultural Organization (herein after referred to as UNESCO), the TRIPS negotiations were conducted within the GATT. Provisions of the resulting agreement are enforceable within the framework of the WTO - a forum without any tradition of work in the field of IPRs.⁶⁵ The premise for linking IPRs with trade regulation is that the value of goods and services in international trade cannot be dissociated from the know-how and creativity incorporated into them.⁶⁶ The inclusion of discussions of intellectual property in the Uruguay Round happened primarily at the instigation of two US companies, Pfizer and IBM⁶⁷. These companies and other US industry leaders they drew around them demonstrated in the 1980s and 1990s an impressive capacity to push their interests in Washington and Geneva. According to Ryan,⁶⁸ pharmaceutical companies justified their lobbying on the basis of the potential for future foreign investment and sales. On the other hand, developing countries (herein after referred to as DCs) in their opposition to the inclusion of IP protection under the WTO regime stated that the measures advocated reinforced the claims of inventors

⁶¹ Clement Ng'ong'lo " The World Trade Legal Order and Developing Countries: An assessment of important concessions and commitments, with special reference to sub Saharan Africa, 15-50, 15.

⁶² The WTO-TRIPS Agreement is commonly known as the Marrakesh Agreement having been enacted in Marrakesh Morocco in 1994, see (www.wto.org), accessed on 23 August 2002.

⁶³ Bermudez et al (n 53 above).

⁶⁴ See (www.southcentre.org), accessed on 26 August 2002.

⁶⁵ Heywood M (n56 above)14.

⁶⁶ WTO Annual Report, 1996, Vol.1,130.

⁶⁷ Heywood M (n56 above) 11.

and producers at the expense of economic and welfare needs of the poor in the developing world.⁶⁹ It was contended that with protection of holders of rights to patented food and medicines, typically monopolistic multinationals, for example, could have the effect of increasing the cost of these items in DCs and LDCs.

2.11 The Role of the Developing and Least Developed World at the Uruguay Round

The Uruguay Round is noted for the involvement and participation of DCs in the actual negotiations and countries in this or the lower category of least-developed countries now dominate the list of WTO membership.⁷⁰ The association of the DCs and LDCs notwithstanding, the results of the negotiations were not enthusiastically acclaimed in sub Saharan Africa where most of the LDCs are located. Political reactions generally portrayed apprehension and anxiety about the economic and welfare implications of an exercise widely regarded as part of the larger process of globalization of the international economy.⁷¹ The somber political outlook was only reinforced by academic assessments suggesting that the exercise involved a retraction of concessions and benefits for DCs and LDCs, which had taken several decades to wring from the multi lateral trading system. This could result in the further marginalisation and impoverishment of mainly African economies and people.⁷²

There are two major reasons which explain why industrialized countries which pressed for the negotiations chose the organization setting rules for world trade as the forum for negotiation and implementation of an agreement on intellectual property rights. Firstly, while developing countries in the WTO have agreed to liberalize trade by reducing or eliminating their tariff and non- tariff barriers, developed countries

⁶⁸ See Ryan, reported in Heywood M (n56 above) 19.

⁶⁹ Hoekman and Kostecki, "The Political Economy of the World Trading System", 151-152. For a detailed description of the TRIPS Agreement from the perspective of some African DCs, see F. Ringo "The Trade Related Aspects of Intellectual Property Rights Agreement in the GATT and Legal Implications for Sub Saharan Africa" 28,6(1994) JWT, 121-139, also reported in Ng'ong'ola Clement (n60 above) 42-45.

⁷⁰ See Ng'ong'ola Clement (n60 above) 39 for a further discussion on classification of countries as developed, developing or least developed, see (www.wto.org) for a detailed list of WTO members with the dates of signing the WTO agreement.

⁷¹ See Ng'ong'ola Clement (n60 above).

⁷² See for example, M. Davenport, A. Hewitt and A Konig, "The Impact of the GATT-Uruguay Round on ACP States", Final Report, Overseas Development Institute, London 1994; E. O Awuku, "How do the results of the Uruguay Round Affect the North- South trade?" 28,2(1994), Journal of World Trade (JWT), 75-93; and M. Rom "Some Early Reflections on the Uruguay Round Agreement as seen from the viewpoint of Developing a Country", 28, 6(1994), JWT, 5-30, reported in Clement Ng'ong'ola (n60 above) 14.

through patents and other protective instruments, are provided with the possibility of exporting products, incorporating innovations under the exclusive or monopolistic rights. That is, technology-holders can exclude competition from domestic producers in importing countries or other foreign firms. Secondly, an agreement with the GATT/WTO facilitates recourse to cross retaliation for non-fulfillment of specific obligations. In other words, countries failing to comply with TRIPS standards could be subject to trade retaliation if the dispute settlement mechanism of the WTO has determined the existence of non-compliance with the TRIPS agreement.

In general the process of drafting the TRIPS can hardly be considered as having been a real negotiating process. The exercise scarcely involved any give and take. The developing countries made considerable concessions in agreeing to the higher levels of protection of intellectual property rights demanded by the industrialized countries but they were not compensated by advantages in this or other areas of the Uruguay round negotiations. The main concession gained by the developing world was the provision in the agreement for transition periods of four years for developing countries and eleven years for the least developed to bring their legislation in line with the TRIPS agreement.⁷³

The discussion of the text was also asymmetric. The asymmetries were reflected first, in the determination of the negotiating agenda. The introduction of IPRs as one of the issues in the Uruguay round was approved at the ministerial meeting in Punta del Este in 1986, but limited in principle to the issue of trade in counterfeit goods. The industrialized countries' proposals concerning matters of negotiation were later extended to standards on practically all aspects of IPRs. Until 1989, developing countries refused to enter into detailed negotiations on standards, but later for fear of the threat of unilateral retaliatory trade sanctions, many of them changed their position. For example China, Brazil, India, Taiwan and Thailand were investigated under the special section 301 of the US Trade Act and other countries like Argentina, Andean Group countries were repeatedly threatened with trade sanctions in order to obtain changes in their IPRs regimes.⁷⁴

The negotiating capacity of developing countries was also skewed due to considerable difference in the specialist knowledge available to them in the conduct of extremely complex discussions. While developed countries were able to mobilize

⁷³ See (www.southcentre.org), accessed on 28 August 2002.

⁷⁴ See Heywood M (n56 above).

teams composed of top specialists in the various areas dealt with; developing countries lacked the necessary technical support.

