Alison Elizabeth Gill
ID NUM: GLLALI003
LLM in International Law Dissertation
SUPERVISOR: Professor Pierre de Vos

# *Is the TRIPS Agreement and its' safeguards still a stumbling block in fulfilling the right to health and if so what should be done?*



Research dissertation presented for the approval of the Senate in fulfilment of the requirements for the LLM in International Law in approved courses and a minor dissertation. The other part of the requirement for this qualification was in completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of LLM dissertations, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

**Signed.** Signed by candidate

**Date**....12/2/10.....

CONTENTS Page

# Acronyms

AIDS – Acquired Immune Deficiency System

ART – Antiretroviral Treatment

ARVs– Antiretrovirals

GATS – General Agreement on Trade and Services

GATT – General Agreement on Trade and Tariffs

G8 – Global Eight

HIV - Human Immunodeficiency Virus

ICESCR – International Covenant on Economic, Social and Cultural Rights

IP – Intellectual Property

IPRs – Intellectual Property Rights

LDCs – Least Developed Countries

MFN – Most Favoured Nation

MSF – Medicines Sans Frontiers

NGO's – Non-Governmental Organisation

NT – National Treatment

R&D – Research and Development

TRIPS – Agreement on Trade-Related Aspects of Intellectual Property Rights

UNDHR – Universal Declaration on Human Rights

UNICEF – United Nations Children's Fund

WHO – World Health Organisation

WIPO – World Intellectual Property Organisation

WTO – World Trade Organisation

WWII – World War Two

## Executive Summary

In order to meet the Millennium Development Goals by 2015 the world must radically rethink the means of achieving the targets set by these Goals. The developing world is crippled by poverty and disease; HIV/AIDS is rife in Africa and is spreading at frightening speed to many other parts of the globe. World Health Organisation (WHO) figures suggest that in 2008 33 million people were infected with HIV.

Chapter 1 shall consider the problem of the AIDS/HIV epidemic in more detail and the international response so far. The chapter shall then look at the various sources of international law within a human rights context to determine whether states have an obligation to do something about the disease.

Preventative strategies on their own however will not effectively deal with the pandemic; in order to reverse the tide medical professionals also require access to essential drugs to treat patients already infected. One of the greatest hurdles to overcome is the patentability of pharmaceuticals in the health sector; such patents are undoubtedly limiting the availability and affordability of the life saving anti-retroviral medicines (hereinafter ARV's) required to treat the disease. If we are to combat HIV/AIDS and other diseases it is essential that society looks towards changing the pharmaceutical protection that is afforded under the TRIPS Agreement. Under this Agreement pharmaceutical manufacturers are able to patent their brand of drug which prevents other companies from selling the same drug without the patent owner's permission for a potential period of 20 years. At present the vast majority of the world's developing population are unable to afford costly life saving medicines. The TRIPS Agreement and the concept of pharmaceutical patents allow drug manufacturers to keep the cost of medicine high without the fear of competitor drugs and the medicines can therefore be given an artificially high price. In the context of HIV/AIDS, in developing countries where people often have to pay for ARV's out of their own pocket it is vital that they are affordable. Countries like India have previously been able to manufacture cheaper generic medicines as the pharmaceutical industry was not protected under Indian patent law, but since the

introduction of the TRIPS Agreement, pharmaceuticals now fall under the rules of international intellectual property protection. Chapter 2 aims to discover the concept behind intellectual protection for pharmaceuticals, it shall also look at the international regulatory bodies of intellectual property.

The World Trade Organisation is the international forum in which the TRIPS Agreement was born and one of the main objectives of the organisation as a whole is to increase standards of living, yet the concept of drug patenting appears to contradict this objective. The TRIPS Agreement therefore includes flexibilities to allow WTO Members to be able to provide essential medicines including ARV's to the public, Chapter 3 shall begin by looking at the TRIPS Agreement and the safeguards provided within the agreement. Over the last decade the provisions of the TRIPS Agreement has been a disputed issue and the Agreement has undergone changes during further WTO negotiation rounds. Concerns were aired during the World Trade Organizations negotiations in 2001 at the Doha Ministerial Conference and the topic has remained a controversial one ever since. Chapter 3 shall continue by looking at the international declarations created from recent WTO negotiations.

Developing countries are pushing for an even broader scope of patent applications which would result in more pharmaceutical products becoming patentable for 20 years. As the process of globalisation continues, new trade agreements are having a greater impact upon access to drugs. On the one hand inventors should be rewarded for their efforts in researching and developing medicines, on the other, humanity has a right to health which includes access to treatment. International Law is often faced with conflicting rights; in this situation a balance must be struck which reflects the interests of the right to health and the right to intellectual property protection.

In recent years the link between the right to health and the topic of medical patents has become an issue for debate on the world stage. The enforcement of the Agreement on Trade-Related Aspects of Intellectual Property has to some extent harmonized patent laws and set a higher minimum standard of protection and for the enforcement of intellectual property for countries to guarantee. This has greatly worried many developing nations and health organisations in relation to the impact this has on access to essential medicines especially in the area of HIV/AIDS

treatment. Chapter 4 shall look at the conflicts of norms in international law and how such situations should be dealt with in both a human rights context and within the WTO framework.

Modern technology makes it possible to treat many diseases including HIV, however until an effective mechanism in dealing with the problems of patenting is enforced the health of some of the poorest nations are unable to benefit. Chapter 5 shall look to the possible solutions in solving this conflict.

The outcome of this dissertation is to show that the current (amended) Agreements and Declarations are still failing in their intention to provide that balance between the right to health and intellectual property rights, using access to HIV/AIDS medicines as a prime example. It shall be argued that conflicts between these norms in International Law must be addressed, and the current flexibilities in the TRIPS Agreement should be reviewed.

# Chapter 1 The Right to Health

## 1.1 The HIV/AIDS Pandemic

The HIV/AIDS virus is recognised as the world's largest health problem; a joint venture has been launched by the United Nations and the Millennium Development Goal Number 6, which states that its aim is to halt and reverse the spread of the disease by 2015. A survey by UNAIDS[1] discovered that,

> Every day, over 6800 persons become infected with HIV and over 5700 persons die from AIDS, mostly because of inadequate access to HIV prevention and treatment services.[2]

Although the problem affects people worldwide statistics report that almost 70% (approx 22 million) of the global total of people living with HIV, live in sub Saharan Africa.[3]

AIDS is caused by the HI virus that weakens the immune system and is transmitted through sexual fluids, blood and breast milk. As Hestermeyer explains,

> HIV attaches itself to the body's T4 lymphocyte cells and reprograms them to produce new viruses which are later released to infect new cells. The T4 lymphocytes are part of the body's immune defence, so the infection with HIV leaves the body defenceless against a number of opportunistic infections, which can cause the death of the patient.[4]

There is no cure for AIDS but HIV may be treated effectively with antiretroviral drugs and sufferers may live for many years without developing AIDS. This is only true however if they have access to antiretroviral drugs. The HIV/AIDS virus can be kept at bay using a combination of ARV drugs. In order to keep HIV from progressing standard ARV therapy uses a combination of a minimum of three ARV drugs.[5] Studies have shown that in countries where HIV patients have access to ARV therapy the mortality rate from AIDS is greatly reduced. The joint report from UNAIDS and WHO on the AIDS Epidemic 2009 found that,

---

[1] UNAIDS available at www.unaids.org
[2] Available at http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf
[3] UNAIDS 2008 Annual Report pg 7 available at http://data.unaids.org/pub/Report/2009/jc1736_2008_annual_report_en.pdf
[4] Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, Oxford University Press, 2007, pg 7
[5] World Health Organisation, 'Antiretroviral Therapy' available at http://www.who.int/hiv/topics/treatment/en/

> In a multicentre study in 12 high income countries, the rate of excess mortality among people living with HIV in comparison with the HIV uninfected population declined by 85% following the introduction of highly active antiretroviral therapy.(Bhaskaran et al.2008).[6]

In order to combat the disease it is essential therefore that patients with HIV have access to ARV treatment. The ARV drugs required to treat HIV feature on the World Health Organisation's list of essential drugs.[7]This is a list that the WHO considers to be essential to the community and necessary to satisfy the basic health care requirements of the majority of a state's population, it is reviewed and updated every two years. The WHO explains that,

> Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[8]

In reality however not everyone that requires ARV's are receiving them. The diagram below shows the estimated number of adults and children (combined) that were receiving antiretroviral therapy and those still needing antiretroviral therapy and the percentage coverage in low- and middle income countries by region, as at December 2008.[9]

[6] The WHO/UNAIDS Epidemic Update 2009 at page 16 'Impact of Increased Access to Treatment on epidemiological trends'

[7] WHO published list of Essential Medicines 16th List, March 2009 available at http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf

[8] World Health Organisation Essential Medicines available at http://www.who.int/topics/essential_medicines/en/

[9] 'Towards Universal Access, Scaling up Priority HIV/AIDS interventions in the health sector', WHO Progress report 2009 available at http://www.who.int/hiv/pub/2009progressreport/en/index.html pg 57
Note: some numbers do not add up due to rounding.
a For an explanation of the methods used see explanatory notes for Annex 1. See Box 4.2 on estimating treatment need for an interpretation of the data on antiretroviral therapy need and coverage in 2007 and 2008.
b The coverage estimate is based on the unrounded estimated numbers of people receiving and needing antiretroviral therapy

| Global Region (low and middle income countries) | Estimated number of people receiving antiretroviral therapy, December 2008 [range] | Estimated number of people needing antiretroviral therapy, 2008 [range]a | Antiretroviral therapy coverage, December 2008 [range]b |
|---|---|---|---|
| **Sub-Saharan Africa** | 2 925 000 [2 690 000–3 160 000] | 6 700 000 [6 100 000–7 100 000] | 44% [41–48%] |
| **Latin America and the Caribbean** | 445 000 [405 000–485 000] | 820 000 [750 000–870 000] | 54% [51–60%] |
| **East, South and South-East Asia** | 565 000 [520 000–610 000] | 1 500 000 [1 200 000–1 900 000] | 37% [31–47%] |
| **Europe and Central Asia** | 85 000 [80 000–90 000] | 370 000 [310 000–450 000] | 23% [19–27%] |
| **North Africa and Middle East** | 10 000 [9 000–11 000] | 68 000 [52 000–90 000] | 14% [11–19%] |
| **Total** | **4 030 000 [3 700 000–4 360 000]** | **9 500 000 [8 600 000–10 000 000]** | **42% [40–47%]** |

The table shows that although the problem of access to ARV's is not confined to the developing world, it is most prevalent there especially in Sub-Saharan Africa. Sub-Saharan Africa is the poorest region in the world, the World Bank estimates that in 2005 384 million people were living on less than $1.25 per day.[10] Poverty and HIV/AIDS are problems that go hand in hand in this region, the Overseas Development Institute produced a working paper in January 2009 that commented,

> Households affected by HIV/AIDS commonly have less income, reduced food security and are more vulnerable to other shocks, such as drought ...HIV/AIDS is also putting considerable strain on public service delivery and government budgets, and on social cohesion and stability.[11]

[10] Online Atlas of the Millennium Development Goals, Map on'Eradicating Poverty and hunger'. Available at http://devdata.worldbank.org/atlas-mdg/

[11] Overseas Development Institute, 'Poverty and poverty reduction in Sub Saharan Africa: An Overview of the issues' January 2009, pg 4 available at http://www.odi.org.uk/resources/download/600.pdf

The spread and severity of the HIV/AIDS epidemic as well as the knock on effects from the disease has led to an international response from governments, international bodies and NGO's. A series of global declarations and commitments, especially in the run up to the Millennium were made by the United Nations in an attempt to deal with the spiralling AIDS epidemic. The UN Millennium Declaration recognised that AIDS was a major barrier in achieving the Millennium Declaration Goals.[12]UNICEF has stated that,

> Poorer countries face the most severe impacts of the epidemic, with the vast majority of all AIDS cases occurring in the developing world. Inadequate nutrition, health care, education and economic opportunities all contribute to the spread of HIV and shorten the life span of those infected. At the same time, the staggering burden that HIV and AIDS imposes on populations and resources worsen poverty in communities most affected. The inability of communities and families to develop the human and social capital required to overcome poverty generates a vicious cycle...[13]