In practice the drafting process was confined to a few countries. The main discussions took place in a so-called five plus five drafting group composed of five developed and five developing countries.⁷⁵ The agreements reached in this group were later referred to a broadened ten plus ten group convened in accordance with the presiding officer's directions. With the exception of the members of these groups, the remaining countries had little real opportunity to influence the outcome of the drafting groups' work. Moreover, during the negotiations the co-ordination of developing countries' positions was in general, weak, though some regional groups like that of Latin America were on the whole able to articulate their negotiating position.⁷⁶ In line with the general practice within GATT, no record of the TRIPS discussions was made unlike the situation with respect to negotiations relating to existing intellectual property conventions.⁷⁷ The various proposals have no recognized source and only the participants directly involved know why and how certain provisions were adopted or not as the case may be. Hence the TRIPS negotiations may be considered the most nontransparent negotiations conducted in IPRs. As a result the contracting parties now lack the back-ground information necessary for interpreting the proposed rules or for clearly understanding the background, premise and intent of the adopted text.

The composition of each working group was decided at the discretion of the presiding officer rather than as a result of consensus or a search for a balanced representation of countries at different levels of development.⁷⁸ The TRIPS agreement itself has asymmetries. The section on patent rights includes high and detailed minimum standards, the adoption of which is forcing changes in legislation in most developing countries. Certainly TRIPS is problematic in that all the world's countries despite different stages of economic and social development, regardless of disease burden and health needs are obliged to comply with its provisions in a relatively short period of time.

On the whole the interests of African and other DCs and LDCs were not really a priority in the TRIPS discussion. However whether by accident or otherwise there remains some room for manoeuvre within the TRIPS agreement as it stands. DCs

⁷⁵ See Bermudez et al (n53 above)22.

⁷⁶ See n43 above.

⁷⁷ *ibid.*

⁷⁸ *ibid.*

and LDCs should exploit this opportunity especially in regard to realising the right to health by making cheap drugs available to their people.

3. Chapter Two

3.1 Parallel Importing

Parallel importing is the importation of goods subject to intellectual property rights through channels of distribution that have not been authorised by the owner of the patent or his or her licensee.⁷⁹ It consists of purchasing proprietary goods from a third party in another country, rather than directly from the local manufacturer. The practise is based on the first sale doctrine, which rests on the principle that the first sale of a product by the patent holder or a licensee exhausts the exclusive rights over the product. Consequently he or she loses his or her legal control over the commercial exploitation of the product thereafter.⁸⁰

The basic justification for the first sale doctrine is that the inventor has been rewarded through the first sale of the product. Therefore his or her further control over the resale of the product would unreasonably or unfairly restrain trade.

Parallel importing is an important policy instrument for mitigating patent price effects and promoting competitive worldwide markets for products.⁸¹ The international exhaustion of intellectual property rights means that the title-holder cannot prevent the importation of a product on the grounds that its importation has not been consented to by the title-holder or the title-holder's licensee.⁸² Thus the importation of such a protected product, which has been put on the market elsewhere in a legitimate manner, can be considered as legal. The application of this principle permits, for instance, the importing of a (legitimate) product from a country where it is sold cheaper than in the importing country, thereby helping to prevent market fragmentation and price discrimination by title-holders.

⁷⁹ There is therefore a fundamental difference between parallel importing and counterfeit goods. For further discussion of the difference, see FM Abbott "First report (final) to the committee on International Trade Law of the International Law Association on the subject of Parallel Importation", (1998), *Journal of International Economic Law*, 607.

⁸⁰ Sisule (n14 above) 35.

⁸¹ D .Kennedy & J. Southwick (Eds) (2001) "The Political Economy of International Trade Law:" Essays in honour of Robert Hudec, London: Cambridge University Press reported in FM Abbott, "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference" (2001), Occasional paper 7 Geneva: Quaker United Nations Office 2.

⁸² D Kennedy & J. Southwick, (n80 above).

3.2 Reading Parallel Importing into the TRIPS Agreement

Parallel importing is not directly provided for in the TRIPS agreement. Article 3⁸³ generally provides for the principle of national treatment where each member is to accord to the nationals of other members' treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property. Article 4⁸⁴ in the same way provides for the Most Favoured Nation treatment. Under this, in regard to protection of intellectual property, any advantage, favour, privilege or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other member countries.

Article 6⁸⁵ subject to articles 3 and 4 provides that for the purpose of dispute settlement under the agreement, nothing in the agreement shall be used to address the issue of exhaustion of intellectual property rights. Article 6 needs to be read together with article 28, which sets out the rights of a patent holder. Reading these articles together, it is clear that the TRIPS agreement allows member countries to provide for the international or national exhaustion of rights where the agreements dispute settlement procedures can not be invoked. This is where parallel importing and other means are implied and made available to members, for the exhaustion of intellectual property rights.

3.3 Parallel Importing and Drugs

In respect to drugs, parallel importing is the purchasing of proprietary drugs from a third party in another country, rather than directly from the manufacturer, and taking advantage of the fact that pharmaceutical companies sometimes charge significantly lower prices in one country than in another.⁸⁶

For instance, in Britain, where parallel importing is common, the list price for Glaxo Wellcome's Retrovir is £125, but consumers can purchase the same

⁸³ See the TRIPS agreement (n61 above).

⁸⁴ Ibid.

⁸⁵ Ibid.

⁸⁶ See Duckett M(n38 above).

proprietary drug imported from other European countries for as little as £54.⁸⁷

Prices for the same product can vary widely among countries because of many factors, such as differences in intellectual property rules, differences in local incomes, and the degree of competition among producers. For example, a 1998 study by the Consumer Project on Technology found prices for SmithKline Beecham's version of Amoxil at \$8 in Pakistan, \$14 in Canada, \$16 in Italy, \$22 in New Zealand, \$29 in the Philippines, \$36 in Malaysia, \$40 in Indonesia, and \$60 in Germany.⁸⁸

By permitting some form of parallel imports, countries can shop around and get better prices, using market forces to lower national expenditures on a range of goods, including pharmaceuticals. It is therefore used and is seen as very effective at equalizing prices. Effectively parallel importing makes more drugs available at cheaper prices.

3.4 Compulsory Licensing and Government Use

Compulsory licensing is the term given to a legal approach that permits the manufacturing and use of generic drugs without the agreement of the patent holder. Compulsory licenses are authorizations, on application, granted by the government or a judge permitting the use of a piece of intellectual property (in the foregoing a patent) without the consent of the titleholder. Under the Paris Convention, subject to certain limitations, member countries could grant compulsory licenses for refusal to deal or non-working.⁸⁹

Government use is similar to compulsory licensing only in this case government is directly in control or appoints an agent to act on its behalf. Government use is where government grants itself, or a third party as its agent, a license to exploit a patented invention.⁹⁰ Government use provisions are therefore akin to a taking under the eminent domain doctrine. The most common situation where the power

⁸⁷ *ibid.*

⁸⁸ *ibid.*

⁸⁹ See Article 5A.2 of the Paris Convention (1883), which provides that, "Each country of the union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work. See also E Ackiron "Patents for critical Pharmaceuticals: The AZT Case" (1991) 17 *American Journal of Law and Medicine* 145,148, reported in Sisule (n14 above) 34.