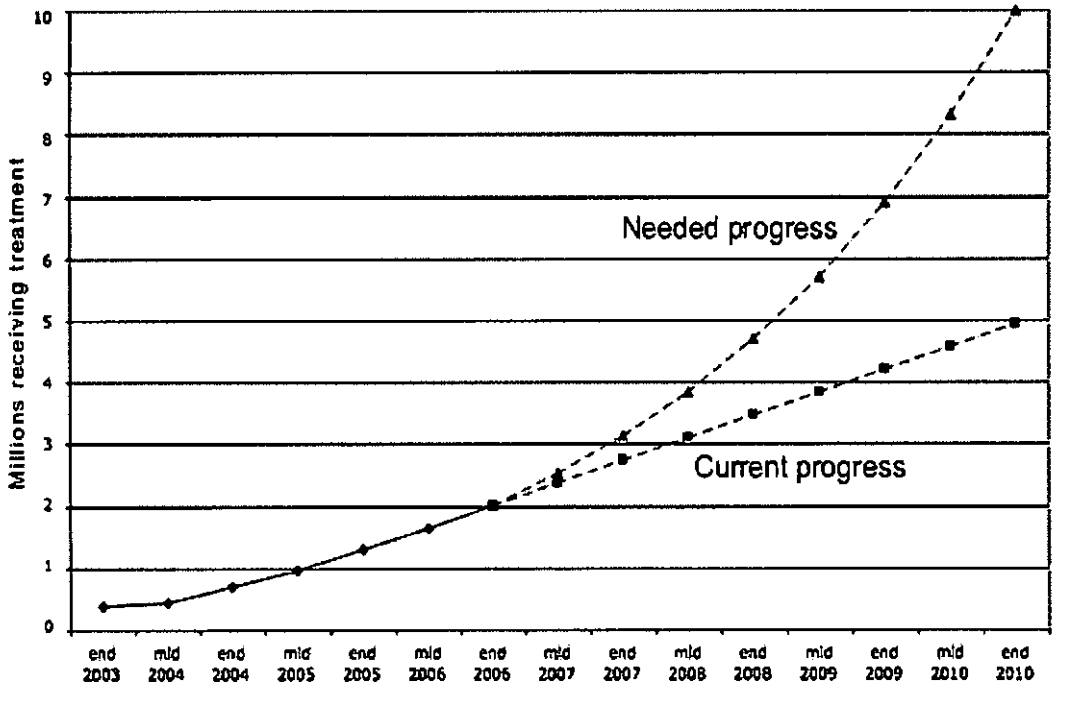
In 2001 the UN adopted a Declaration of Commitment on HIV/AIDS, calling for countries to have appropriate care strategies in place by 2005.[14]The WHO and UNAID launched the '3 by 5' initiative which aimed to have 3 million infected people in low and middle income countries receiving antiretroviral treatment (ART) by 2005.[15]At the G8 Summit in 2005 a milestone was reached when leaders agreed on a package for development for Africa, which outlined the plan to have '[a]s close to universal access to HIV/AIDS treatments as possible by 2010;'[16]In 2006 WHO carried out a progress study entitled 'Towards Universal Access - Scaling up priority HIV/AIDS interventions in the health sector'. The UN AIDS Report estimates that for every two people that start ARV treatment another five become infected.[17]Therefore there is a constant need to ensure that access to lifesaving ARV's is a priority in order to tackle the AIDS problem. The UN has also adopted a

[12] UN Millennium Declaration 2000 Available at http://www.un.org/millennium/declaration/ares552e.htm
[13] UNICEF Caring for Children Affected by HIV and AIDS 2006, Innocenti Research Centre, Tipografia Giuntina, Florence, Italy 2006 pg 6
[14] Declaration of Commitment on HIV/AIDS 2001 Available at http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html
[15] WHO The 3 by 5 Initiative Available at http://www.who.int/3by5/en/
[16] G8 Policy Issues Available at http://www.g8.gov.uk/servlet/Front?pagename=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1094235520151
[17] UNAIDS Annual Report 2008 Pg 11 Available at http://www.unaids.org/pub/Report/2009/jc1736_2008_annual_report_en.pdf

resolution indicating its support for the 2010 target.[18]The Political Declaration on HIV and AIDS 2006 furthered this plan when the General Assembly recognised in the resolution adopted on 2nd June 2006 that;

> ...to mount a comprehensive response, we must overcome any legal, regulatory, trade and other barriers that block access to prevention, treatment, care and support; ...promote and protect all human rights and fundamental freedoms for all;[19]

In 2009, statistics showed that the current trend is positive; more people are now receiving ART than ever before but to celebrate this achievement would be premature. In order to achieve close to universal access to ARV's for people who need them by 2010 the pace will have to quicken. The international AIDS organisation Avert has estimated that a much greater effort is needed.




The Need for Faster Progress[20]

In constructing an argument that individuals should have a right to access ARV treatment international law can provide a foundation platform under various human

[18] Resolution 60/224. Preparations for and organization of the 2006 follow-up meeting on the outcome of the twenty-sixth special session: implementation of the Declaration of Commitment on HIV/AIDS Available at http://data.unaids.org/topics/ungass2003/a60-l43_2005_en.pdf

[19] Resolution 60/262 Political Declaration on HIV/AIDS paragraph 15 http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf

[20] Avert The need for faster progress Available at http://avert.org/aidstarget.htm

rights conventions. The next section shall look at international law in the context of the HIV/AIDS debate in an effort to seek support for the view that individuals have a right to health and within that right, access to essential medicines.

### 1.2 International Law, the Right to Health & Access to Essential Medicines

International law is comprised of a variety of sources each of which will be analysed in turn. The Universal Declaration on Human Rights is one of the most significant international human rights documents and provides a starting point.

> Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.[21]

Article 25(1) of the Universal Declaration on Human Rights recognises that a right to health certainly exists,[22] yet despite the right being acknowledged as early as 1948 the world is struggling to define and indeed achieve such a standard. The United Nations, NGO's and governments alike have all expressed a commitment to improving the health of the worlds' people but the challenge has been greater than anyone imagined. This chapter hopes to focus on the concept of the right to health and to assess its justiciability within the international rights framework. If it can be shown that access to medicines is included as a component of the right to health the case strengthens for ARV's to be available for all.

The World Health Organisation was established under Article 57 of the UN Charter in 1948 and brought into existence an organisation to take control of global health. The WHO Constitution recognised in its preamble that the world population had a right to 'the enjoyment of the highest attainable health' and explains the right under the broad terms of, 'complete physical, mental and social wellbeing.'[23] Whilst this broad view of the right can be said to be positive in extending the scope of health

---

[21] Universal Declaration on Human Rights, Article 25(1). http://www.unhchr.ch/udhr/lang/eng.htm

[22] Note it is acknowledged that the UDHR is not a binding treaty but it is highly regarded within the international community and can be described as the inspiration for later human rights treaties that are of a more binding nature. See *Hestermeyer*, supra note 4 at pg 120

[23] World Health Organisation Constitution Preamble available at http://www.who.int/governance/eb/who_constitution_en.pdf

beyond a limited definition the WHO Constitution preamble has no legal enforcement under international law.[24]

### 1.3 International Covenant on Economic, Social and Cultural Rights

It was only after the introduction of the International Covenant on Economic, Social and Cultural Rights did the right take on more meaning. The ICESCR is the most widely Covenant on economic, social and cultural rights with 160 states having ratified.[25]The Covent is binding on all those that are a state party to it and can be described as 'one limb of the hard version of the UDHR'[26] and places the following obligations on states under Article 2(1).

> Each State Party to the present Covenant undertakes to take steps individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.[27]

The monitoring body for the Covenant known as the Committee on Economic, Social and Cultural Rights can provide guidance by way of issuing General Comments for states to follow.[28] The Committee gives a further explanation of Article 2 and the nature of a state's obligations in General Comment Number 3. The Committee recognises that states will each have differing resources and other constraints and therefore they appreciate that the rights under the ICESCR are progressive. However they stress that the full realisation of rights is ultimately the final goal; a country's difficult financial situation does not release it from continuing to progress towards this end result.[29]

The Committee thus introduces the concept of meeting minimum core obligations in General Comment Three explaining,

---

[24] *Hestermeyer*, Supra note 4 at pg 113

[25] As at 25th January 2010 according to the United Treaty Collections available at http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en

[26] Chirwa, Danwood, 'The Right to Health in International Law: Its implications for the obligations of state and non state actors in ensuring access to essential medicines'. (2003) 19 SAJHR

[27] International Covenant on Economic, Social and Cultural Rights 1976 Article 2(1) available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm

[28] The general comments issued by the Committee are not legally binding but they are often influential sources in the interpretation of the provisions of the treaty.

[29] General Comment 3 'The Nature of State Parties' Obligations (art 2(1) of the ICESCR) (5th session, 14 December 1990) Para 9.

> ...at the very least, minimum essential levels of each of the rights is incumbent upon every State party. Thus, for example, a State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, failing to discharge its obligations under the Covenant.[30]

In relation to the right to health Article 12 of the ICESCR defines the right as,

> ...the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.[31]

The recognising that the right to health under the Covenant is a progressive right, states are reminded that they still,

> ...have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of the right to health.[32]

The state must therefore take positive steps to realise the right to health, it cannot simply sit back and do nothing despite lacking in resources. The Limburg Principles on the Implementation of the ICESCR confirm this approach at paragraph 23,

> The obligation of progressive achievement exists independently of the increase in resources; it requires effective use of resources available.[33]

A major problem with the right to health is often in understanding what the right actually entails and what is expected of the state. The scope of Article 12 was felt too broad to have any specific meaning and therefore further clarification was required.[34] The Committee have explained in General Comment 14 that 'The Right to the Highest Attainable Standard of Health' does not mean a right to be healthy but instead encompasses the idea that everyone has a right to access health care.[35]Article 12(2)(c) and (d) of the ICESCR illustrate that medication is an integral part of that right,

---

[30] Ibid
[31] International Covenant on Economic, Social and Cultural Rights 1976 Article 12 http://www.unhchr.ch/html/menu3/b/a_cescr.htm
[32] Mission to the World Trade Organization, 2004, The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Report of the Special Rapporteur, Paul Hunt E/CN.4/2004/49/Add.1
Available at http://www2.essex.ac.uk/human_rights_centre/rth/docs/WTO.pdf
[33] The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, U.N. Doc. E/CN.4/1987/17
[34] *Hestermeyer*, Supra note 4 at pg 103
[35] CESCR General Comment 14 The Right to the Highest Attainable Standard of Health U. N. Doc. E/C.12/2000/4

> The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Access to medicine such as ARV therapy in treating and controlling the spread of HIV/AIDS is a necessary and vital component if states are to achieve the above steps.

Under General Comment 14 the state must work towards guaranteeing the availability, accessibility, acceptability and quality of health facilities, goods and services. In General Comment 14[36] they give some additional clarification on the model of AAAQ as a scale in understanding the progress a state is making in achieving the right to health. AAAQ stands for availability, accessibility, acceptability, and quality. This model focuses on the idea that health care services should be available in an adequate amount,[37]accessible to everyone in the community,[38]acceptable in both cultural views and medical ethics[39] and finally of an adequate quality.[40]

In considering access to ARV medicines and the HIV/AIDS crisis, General Comment 14 lays out and expands on the core obligations that the state should meet.

> 43. In General Comment No.3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of the rights enunciated in the Covenant, including essential primary health care. Read in conjunction with more contemporary instruments, such as the Programme of Action of the International Conference on Population and Development, the Alma-Ata Declaration provides compelling guidance on the core obligations in at least the following obligations:
> .....