⁹⁰ Lettington RJL and SF Musungu "In defence of Kenya's health: Proposed amendments to the industrial property bill 2000" (2000) 31.

is exercised is in cases of public emergency.⁹¹ In practice government use has also been predominantly a public non-commercial activity.

Article 8 of TRIPS provides some flexibility for governments to enact legislation providing for the grant of compulsory licenses to protect public health and nutrition and promote public interest in sectors of vital importance and technological development. This is subject to the provisions of article 31⁹², which specify conditions for such unauthorized use. Articles 31 and 8 of the agreement should be read together with articles 1, 7, 27.1, 30 and 44.

Article 1 provides that countries are not obliged to provide more extensive protection than the TRIPS, and shall be free to determine the appropriate method of implementing the provisions of the agreement within their own legal system and practice. Article 7 provides that the TRIPS agreement seeks to achieve the objectives of the transfer and dissemination of technology in a manner conducive to social and economic welfare. Article 27.1 has been discussed under parallel importing (above) and article 30 is the general clause on exceptions to patent rights.⁹³

The latter allows members to provide limited exceptions to the exclusive rights conferred by a patent. Provided that such exceptions do not unreasonably conflict with a normal exploitation of a patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The inference here is that countries are allowed, under certain conditions, to issue compulsory licenses against the will of the patent holder. For example, for a country with high HIV prevalence, the government could decide that it is in the public interest to ensure that appropriate drugs are manufactured locally and made available at a cheaper price, hence issue compulsory licenses to other producers of a necessary drug in the given situation. Article 30 however should be read together with article 31 setting down conditions for other use without authorization of the rights' holder. These include individual merit consideration, request for prior authorization from right holder, limited scope and duration to the purpose of authorization, non-exclusive use, non-assignable

⁹¹ See Sisule (n14 above) 35.

⁹² See addendum, page 65.

⁹³ See addendum, page 64.

use, authorization predominantly for supply of the domestic market, subject to adequate protection of legitimate interests, adequate remuneration and judicial review.

3.5 The Early Working (Bolar) Exception

Although not explicitly provided for in the agreement the early working exception is a widely accepted exception under article 30. The exception relates to a situation where a potential competitor uses an invention without the authorization of the patent holder.⁹⁴ However, such use is only for purposes related to research and other acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. In the pharmaceutical and related industries such as the agro- chemical industry, the purpose of the exception is to permit the performance of technical activities necessary in obtaining regulatory approval and securing capital.⁹⁵ Under this exception, generic producers are not allowed to commercially exploit the invention before the expiration of the patent term and therefore there is no prejudice to the legitimate interests of the patent owner.

The mechanism ensures that generic versions of the product are available on the market immediately or within a reasonable time of the expiry of the patent.

3.6 Analyzing the Flexibility within TRIPS

The law contained in TRIPS is in its embryonic stage and the next few years will be crucial in determining the balance between interests of health and profit.

TRIPS allows for the adoption of measures necessary to protect public health,⁹⁶ utilise compulsory licensing and other means, and waiver of the requirement to obtain authority in cases of national emergency.⁹⁷

These are all potentially important windows that can be kept open in the interest of public health. However the lack of skilled intellectual property lawyers in many

⁹⁴ Sisule (n14 above) 38

⁹⁵ The Supreme Court of Japan in *Ono pharmaceuticals Co. Ltd v Kyoto Pharmaceutical Co. Ltd*, Case No. Hesei 10 (JN) 153, 198 in relation to the Bolar exception observed that; without a bolar exception, third parties would not be in position to exploit freely the patented invention for a certain period even after the patent had expired. This in turn would conflict with the basic principle of the patent system.

⁹⁶ Article 8 of TRIPS (n 61 above).

⁹⁷ *ibid*, article 31.

developing and least developed countries may most likely result in the law being less able to take full advantage of the provisions of TRIPS and unworkable patenting systems. This will be to the advantage of the developed powerful nations and to the detriment of health.

The UN Commission for Human Rights recognises that:

“The various links (in TRIPS) with the subject matter of human rights –the promotion of public health, nutrition, environment and development are generally expressed in terms of exceptions to the rule rather than guiding principles themselves and are made subject to the provisions of the agreement”⁹⁸

In recent years, prominent economists like Joseph Stiglitz, winner of the Nobel Prize in 2001, senior economist for the World Bank, and Jagdish Bagwati have begun to see “patent protectionism” as unfair, inefficient and inconsistent with free trade agenda.⁹⁹

The WHO believes that an infectious disease crisis of global proportions is today threatening hard won-gains in health and life expectancy.¹⁰⁰ In light of all this it remains the duty of individual member states to utilize the flexibility within TRIPS to the maximum for health.

3.7 South Africa; A Case Study for the Implementation of the Exceptions; NGOS Taking on the Role of Government

At the United Nations General Assembly Special Session on HIV/AIDS, member states made a declaration of commitment that by the year 2003, in all countries, there shall be established strategies, policies and programmes that identify and begin to address those factors that make individuals particularly vulnerable to HIV infection.¹⁰¹ Today as nationals await these member states to account to them on their

⁹⁸ See TRIPS report (n 10 above), para 22

⁹⁹ Knight-Ridder Tribune Media Services, “Rich country Protectionism puts WTO on the slow Track” 16 November, 2001, available at www.cerp.net/columns/weisbrot/rich_coUnitedNationstry_protectionism.htm, accessed on 3rd May 2002). In the same vein, James Love, the director of the Consumer Project on technology states simply that “market incentives for health care R&D are not efficient” See J Love, “Paying for health care R&D: Carrot and sticks” paper prepared for Medecins Sans Frontiers, Drugs for Neglected Diseases, working group.

¹⁰⁰ World Health Organization, “Removing Obstacles to Healthy Development,” report on infectious diseases, Switzerland, (1992) 2.

¹⁰¹ See UNGASS (n4 above) para 62.

commitment, the victims of the HIV/AIDS pandemic remain the most eager category of people in need of the commitment.