[36] As adopted by the ICESCR Treaty monitoring body available at http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En
[37] Ibid para 12(a) which details that the condition of availability includes the availability of essential medicines as listed by the WHO Action Programme on Essential Drugs
[38] Ibid para 12(b)
[39] Ibid para 12(c)
[40] Ibid para 12(d)

> (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs: [41]

The Committee further highlighted in the following paragraph that a state should hold in the same urgency the aim,

> (c) to take measures to prevent, treat and control epidemic and endemic diseases;[42]

The concept of the minimum core obligations is designed to ensure states make every effort to achieve the final goal of the highest attainable standard of health. The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights hold that a failure to adhere to minimum core obligations constitutes a violation of the Covenant.[43]The Guidelines state at paragraph 9,

> Violations of the Covenant occur when a State fails to satisfy what the Committee on Economic, Social and Cultural Rights has referred to as "a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights [...]. Thus, for example, a State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, violating the Covenant." Such minimum core obligations apply irrespective of the availability of resources of the country concerned or any other factors and difficulties.[44]

Violations of the Covenant are serious and although the Covenant has no direct complaints mechanism the rights are justiciable as confirmed by the International Court of Justice.[45] In ratifying the ICESCR, Member States therefore agreed to and are legally bound by the obligations entrenched within and they must ensure they respect, protect and fulfil them.[46]

In relation to Article 12 and the right to health states are required to respect the right to health by not interfering with the enjoyment of that right. Access to essential medicine, under the right to health, requires the state to abstain from denying or

---

[41] CESCR General Comment No 14 para 43 available at http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[42] Ibid para 44

[43] The Maastricht Guidelines were determined by a group of experts in Maastricht in January 1997, they are designed to provide advice to those working in the sector of economic, social and cultural rights particularly the monitoring and adjudicating bodies at all levels. Available at http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html

[44] Ibid paragraph 9

[45] *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, ICJ Judgement 9 July 2004

[46] CESCR General Comment No 14 paragraph 33 supra note 41

limiting access to drugs. States are under the obligation to protect the right to health from interference by third parties. As health care around the world is becoming more privatised, pharmaceutical companies may be classed as 'third parties' and states must ensure that privatisation still has a view to enhance the right to health and not merely the view that it can be a commercial commodity.

> Obligations to *protect* include, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services[47]

The obligation to fulfil implores states to guarantee that appropriate legislative, administrative and budgetary measures are taken towards the full realization of the right to health. Examples include appropriate health insurance schemes, and state funding for medicines along with policies on generic medicines and other pharmaceuticals. Paul Hunt furthers this in his Mission to the WTO by saying,

> This includes the residual obligation to provide the various elements of the right, such as access to an essential medicine where an individual or group, for reasons beyond its control is unable to enjoy that element itself by the means of its disposal.[48]

A practical example of a state failing to protect, respect and fulfil their obligations is seen in the. *Minister of Health in South Africa v Treatment Action Campaign.*[49] The case involved a pilot scheme which offered treatment to a group of pregnant women suffering from the HIV virus to prevent mother to baby transmission of the disease. The treatment was only available to women who lived in a small region in South Africa and the NGO, TAC took the case to court invoking the South African Bill of Rights to have access to public health care services. The High Court found that the South African government had failed in their duty to protect by excluding access to treatment to a large majority of mothers and failed to fulfil the right by implementing an inappropriate scheme. The Government was ordered to extend the scheme to all

---

[47] Ibid

[48] Paul Hunt, Mission to the World Trade Organization, 2004, The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Report of the Special Rapporteur, E/CN.4/2004/49/Add.1
Available at http://www2.essex.ac.uk/human_rights_centre/rth/docs/WTO.pdf

[49] *Minister of Health et al v Treatment Action Campaign et al* 2002 (5) SA 721(CC)

mothers and to improve its policy.[50] The decision shows that courts are willing to uphold state obligations undertaken in respect to the right to health and access to medicine. States that lack the means to fulfil their obligation to the right to health by funding medicines must find other ways that use less of the all ready limited state resources. They can protect the right to health by ensuring that pharmaceutical companies do not over price medicines.

### 1.4 International Covenant on Civil and Political Rights

The ICESCR is not the only human rights instrument that provides support for the view that there is a right to access essential medicines such as ARV's. The International Covenant on Civil and Political Rights contains the right to life in Article 6(1), 'Every human being shall have the right to life'.[51] It can be said that the right to life is the most important human right, and is one which may not be derogated from even in times of public emergency.[52]Whether the right includes access to essential medicine depends on the interpretation. A narrow interpretation has meant the right has been historically confined to the act of murder and obliged states to stop citizens from killing. Hestermeyer comments however that,

> There is no reason why a lack of food or medical services should be less significant for the right to life than insufficient penal laws on murder. To be effective the right to life has to extend to the basic conditions of life, the components necessary for survival, even if that part of the right is to some extent coextensive with economic, social, and cultural rights.[53]

The Human Rights Committee which monitors state compliance with the ICCPR extended the meaning in General Comment No.6 including that states are under an obligation to implement measures aimed at eliminating epidemics.

> "inherent right to life" cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.[54]

---

[50] Case CCT 8/02 Available at http://www.tac.org.za/Documents/MTCTCourtCase/ConCourtJudgmentOrderingMTCTP-5July2002.pdf

[51] Article 6 ICCPR Available at http://www2.ohchr.org/english/law/ccpr.htm

[52] Article 4 Ibid

[53] *Hestermeyer*, Supra note 4 pg 116

[54] General Comment No.6, The Right to Life, Human Rights Committee, UN DOC. A/37/40 Para 5 Available at http://www.unhchr.ch/tbs/doc.nsf/0/84ab9690ccd81fc7c12563ed0046fae3

It is should hopefully be clear from this dissertation that HIV/AIDS is classed as an epidemic and one measure in coping with the disease is to prescribe sufferers with ARV's. There are 165 state parties[55] to the ICCPR and those states are obligated under Article 2(1) of the Covenant to respect and ensure the rights enshrined within it. If the right to life is viewed in the wider context of including the obligation to deal with epidemics then it can be argued that access to ARV's forms part of this fundamental human right.

In relation to the HIV/AIDS pandemic, if states are to meet their obligations in providing the highest attainable standard of health and to achieving the Millennium Development Goals then they must ensure their citizens have access to affordable ARV's. Human Rights instruments have shown that there is a right to have access to affordable medicines, especially essential medicines needed to treat diseases such ARV's in the treatment of HIV. Although access to ARV's is a basic right under international law statistics show many patients do not have access to treatment. This is a fundamental task in combating and eradicating the disease, however this task has become somewhat more complex since the introduction of patents and international agreements that protect pharmaceutical companies and the life saving drugs they manufacture. It is to this issue that I will turn in the following chapter.

[55] http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-4&chapter=4&lang=en

## Chapter II Intellectual Property Rights

In assessing whether the TRIPS Agreement affects the right to health and access to essential medicines by allowing patents on pharmaceuticals including ARV's, background knowledge of intellectual property law is vital. The aim of this chapter is to provide the reader with a historical insight into the concept of patent protection and to explain the origins of the World Trade Organisation, the international body that oversees the protection mechanism.

### 2.1 Patents and Pharmaceuticals

The philosopher John Locke was instrumental in advocating the concept that property rights arise from labour and therefore when work is put into an object or process, that object or process becomes the property of the maker.[56] Traditionally intellectual property rights were legislated for under national domestic laws. Locke's concept progressed internationally with time and in 1883 the International Union for The Protection of Industrial Property was established by the signature of the Paris Convention.[57]A further shift towards an international right to property emerged in the Universal Declaration on Human Rights with Article 27.2 and the ICECSR Article 15.1(c) which further gave rise to the idea of intellectual property rights,

> Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[58]

Patents, a sub category of intellectual property, grant specific rights to the patent holder in respect of their invention. Patents can cover either a product or the process if it contains a new aspect. A patent prohibits the use of the holder's invention without a license for a specific period of time.[59] The raison d'être for granting such a right is to reward the inventor and to act as an incentive to encourage research and

[56] John Locke, Stanford Encyclopaedia of Philosophy Available at http://plato.stanford.edu/entries/locke-political/#Pro
[57] Paris Convention for the Protection of Industrial Property March 20, 1883, Article 1
[58] Universal Declaration on Human Rights, Article 15(c). Available at http://www.unhchr.ch/udhr/lang/eng.htm
[59] World Intellectual Property Organization available at http://www.wipo.int/patentscope/en/patents_faq.html#patent

development. Effectively a patent provides a monopoly in the production and sale of a product in that specific market for a certain length of time.[60]

Pharmaceutical companies seek patents for several reasons. Firstly, the research and development of drugs is a costly process, and patents allow developers to recoup the money they invested in the research which led to the invention of a particular drug. As Correa explains, the pharmaceutical industry estimate that a new drug can typically take ten to fifteen years to complete at an average cost of US$800 million.[61] GlaxoSmithKline, a large pharmaceutical manufacturer, including antiretroviral medicines, defends patent protection by explaining;

> Patents and other intellectual property rights play a vital role in encouraging the innovation needed to develop new treatments for many of the most serious and life-threatening diseases. We invest considerable time and money to develop each new pharmaceutical product - an average of $800m per product. If a new product could immediately be copied and sold by others we would not be able to continue to fund new research. This would discourage innovation and limit research into newer and better medicines and vaccines.[62]

Therefore a patent can provide protection for a period of time from facing the competition of generic versions of the drug.[63]One major worry with intellectual property protection is that this protection has the potential to raise prices by allowing monopolies on medicines, especially the antiretroviral treatment required for HIV/AIDS. It is widely accepted that patented drugs are, in general, more expensive than their generic counterparts. Simple economics show that if there is no other competition in the market, there will be no incentive to lower the drug price.

> ...most rigorous economic studies concur that patents would lead to a significant price increases, generally over 100 per cent...Since patents lead to higher prices for pharmaceuticals, they reduce the accessibility of the medicine for the poor. Developed countries have the financial means to assist their populace in the provision of expensive patented medicine...

---

[60] Heywood, Mark, *Drug Access, Patents and Global Health: 'Chaffed and Waxed Sufficient'*, Third World Quarterly, Vol. 23, No.3, Global Health and Governance: HIV/AIDS (Apr.2002) pp.217-231

[61] Correa, Carlos, *'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, as in Negotiating Health, Intellectual Property and Access to Medicines, Chapter 6

[62] GlaxoSmithKline Available at http://www.gsk.com/responsibility/cr_issues/intellectual_property.htm

[63] A Generic version is one that is chemically identical to the original brand drug; essentially generic makers take apart the known brand drug in order to ascertain its compounds. Generic copying is a much cheaper way to manufacture pharmaceuticals are there are far fewer costs involved than the original brand maker incurred. Generic versions are marketed after the brand drug patent has expired. Available at http://www.who.int/trade/glossary/story034/en/index.html

development. Effectively a patent provides a monopoly in the production and sale of a product in that specific market for a certain length of time.[60]

Pharmaceutical companies seek patents for several reasons. Firstly, the research and development of drugs is a costly process, and patents allow developers to recoup the money they invested in the research which led to the invention of a particular drug. As Correa explains, the pharmaceutical industry estimate that a new drug can typically take ten to fifteen years to complete at an average cost of US$800 million.[61] GlaxoSmithKline, a large pharmaceutical manufacturer, including antiretroviral medicines, defends patent protection by explaining;

> Patents and other intellectual property rights play a vital role in encouraging the innovation needed to develop new treatments for many of the most serious and life-threatening diseases. We invest considerable time and money to develop each new pharmaceutical product - an average of $800m per product. If a new product could immediately be copied and sold by others we would not be able to continue to fund new research. This would discourage innovation and limit research into newer and better medicines and vaccines.[62]

Therefore a patent can provide protection for a period of time from facing the competition of generic versions of the drug.[63]One major worry with intellectual property protection is that this protection has the potential to raise prices by allowing monopolies on medicines, especially the antiretroviral treatment required for HIV/AIDS. It is widely accepted that patented drugs are, in general, more expensive than their generic counterparts. Simple economics show that if there is no other competition in the market, there will be no incentive to lower the drug price.

> ...most rigorous economic studies concur that patents would lead to a significant price increases, generally over 100 per cent...Since patents lead to higher prices for pharmaceuticals, they reduce the accessibility of the medicine for the poor. Developed countries have the financial means to assist their populace in the provision of expensive patented medicine...