By the end of 2001, an estimated 28 million Africans were living with the HIV/AIDS virus of which 2,4 million were children under the age of 15.¹⁰² South Africa has more people infected with HIV than any other country on earth with about 20 percent of its adults carrying the virus.¹⁰³ In the TAC appeal case, the pandemic was described as an incomprehensible calamity and the most important challenge facing South Africa since the birth of their new democracy, and government's fight against it is a top priority.¹⁰⁴

The right of access to health care is provided under Section 27 of the South African Constitution. South Africa signed the WTO Convention on 1 January 1995.¹⁰⁵ As a first step in an effort to meet the need of availability and accessibility to cheap drugs and within the TRIPS regime, government enacted The Medicines and Related Substances Control (Amendment) Act (herein after referred to as the Amendment Act).¹⁰⁶ The Amendment Act had at its heart the issue of making medicine more affordable with measures such as generic substitution, parallel importation, compulsory licensing, pricing committee and international tendering system built in it to bring this about.¹⁰⁷ S.15 (c) of the Amendment Act provided for the adoption of compulsory licensing and parallel importing by operationalising key elements of the national drug policy including generic substitution, establishment of a pricing committee, greater competition in public drug procurement, improved drug quality and more rational use of medicines.¹⁰⁸ In spite of denying it, the pharmaceutical industry contested the Amendment Act from the time of inception. At the time of its drafting, many multi-national pharmaceutical companies that operated in South Africa were angered and used all their influence to get this section out of the Act. For example chief executive officers of US based pharmaceutical companies summoned

¹⁰² AIDS epidemic update- December 2001, available at (www.unaids.org/worldaidsday/2002/Epiupdate2001_en.doc), accessed on 28 January 2002, see also Baimu E, "The governments obligation to provide anti retrovirals to HIV- positive pregnant women in an African human rights context: The South African Nevirapine case"(2002) *African Human Rights Law Journal* 160.

¹⁰³ See Swarns R (n58 above).

¹⁰⁴ See TAC Appeal (n17 above) para 1.

¹⁰⁵ See (www.wto.org), for a list of WTO member states and dates of signing the convention.

¹⁰⁶ The Medicines and Related Substances Amendment Act No. 90 of 1997.

¹⁰⁷ For a further discussion of the Medicines and Related Substances Act of 1997, see (www.tac.org.za), accessed on 12 September 2002.

¹⁰⁸ See "UNAIDS welcomes outcome of South African Court case," available at (www.unaids.org), accessed on 12 September 2002.

then minister of health and had one message for him, “get rid of section 15(c).”¹⁰⁹ In the UK, a similar showdown was taking place, there the South African High Commissioner effectively faced attacks from the UK pharmaceutical company heads to inform the South African government that the new law constituted a serious problem. Back in South Africa, the company members of the Pharmaceutical Manufacturers Association (herein after referred to as PMA) eventually responded by serving the health director general Ayanda Ntsaluba with a notification that government would be taken to court by the association and its members.¹¹⁰

Eventually the Bill was passed into law. However at the time, much of government’s heroic glow was by default as HIV/AIDS was not quite the burning issue it is currently. It cannot be ruled out that at the time, government did not understand the implications of providing for compulsory licensing, parallel importing and other measures in the Amendment Act. While the world’s consciousness of the disease was being raised, both Zuma, the minister of health and president Mbeki found themselves punting an industrial solvent Virodene to treat AIDS patients. The then head of the Medicines Regulatory Authority Peter Folb was fired when he would not deal with Virodene.¹¹¹ Then spectacularly, the president cast doubt on the accepted causes of AIDS¹¹². His government and the health ministry were silently compliant and for a while the pharmaceutical industry looked good.

However while the AIDS pandemic was deepening, it was the non-governmental organizations (NGOs) like the Treatment Action Campaign (TAC), and Medecins Sans Frontiers (MSF) that took up the cudgels and fought the pharmaceutical companies and foreign governments.¹¹³ The pressure the industry later found itself under was largely the work of local and overseas AIDS activist groups, not the government. Government seemed to have dropped out of the struggle after realizing that S15 (c) of the Amendment Act put it in conflict with the pharmaceutical multinationals, only it was then too late. It was already in an Act to become law. Eventually largely due to pressure from civil society concerned about the AIDS epidemic, and lack of a united front among members, the PMA agreed and withdrew

¹⁰⁹ See S. 15(1)c former, (inserted under S. 10) of the Medicines and Related Substances Amendment Act No. 90 of 1997. Also see “S. 15 (c) at the centre of AIDS drug controversy”, available at (www.bdfm.co.za/cqi), accessed on 3 January 2001.

¹¹⁰ See Swarns R (n58 above).

¹¹¹ Ibid.

¹¹² Ibid.

¹¹³ See Heywood M “Debunking ‘Conglomo-talk’: A case study of the Amicus Curiae as an instrument for Advocacy, Investigation and Mobilisation 1, for a detailed discussion of the important role of national and international civil society and government’s negligible role and double standards in the battle against pharmaceutical companies in South Africa. Available at (www.tac.co.za/Documents/MedicineActCourtCase), accessed on 12 September 2002.

the case they had instituted in court against government.¹¹⁴ Of significance in this case is the manner in which the mere threat of a law providing for compulsory licenses and all the other pro- health mechanisms led to rapid and deep drops in the prices of patented anti- retro-viral medicines. At the beginning of 2001, triple therapy had cost approximately R3500 (US\$ 450) per month. By June 2001, the price of the same medicines had dropped to approximately R1000 (US\$125) per month. This may be argued as indicative of the size of the surplus that was being extracted from these medicines by the patent holders before they faced a challenge. On the other hand it highlights a distinction between issues of cost of research and development (herein after referred to as R & D) and price of drugs.

In response, the government gazetted regulations and later an amendment bill was tabled in parliament for debate.¹¹⁵ However to date these have only served to slow down the process of implementing a patent regime that makes drugs more cheaply available in South Africa. This position has also been strengthened by the president's lack of commitment to this cause evident in his reluctance and failure to sign the legal instruments necessary for the enforcement and implementation of a pro- health legal regime. Effectively the opportunities for health under the TRIPS agreement remain largely untested in South Africa.

3.8 The Case of an Application for a Compulsory License by Cipla Ltd

In March 2001, Cipla Ltd of Bombay, a pharmaceutical company operating in South Africa offered to sell a triple combination pill -Triomune similar to Trizivir patented by Glaxo Wellcome in South Africa.¹¹⁶ The company wrote to the department of Trade and Industry asking for a patent commissioner to grant it a compulsory license to sell up to eight AIDS drugs that were available at the time only from patent holding multi nationals.¹¹⁷ In effect Cipla was to sell drugs to South Africa for 600 dollars a year per

¹¹⁴ The legal suit that had initially been instituted was Pharmaceutical Manufacturers Association and others v President of the Republic of South Africa and others (TPD case no: 4183/98).

¹¹⁵ For a further discussion of the regulations and recommendations thereto, see Joint Submission: Medicines and Related Substances Amendment Bill, 2002, Portfolio Committee on Health, National Assembly, Parliament, 17 September 2002 (Joint submission by Treatment Action Campaign and Aids Law Project.(Drafted by Jonathan Berger of the AIDS Law Project).

¹¹⁶ See Heywood, M (n56 above) 9.

¹¹⁷ See Swarns, R (n58 above).

patient, a price about 400 dollars below the price offered by most big pharmaceuticals that held the patent. South Africa could have taken advantage of the offer only if it granted a compulsory license to Cipla, for instance on the ground that it was a situation of emergency and demand was not being met at fair prices. However with the patent law in South Africa it is unlawful to import, manufacture or distribute Triomune in view of the patents held on it. Effectively if the Medicines Control Council granted Cipla the said license, it would be breaking patent law thus no license was granted and the offer was never exploited, needless to say to the detriment of health in South Africa. There is a need to amend the patent laws so as to provide for compulsory licensing, parallel importing and other means of making drugs more cheaply available to the people through effective control of patent rights.

3.9 Brazil, A Comparative Study. Government Commitment is Essential

Although there are differences in the scale of the HIV/AIDS epidemic in Brazil and South Africa, the two countries have significant similarities. Both are middle-income countries and both have the capacity within the public health infrastructure to treat HIV, if there was political will and medicine made available. For example both countries have high rates of immunization against measles and TB, and high percentages of births attended by skilled staff.¹¹⁸ The most pertinent difference between South Africa and Brazil is that in the latter there is political commitment that has made it possible to utilize the TRIPS exceptions and demonstrated the relationship between patents, prices and the number of people on treatment. Since 1996 when Brazil took the decision to ensure access to anti retro-virals to 100% of identified HIV patients in the country,¹¹⁹ Brazil has repeatedly asserted its right to take legal measures to ameliorate the abuse of patent powers by excessive pricing. Brazil has embarked on generic production of the necessary drugs even before it became TRIPS compliant in 1996. This included drugs like Zidovudine patented by Glaxo Wellcome and Pfizer's anti-fungal Diflucan. The benefits of Brazil's generic production policy have been internationally recognized. According to UNAIDS, the annual cost of double therapy with nucleoside analogues decreased on average by 80% between 1996 and 2000. For a triple therapy the

¹¹⁸ UNDP, " Human Development Report, 2001, see Human Development Indicators (6) Commitment to Health: Access, services and resources 159.

¹¹⁹ According to the National AIDS Drug Policy of the Brazilian ministry of health, 2001, "Congressional Bill 9113 of 13 November 1996 guarantees every patient access, free of direct costs, to all the medication required for his/her treatment, including protease inhibitors."

cost reduction was 36% over the same period.¹²⁰ In the same breath the United Nations High Commissioner on Human Rights noted approvingly that generic production of anti retro-virals had saved the Brazilian government an estimated \$ 230 million.¹²¹ Another positive consequence of generic competition in Brazil was a drop in the prices of patented medicines as multinational companies aimed to compete with local manufacturers.¹²²

Despite pressure from the United States, the Brazilian government drafted its intellectual property law ensuring that the space left in TRIPS allowing countries to utilize compulsory licensing was exploited.

Since the law was passed, government has been prepared to use it and this has brought significant results.

In 2001, Brazil negotiated a price reduction of almost 70% for the anti retro-viral drug Efavirenz (patented by Merck) When similar negotiations failed to bring about a satisfactory result, it threatened to issue compulsory licenses for Nelfinavir, a protease inhibitor patented by Pfizer but licensed to Roche. This threat brought about a price reduction of 40% (from \$1.07 per pill to 64 cents per pill).¹²³ This elasticity in pricing is also an example of the lack of transparency in the real costs of drug development.

Pertinent to the foregoing argument is the manner in which government's commitment and thus positive implementation of the flexibilities within the TRIPS agreement resulted in better access and availability of drugs and improved health. This is true to the extent that despite the challenges to its success, Brazilian law providing for compulsory licenses and other TRIPS compliant means made possible a bold HIV/AIDS treatment program that has quickly become the largest in the world with demonstrable health outcomes. Corollary to this the United Nations Commissioner for Human Rights observed that in terms of the enjoyment of Brazilian's right to health, there has been a reduction in deaths due to AIDS by 50% over the last four years.¹²⁴ Further there has been a reduction of 80% in cases of hospitalisation due to opportunistic diseases with a reduction in the appearance

¹²⁰ UNAIDS, "Report of the Global HIV/AIDS epidemic" (June 2000)102.

¹²¹ Report of the High Commissioner (n10 above) para 52.

¹²² See Medecins Sans Frontieres, " Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing countries" (2001) 3: "Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over 5 years as a result of generic competition."

¹²³ In an "Official Note" issued by the Brazilian Ministry of Health on 22 August 2001 announcing the intention to "break the patent of the drug Nelfinavir" it was pointed out that a Brazilian government laboratory " had succeeded in producing the drug at a saving of 40% over that charged by Roche. This meant a saving of 88 million reais per year." Consumer Project on Technology, Brazil, accessed on 6 March 2002.

¹²⁴ See Pills and pocket books (n122 above).

of the most serious opportunistic diseases, tuberculosis (by 60%), citomeglovirus (by 54%) and Kaposi's sarcoma (by 38%).¹²⁵

Needless to say, the Brazilian example is a real lesson not only for South Africa but all those other developing and least developed countries in the process of making their laws TRIPS compliant amidst serious health crises.

3.10 The Question of Research and Development

Predominantly, multinational pharmaceutical corporations rely on the argument that increased use by developing countries of compulsory licensing and parallel importing is a serious threat to R & D funding for new drugs.

The International Federation of Pharmaceutical Manufacturers Associations (herein after referred to as IFPMA), which represents the research-based pharmaceutical industry and other manufacturers of prescription medicines also argues that compulsory licensing discourages research and development.¹²⁶ IFPMA suggest that compulsory licensing will slow the search for effective new medicines that are needed to address existing and emerging public health challenges. Specifically, IFPMA states that the use of compulsory licensing will lessen development of new AIDS drugs and other drugs for infectious diseases.¹²⁷

There is no doubt that R&D for new drugs is expensive and that R&D costs should be recovered during the initial years of marketing. Currently, most of the R&D costs are recovered from sales in industrialized countries where most of the patients have health insurance.¹²⁸ The main question is whether patients in poor countries should also pay for these costs.

Although the majority of the world's population lives in developing countries, these countries represent only a small proportion of the global pharmaceutical market. Africa, for example, accounts for only 1.3 percent of that market.¹²⁹ Consequently, lower prices for essential drug therapies in developing countries should not be a serious threat to R&D funding.

The very small size of the global pharmaceutical market represented by developing countries is the reason why only extremely limited investments are made into the diseases that mainly or solely affect people in developing countries.

¹²⁵ Ibid.

¹²⁶ See Duckett M (n38 above).

¹²⁷ Ibid.

¹²⁸ Ibid.

¹²⁹ Ibid.

Richard Laing has argued¹³⁰ that the global pharmaceutical market is so large (over \$400 billion per year) and the proportional contribution of Africa, Southeast Asia, and the Commonwealth of Independent States to both turnover and profit so small, that these markets could be completely isolated from the global total and pharmaceutical manufacturers would not be affected in any measurable way.