---

[60] Heywood, Mark, *Drug Access, Patents and Global Health: 'Chaffed and Waxed Sufficient'*, Third World Quarterly, Vol. 23, No.3, Global Health and Governance: HIV/AIDS (Apr.2002) pp.217-231

[61] Correa, Carlos, '*Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements*, as in Negotiating Health, Intellectual Property and Access to Medicines, Chapter 6

[62] GlaxoSmithKline Available at http://www.gsk.com/responsibility/cr_issues/intellectual_property.htm

[63] A Generic version is one that is chemically identical to the original brand drug; essentially generic makers take apart the known brand drug in order to ascertain its compounds. Generic copying is a much cheaper way to manufacture pharmaceuticals are there are far fewer costs involved than the original brand maker incurred. Generic versions are marketed after the brand drug patent has expired. Available at http://www.who.int/trade/glossary/story034/en/index.html

> However, developing countries lack the resources to cover the additional price tag...and hence can only safeguard access to medicine by guaranteeing an adequate price level. As patent rights raise this price level, patents interfere with access to essential medicine in developing countries.[64]

There is no global patent office and thus the extent of patent protection varies considerably around the world. The World Intellectual Property Organization acts as an administrator in the application of conventions within its mandate, such as the regional Paris Intellectual Property Convention but it does not grant patents. The WIPO Convention only provides general guidelines and rules regarding intellectual property protection.[65] The Paris Convention of 1883 allowed states the freedom to choose which industries and fields could attract property protection rights. In the context of patents the Convention leaves it up to the individual state to determine for example the criteria for patentability and the term.[66]As a result some countries have a very strict patent regime where as others excluded product patents on pharmaceuticals on public health grounds. The argument was based upon the idea that the nature of pharmaceutical products is extremely different to the other forms of products that seek patent protection.[67] However with increasing globalization, the establishment of the World Trade Organisation (WTO) brought about changes in the intellectual property regime. The WTO marked the beginnings of an international trading system which incorporated patent protection firmly under international law.

## 2.2 The World Trade Organisation (WTO)

After WWII, the General Agreement on Tariffs and Trade (GATT) created an international trading arrangement for the reciprocal reduction of tariffs on trade in goods in 1947.[68]The GATT developed through a series of negotiations however it was not until 1994 that the World Trade Organisation came into existence. The Organisation was created after the Uruguay Round of Negotiations which lasted from 1986 until 2004. Originally the GATT had only considered the regulation of trade in

---

[64] Hestermeyer, Supra note 4 pg 149

[65] Convention establishing the World Intellectual Property Organization, July 14 1967 Articles 3 and 4 available at http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html#P68_3059

[66] Guide to the Application of the Paris Convention for the protection of Industrial Property, Professor G.H.C. Bodenhausen 1968, WIPO Publication pg 15.

[67] *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health,* P.Roffe with C.Spennemann and J Von Braun as found in *Negotiating Health* P.Roffe, G Tansey and D Vivas-Eugui at pg 12

[68] The General Agreement on Trade and Tariffs 1947, signed on 1st January 1948 available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#GATT94

goods, it was anticipated that the new WTO would also deal with trade in services under the General Agreement on Trade in Services (GATS) and also with trade and regulation of Intellectual Property under the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).[69]The Organisation was created under the Marrakesh Agreement which laid down the governing rules and principles. The Marrakesh Agreement also incorporated the original GATT Agreement of 1947. Under the Marrakesh Agreement it is recognised that the objectives of the WTO is to create a multilateral trading system with a view to,

> ...raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services.[70]

The WTO today provides a forum for negotiations among its 153 members[71] and since 1994 many agreements relating to trade have been agreed upon and implemented under the auspices of the WTO. The member states of the WTO promote and encourage freer trade by participating in negotiating rounds in an attempt to agree on lowering barriers to trade. The main agreements correspond to trade in goods (GATT), services (GATS) and intellectual property (TRIPS) and they are aided by extra agreements and annexes in specialised areas and schedules of commitments.[72]

There are two main principles that the WTO is based upon, and these relate to the fundamental idea that world trade should be based on non-discrimination. The first principle is known as Most Favoured Nation Treatment (MFN) and outlines that countries cannot normally discriminate between their trading states.[73]If you grant one country a special favour for example lower customs duty rate then you must grant all other WTO member states the same, giving them equally 'most favoured nation' treatment. The second principle is known as the National Treatment Principle and

[69] Understanding the WTO, World Trade Organisation Publication 4th Edition 2008
[70] Preamble of the Marrakesh Agreement Available at http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm
[71] Available at http://www.wto.org/english/theWTO_e/whatis_e/tif_e/org6_e.htm
[72] All legal texts, agreements and annexes are available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm
[73] GATT Art 1, GATS Art 2, TRIPS Art 4

encompasses the rule that imported and locally produced goods, services or patents for example should be treated equally.[74]

The concept of granting patents seems to therefore be at odds with the general goal of promoting freer trade but the protection of intellectual property rights are a legitimate exception under the GATT exceptions Article XX(d). These general exceptions allow a state to take measures that are,

> necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;[75]

Trade Agreements and patent protection relate to the human right to health in various ways, Paul Hunt, Special Rapporteur to the Right to Health notes in his mission to the WTO that:

> First, trade has the potential to increase resources and thus to contribute to the progressive realization of the right to health. Second, if trade generates more resources, they have to be allocated in such a way that they do, in practice, contribute to the progressive realization of the right to health for all; a national health strategy and plan of action can help to ensure that the necessary allocations occur. Third, the effect of trade on the progressive realization of the right to health depends upon the trade rules chosen: different forms, pacing and sequencing of trade liberalization have different effects on progressive realization. The right to health requires that the form, pacing and sequencing of trade liberalization be conducive to the progressive realization of the right to health.[76]

It is therefore clear that if the WTO is to uphold its objectives of increasing standards of living for the world's population it is imperative that the WTO Agreements respect the right to health. Under Article XX(b) of the GATT it is stated that,

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

---

[74] GATT Art 3, GATS Art 17, TRIPS Art 3

[75] GATT Art XX(d)

[76] Paul Hunt, Mission to the World Trade Organization, 2004, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Report of the Special Rapporteur, E/CN.4/2004/49/Add.1
Available at http://www2.essex.ac.uk/human_rights_centre/rth/docs/WTO.pdf

(*b*) necessary to protect human, animal or plant life or health. [77]

In providing access to medicines it is essential that a balance between the values of public health and intellectual property regimes is struck so that all of the world's population, no matter what their economic status is, can afford medication.