In addition, universal or widespread health insurance in most industrialized countries ensures that the burden of drug costs is rarely substantial for any individual. This is in marked contrast to the situation in most developing countries.¹³¹

3.11 Distinguishing the Case of Developing Countries

There is considerable debate about what level of return is required for marketed drugs, to compensate both for the R&D done for that product and for the R&D done in unsuccessful attempts to develop other drugs.

The argument that the only feasible model for promoting innovation in the high-risk and resource-intensive pharmaceutical industry is to guarantee the companies that invest in research an adequate period of exclusive rights for their products is devoid of the social responsibility that the pharmaceutical companies admit to.

IFPMA confirms that research-based pharmaceutical companies are socially responsible, and that Merck, Pfizer, Glaxo-Wellcome, SmithKline Beecham and other companies have made major financial and corporate commitments to addressing diseases that affect developing countries through product donation programs and price concessions. These programs are well appreciated but the companies' social responsibility remains even as the programs have failed to sufficiently deal with the AIDS crisis in the third world. In the context of social responsibility there is therefore need to adopt more effective means for the crisis facing human kind.

The total cost of drug development can be as high as \$500 million per drug.¹³² However, with respect to HIV-related drug therapies, it has usually been governments (rather than drug companies) that have paid for initial development, pre-clinical research and clinical research. For the pharmaceutical companies, this

¹³⁰ Richard Laing, Associate professor department of International Health, Boston University school of Public Health, reported in Duckett M,9 (n38above).

¹³¹ See Duckett M, (n38 above).

significantly lowers the costs of bringing these products to the market. For example, the costs of securing Federal Drug Authority (FDA) approval in the United States for HIV/AIDS drugs have been estimated to be only about \$25 million per drug.¹³³

There is the school of thought that the industry does not in fact engage in any significant effort to find cures to illnesses. That the efforts are superficial and primarily restricted to the refinement of government-produced products (e.g., T-20, ddI) or the development of alternative copycat drugs to government-sponsored efforts (e.g., the protease inhibitors, new nucleoside analogues). This is particularly obvious in the case of the HIV disease where every class of drug was discovered tested and developed by government agencies. Among these drugs are ddI, AZT, d4t, Ritonavir (including the structure of the proteinase enzyme), and T-20.¹³⁴ If this argument is believed then the pharmaceutical companies' contention of R&D costs may be devoid of substance.

Further support for the position that drug prices are not related to replacement of R&D costs is provided by the current price for Pentamidine.¹³⁵ Pentamidine was a cheap treatment developed to treat sleeping sickness. However, when it was found to be effective in the treatment of AIDS-related PCP (pneumocystis carinii pneumonia), the price of Pentamidine increased 500%. A recent survey of 20 African and Southeast Asian Countries conducted by UNAIDS found that Pentamidine is now available in only one of these countries.¹³⁶

The importance of R & D is acknowledgeable, but in light of social responsibility there remains no justification for the companies' uprising against the adoption of parallel importing, compulsory licensing and other pro-health strategies which are catered for in the TRIPS regime and are clearly effective tools in the fight to make drugs more cheaply accessible. Social responsibility should not be restricted to what the pharmaceutical companies choose to offer but on a holistic approach. In this context, poverty and the lack of affordability by the third world of even the reduced prices that the companies offer and the seriousness of the epidemic should be taken into consideration.

¹³² For a detailed report on costs of clinical trials, see Journal of health economics paper (1991).

¹³³ See Duckett M (n38 above).

¹³⁴ Ibid.

¹³⁵ Ibid.

¹³⁶ Ibid.

3.12 The Doha Declaration on TRIPS and Public Health

Led by Brazil, South Africa and India, the late 1990s saw a movement to mitigate the worst impacts of TRIPS aimed at creating a countervailing set of state duties. This battle popped up from time to time at the World Health Assembly, particularly at the time of discussion of the Revised Drug Strategy and in other fora. In 2001, it received renewed impetus from the South African court case¹³⁷, leading to better coordination between developing countries, better technical support from NGOS and high impact lobbying of industrialized countries.

In no unclear terms, the concern about TRIPS found its way to the meeting of the ministerial council of the WTO in Doha Qatar from 9 - 13 November 2001.¹³⁸

It can be argued that the anthrax scares that followed the terrorist attacks in the United States on September 11th 2001, also created a changed international mood where there was greater sensitivity to the centrality of access to medicine and health. As demand grew in the United States and Canada for drugs to combat anthrax, the pharmaceutical company Bayer was forced to sell Ciprofloxacin at a substantially reduced rate after threats that both countries would otherwise issue compulsory licenses. The parallels with the demand for AIDS medicine were unavoidable.

By the time of the Doha meeting it would have appeared unconscionable to deny other countries the right to determine what constituted a public health emergency. The ministerial Declaration on the TRIPS Agreement and Public Health resulting from the meeting recognizes that TRIPS does not prevent countries from taking measures to protect public health and that the WTO members are entitled to use TRIPS provisions which provide flexibility for this purpose. The Declaration states that:

“(b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”

“(c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”¹³⁹

¹³⁷ See TAC appeal case (n17 above).

¹³⁸ The ministerial conference is the highest decision making body of the WTO and it can make decisions on all matters under any of the WTO Agreements, including the TRIPS Agreement

¹³⁹ Available at (http://www.chil.wto-ministerial.org/english/thewto_e/minist_e/min01_mindecl_trips_e.htm), accessed on 11 December 2001.

In addition the Declaration extends until January 2016 the obligation for least developed countries to fulfill their obligations under TRIPS. It also recognizes the difficulty countries with insufficient manufacturing capacity face in making effective use of compulsory licensing provisions. Thus the council for TRIPS is instructed to find an expeditious solution to this problem before the end of 2002.

The Declaration is the strongest and most important international statement yet on the need to refashion national patent laws to protect public health interests. It recognizes the sovereignty of governments to take appropriate measures to get around to the expectations of the poor patients in their countries. It is a political statement that did not modify the TRIPS Agreement and a road map for using the flexibility of the TRIPS to protect public health and sets a standard to measure any new bilateral or regional trade agreement. In practical terms it means that national governments are not at the mercy of multinational corporations when they practice price gouging.

One particular area that remains a concern that the TRIPS council must sufficiently deal with is the Article 31 (f)¹⁴⁰ limitations on exports of medicines manufactured under a compulsory license. One proposal in this regard is use of Article 30 of TRIPS to export medicines to countries that do not have the domestic capacity for manufacturing.

The Doha Declaration on TRIPS contains both a promise and an obligation to interpret and implement the TRIPS Agreement in a manner supportive of the WTO members' right to protect public health and promote access to medicines for all. It now remains the duty of the TRIPS council to implement the entire Declaration in good faith, ensuring that the safeguards of the TRIPS work for both rich and poor countries, for countries with large or small domestic markets, and for countries with different levels of technological development.

¹⁴⁰See addendum (page 64).

4. Chapter Three

4.1 Other Means of Lowering Drug Prices

To lower the cost of HIV/AIDS drug therapies in developing countries, a number of approaches have been tried or are currently being used, of which parallel importing and compulsory licensing are but two. The adaptation of a particular approach largely depends on factors prevailing at the national level.

4.2 Generic Substitution

Generic substitution compels pharmacists to prescribe a cheaper generic version of a medicine, if one exists, when presented with a prescription from a patient. For example if a doctor in South Africa prescribes Bactrim (at approximately R95 for a pack of 20), the formerly patented brand name of an essential medicine with the scientific name of cotrimoxazole, to a patient, who then goes to a pharmacy to obtain the medicine. The pharmacist will be obliged to prescribe a cheaper generic version such as Purbac (at approximately R16 for a pack of 20)¹⁴¹. However if the doctor prescribed “no substitution” then the pharmacist does not have to substitute a brand-name drug with a generic.

Generic substitution however does not apply to medicines under patent unless a compulsory license has been granted for a generic.

4.3 Pricing Committee and International Tendering System

The idea behind having a pricing committee within a patent legal system is to ensure that pharmacists and pharmacies are accountable for the prices they set. The pricing committee has to set up transparent pricing mechanisms through which pharmaceutical companies have to justify the prices they charge for medicines.¹⁴²

A pricing committee can recommend that the minister of Health make regulations on the introduction of a transparent pricing system for all medicines. Drug companies may be allowed to set a single exit price for any medicine, meaning that pharmacies will not be allowed to charge an amount higher than the exit price.

¹⁴¹ “An explanation of the Medicines Act and the Implications of the court victory” available at www.tac.org.za/newsletter/ns0101424.txt+regulations, accessed on 20 October 2002.

¹⁴² See Berger J, joint submission (n111 above).

Instead the committee may recommend a fair dispensing fee that pharmacists can charge instead of a markup.

4.4 Therapeutic Value Pricing

This approach has been adopted in Australia.¹⁴³ The Pharmaceutical Benefit Pricing Authority (an official, independent body) determines the drug price on the basis of therapeutic value. When a new drug becomes available for marketing, the benefits and health outcomes of the new drug are carefully compared with similar, existing drugs and a comparative price is estimated.¹⁴⁴ For example, a new drug may provide a small benefit compared to an existing drug, so the Pricing Authority may declare that the government will be willing to purchase the new drug at a 10% increase over the price of the existing drug. The manufacturer then determines if it wishes to sell its drug at this price. Sometimes, negotiation for a mutually acceptable price can take months.

4.5 Pooled Procurement

For countries with small national populations, pooled procurement may be an option. This has been tried in the Caribbean, where seven different countries have joined together to purchase drugs.¹⁴⁵ This approach, which started in the 1980s, has enabled these countries to reduce prices by around 50%¹⁴⁶. In addition, this combined operation has allowed the countries involved to develop a single multi-country unit with expertise in drug evaluation and price negotiation.

4.6 Negotiated Procurement.

Large organizations buying drugs in large amounts can also bring down prices. For instance, some large health maintenance organizations in the United States have been able to negotiate significantly lesser prices than the official price of a drug (i.e. more than official discounts for bulk orders)¹⁴⁷.

¹⁴³ See Duckett M (n38 above).

¹⁴⁴ Ibid.

¹⁴⁵ Ibid.

¹⁴⁶ Ibid

¹⁴⁷ Ibid.

4.7 Planned Donations

In the past, many countries have received donations of about-to-expire stocks of drugs. The World Health Organization (WHO) is now encouraging planned donation programs for drugs that are still in use. For example, Johnson and Johnson now have a planned giving program (addressing a range of diseases), with three years of donations planned three years in advance¹⁴⁸.

4.8 Lobbying Pharmaceutical Companies

UNAIDS has lobbied pharmaceutical companies to lower the prices of their drugs in developing countries.¹⁴⁹ Their current four-country treatment pilot initiative has resulted in slightly lower initial prices for retroviral and other drugs bought through the pilot program. In addition, treatment activists in many countries have been lobbying many pharmaceutical companies directly for some years¹⁵⁰. One result was the decision by Glaxo Wellcome in 1997 to halve the then cost of an annual course of AZT - the price is still substantial however.

¹⁴⁸ See Duckett M (n38 above).

¹⁴⁹ Ibid.

¹⁵⁰ Ibid.

5. Recommendations and Conclusion

In May 1999, the 52nd World Health Assembly in Geneva passed a resolution, which urged countries to "explore and review their options under international agreements, including trade agreements, to safeguard access to essential drugs."¹⁵¹ It charged the WHO with, "monitoring and analyzing the pharmaceutical and public health implications" of these agreements.

As part of the process, NGOs are working with WHO to develop a monitoring system to enable NGOs, WHO and other actors to track drug prices and assess the level of access to essential drugs.¹⁵²

In line with all these and other efforts to realize the right to health, it would seem obvious that any government or pharmaceutical company would be committed to the cause. However as is apparent from the discussion above, when it comes to realizing the right at the national level, there is more than meets the eye. Informal pressure from within and abroad influences to a great extent the decisions of governments in the third world. Indeed the motives of the foreign governments and multi national corporations (MNCs) are purely profit. The profit drive is being fronted at the expense of human wellbeing, in contradiction of government and the MNCs commitment to good leadership and making drugs available to developing countries at affordable prices respectively.¹⁵³ There is need to refocus the urgent need to make health a reality for all by all actors. The double standards should be dropped.

The Doha Declaration on the TRIPS agreement and Public Health is an indication of how crucial the debate on realizing the right to health in the IP regime has become. The submission of this thesis is that the guarantee for the right to health is at the national level. The opportunity available at the international level remains only an opportunity unless positively exploited at the national level, and this involves all actors.

¹⁵¹ Available at (www.who.org), accessed on 8 September 2002.

¹⁵² Duckett M, (n23 above).

¹⁵³ See Piot P speech (n1 above).

5.1 Recommendations at the National Level

People with greater knowledge of the role strategies such as parallel importing and compulsory licensing can play in improving access to medicines should work with relevant authorities as new patent legislation is being put in place. If domestic governments request it, technical assistance to frame their laws to meet the requirements of TRIPS is available from WIPO¹⁵⁴.

Decisionmakers in the health sector can obtain useful information from “Globalization and Access to Drugs: perspectives on the WTO/TRIPS Agreement,” a WHO/DAP publication that discusses the impact of trade agreements in the pharmaceutical field and offers guidance on how to interpret the requirements of TRIPS.

NGOs and other civil society groups should inquire about the status of their domestic law provisions covering compulsory licensing and parallel importing, and lobby for changes in these laws if they are more restrictive to health than the requirements of the TRIPS Agreement.

There should be networking between local and international NGOs. International NGOs are able to keep track of events at international level and they can inform local NGOs of new developments so as to lobby the national authorities for pro-health developments. National NGOS would also benefit from the fact that the international NGOs are directly involved in the TRIPS, patents, drugs and other health issue discussions that prevail at international level.

In addition, legal professionals in the relevant offices in developing and least developed countries should be trained in issues of intellectual property and health so as to acquire the necessary expertise to analyze the arising issues in the international arena. Such education would also enable relevant national offices to appreciate the need for the adoption of pro-health national patent regimes.

There should be dialogue between NGOs, national authorities and pharmaceutical companies about the issues of health and drug affordability and accessibility with a view to try and find some common ground. Above all, all actors should refocus their

¹⁵⁴ The World Intellectual Property can be accessed on (www.wipo.org) and further information on TRIPS, patents and availability of drugs is available at (www.wto.org), (www.cptech.org), (www.tac.org.co.za), (www.icaso.org), (www.unaids.org).

commitment to the realisation of the right to health.

5.2 Conclusion

Ultimately, a human rights approach requires that intellectual property protection serve the objective of human well-being, to which the international human rights instruments give legal expression. Human rights are inalienable and universal claims belonging to individuals and in some situations to communities, but never to multi national corporations. Human rights are understood to exist independent of recognition or implementation while intellectual property rights are granted by the state according to criteria defined by national legislation. In contrast with human rights establishing permanent and irrevocable entitlements, intellectual property rights are temporary; they exist for a limited period and can be revoked, licensed or assigned to someone else.¹⁵⁵

This argument has received renewed impetus in 2001 as a result of the actual clashes between intellectual property rights and the rights to health. In April 2001 for example, the United Nations Human Rights Commission approved a resolution, sponsored by Brazil on "Access to Medication in the context of pandemics such as HIV/AIDS (from which the United States was the only country to abstain)."¹⁵⁶ In June 2001, the UN High Commissioner for Human Rights published a report on The Impact of the Agreement on Trade 'Related Aspects of Intellectual Property Rights on Human Rights. In December 2001, the U N Committee on Economic Social and Cultural Rights issued a statement on Human Rights and Intellectual Property. This statement includes the unambiguous assertion that any intellectual property regime that makes it more difficult for a state party to comply with its core obligations especially in relation to health, food, education or any other rights as set out in the ICESCR is inconsistent with the legally binding obligations of the state party."¹⁵⁷

Regulation of the global economy must not be divorced from global social problems. Intellectual property law should be considered within the body of international human rights law, and be implemented consistently with human rights. A new

¹⁵⁵ Audrey Chapman, "American Association for the advancement of Science: New Projects focus on Intellectual Property and Human Rights" Report on Science and Human Rights Winter, 202Vol. XX11, No.1, available at (<http://shr.aaas.org/report/xxii/ip>), accessed on 17 March 2002.

¹⁵⁶ 'United States Abstains from vote on AIDS Drugs Resolution: Measure to increase access is "flawed," ambassador says' Washington File USIS-23 April 2001, available at (www.aegis.com/news/usis/2001), accessed on 17 May 2001.

international legal creation should be constructed that both makes bodies like the WTO accountable for their actions and builds within them a consciousness of human rights. A human rights approach would explicitly place the protection and promotion of human rights in particular those in the ICESCR at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinate to other provisions of the TRIPS agreement.

Many factors contribute to health. Access to food, clean water, general sanitation and shelter are all as important as political will within a country. Both prevention and treatment programs and services are necessary as is research directed towards diseases affecting those in developing countries. To suggest that any of these measures may be sacrificed is to take a simplistic view of a highly complex world. But to suggest that intellectual property law now partnered with world trade law is not a significant factor in determining accessibility to and availability of drugs is an even more simplistic view. This law was clearly designed to ensure control over access to patented drugs by the manufacturer, predominantly the research based pharmaceuticals of the developed world.

The impact of patent law on health is significant and needs to be addressed. It must be judged against and made accountable to other more pressing ethical and legal considerations.

That said however, the era of globalisation of which the WTO and TRIPS are instruments is regrettably here to stay. As human rights activists struggle with bringing it in line with human right norms, the main proposal of this research is that in the meantime national governments should ensure that their national patent laws wring from the system as much as it can. In the context of the TRIPS and the right to health particularly in developing countries, national governments remain obliged to create the enabling environment and pharmacists to refocus their commitment particularly in terms of their social responsibility for the realisation of the right to health. This can be done by adopting (and monitoring the effectiveness of) national patent laws that allow compulsory licensing, parallel importing and all other pro-health strategies with the commitment to realise the right to health of the people.

Word count: 17,202 (including footnotes)

¹⁵⁷ Human Rights and Intellectual Property, Statement by the Committee on Economic Social and Cultural Rights, United Nations Economic, Social and Cultural Council, 14 December 2001 (E/C.12/2001/15) paras 4 and 6.

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Convention on the Rights of the Child

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International Covenant on Economic, Social and Cultural Rights

Universal Declaration on Human Rights

The Vienna Convention on the Law of Treaties

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7. Addendum

At the close of this writing, discussions by the TRIPS council following the Doha Declaration on TRIPS and Public Health have started, and the world waits to see whether they shall create fruitful and binding obligations in respect to enhanced realisation of the right to health. For a clear understanding and evaluation of what the council may come up with and the discussion above, this addendum outlines the articles of the TRIPS Agreement that have formed the discussion in the thesis for further reference.

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.¹⁵⁸ In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.¹⁵⁹ Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the

¹⁵⁸ When nationals are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

¹⁵⁹ In this Agreement, “Paris Convention” refers to the Paris Convention for the Protection of Industrial Property; “Paris Convention (1967)” refers to the Stockholm Act of this /convention of 14 July 1967. “Berne Convention” refers to the Berne Convention for the Protection of Literary and Artistic Works, “Berne Convention (1971)” refers to the Paris Act of this Convention of 24 July 1971. “Rome Convention” refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, adopted at Rome on 26 October 1961. “Treaty on Intellectual Property in Respect of Integrated Circuits” (IPIC Treaty) refers to the Treaty on Intellectual

Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the “Council for TRIPS”).

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological

Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. “WTO Agreement refers to Agreement establishing the WTO.

development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27

Patentable subject matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.¹⁶⁰ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

¹⁶⁰ For the purposes of this article, the terms “inventive step” and “capable of industrial application” may be deemed by a member to be synonymous with the terms “non obvious” and “useful” respectively.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorisation of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.¹⁶¹

¹⁶¹ It is understood that those members who do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Article 66

Least-Developed Country Members

In view of the special needs and requirements of least developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this agreement other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of article 65. The council for TRIPS shall, upon duly motivated request by a least developed country member accord extension of this period.

Developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to

least developed country members in order to enable them to create sound and viable technological base.