### 2.3 WTO Dispute Settlement

The WTO forum provides for a unique dispute settlement procedure via the Understanding on Rules and Procedures Governing the Settlement of Disputes.[78]The Understanding was a result of the Uruguay Round and established strict rules and guidelines for an effective system. The Dispute Settlement Body (DSB) is charged with settling disputes between member states.[79] The DSB establishes panels which consist of trade experts to hear a member dispute.[80] There is an emphasis on member consultations in the hope to resolve matters peacefully between the concerned states first.[81] Failing this a panel may hear the case and decide on the matter, the findings of the panel are binding upon the parties in question and provide guidance for all other WTO member states. It is possible for either side to appeal a Panel Report and the Appellate Body of the DSB will hear such a matter. The Appellate Body consists of seven individuals who are recognised internationally in the field of law and trade and are not affiliated with any government. An appeal will be heard by three members of the Appellate Body.[82] The DSB must conform to strict time constraints in dealing with trade disputes as time is often of the essence in most matters.[83] The DSB has the power to decide member states at fault should pay compensation the aggrieved member state or/and impose in serious cases trade penalties.[84]

### 2.4 The North South Divide and WTO negotiations

There is however often a rich /poor divide between developed countries that seek strong patent protection for their pharmaceutical industry and the developing

[77] GATT 1947 Article XX(b) Available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#gatt47
[78] Agreement on the Understanding on Rules and Procedures Governing the Settlement of Disputes Article 2
[79] Ibid
[80] Ibid Articles 6-8
[81] Ibid Article 4 and 5
[82] Ibid Article 16
[83] Ibid Article 20
[84] Ibid Article 22

countries resisting this in order to protect their populations and developing economies.[85] Developed countries often have a higher bargaining power in trade negotiations and often big political powers put pressure on weaker developing countries to back down.

The governments of developed countries especially the USA are firmly in the driving seat of trade talks and in negotiating the agreements in their best interests not in the interests of the developing countries or the development agenda.[86] During the Uruguay Round the split was obvious with coalition groups between the developing countries forming, for example the African Group and the Least Developed Countries Group stood together on common interests.[87]The Uruguay negotiations did not only involve states, fierce corporate lobbying also put pressure on governments to reach agreements on trade matters.

> A former WTO negotiator commented that, 'without the enormous pressures generated by the American financial services sector...there would have been no GATS service agreement.' The pressure came especially from the US Coalition of Service Industries, the European Services Forum, and the UK's Liberalisation of Trade in Services (LOTIS) group' (World Development Movement, 2002).[88]

Lobbying from corporations was also extremely dominant in the fight for stronger patent protection and throughout the negotiations of the Agreement on Trade-related Aspects of Intellectual Property. Statistics show the pharmaceutical industry greatly contributed to political campaigns in what is suggested as a way to ensure the political parties would fight for their interests in trade talks on the protection of intellectual property.[89]

---

[85] *International Protection of Intellectual Property*, G.M.Grossman and Edwin L.C.Lai, *The American Economic Review*, Vol. 94, No. 5 (Dec., 2004), pp. 1635-1653 Published by: American Economic Association

[86] Robert Wade, '*Which Strategies are viable for developing countries today? The World Trade Organization and the shrinking of 'development space'*, Review of International Political Economy, Vol 10, No.4, Tenth Anniversary Issue (November 2003)

[87] *Understanding the WTO*, World Trade Organisation Publication 4th Edition 2008

[88] *The Uruguay Round North-South Grand Bargain: Implications For Future Negotiations*, Sylvia Ostry, *The Political Economy of International Trade Law*, University of Minnesota September,2000 available at http://www.utoronto.ca/cis/Minnesota.pdfS

[89] Campaign Contributions from the drug industry in 1994 for example accounted for 60% of the Republicans donations at $3,326,633 and 40% of the Democrats at $2,247,543. Congressional Budget Office 2001, as found in '*Understanding Patents and Medicine Access, the WTO, Free Trade Agreements and Patent Law*' Kapczynski, Yale Aids Network Presentation Available at www.yale.edu/aidsnetwork/TRIPS%20Teach-In.ppt

countries resisting this in order to protect their populations and developing economies.[85] Developed countries often have a higher bargaining power in trade negotiations and often big political powers put pressure on weaker developing countries to back down.

The governments of developed countries especially the USA are firmly in the driving seat of trade talks and in negotiating the agreements in their best interests not in the interests of the developing countries or the development agenda.[86] During the Uruguay Round the split was obvious with coalition groups between the developing countries forming, for example the African Group and the Least Developed Countries Group stood together on common interests.[87]The Uruguay negotiations did not only involve states, fierce corporate lobbying also put pressure on governments to reach agreements on trade matters.

> A former WTO negotiator commented that, 'without the enormous pressures generated by the American financial services sector...there would have been no GATS service agreement.' The pressure came especially from the US Coalition of Service Industries, the European Services Forum, and the UK's Liberalisation of Trade in Services (LOTIS) group' (World Development Movement, 2002).[88]

Lobbying from corporations was also extremely dominant in the fight for stronger patent protection and throughout the negotiations of the Agreement on Trade-related Aspects of Intellectual Property. Statistics show the pharmaceutical industry greatly contributed to political campaigns in what is suggested as a way to ensure the political parties would fight for their interests in trade talks on the protection of intellectual property.[89]

---

[85] *International Protection of Intellectual Property*, G.M.Grossman and Edwin L.C.Lai, *The American Economic Review*, Vol. 94, No. 5 (Dec., 2004), pp. 1635-1653 Published by: American Economic Association

[86] Robert Wade, '*Which Strategies are viable for developing countries today? The World Trade Organization and the shrinking of 'development space'*, Review of International Political Economy, Vol 10, No.4, Tenth Anniversary Issue (November 2003)

[87] *Understanding the WTO*, World Trade Organisation Publication 4th Edition 2008

[88] *The Uruguay Round North-South Grand Bargain: Implications For Future Negotiations*, Sylvia Ostry, *The Political Economy of International Trade Law*, University of Minnesota September,2000 available at http://www.utoronto.ca/cis/Minnesota.pdfS

[89] Campaign Contributions from the drug industry in 1994 for example accounted for 60% of the Republicans donations at $3,326,633 and 40% of the Democrats at $2,247,543. Congressional Budget Office 2001, as found in '*Understanding Patents and Medicine Access, the WTO, Free Trade Agreements and Patent Law*' Kapczynski, Yale Aids Network Presentation Available at www.yale.edu/aidsnetwork/TRIPS%20Teach-In.ppt

> Big Pharma has spent the last decade trying to suppress attempts by developing country governments to loosen patent rights and thus deliver affordable antiretroviral drugs to millions of HIV-AIDS afflicted patients.[90]

Developed Countries finally achieved an agreement that regulates intellectual property and affords a greater standard of protection in the form of minimum standards of patent protection which includes the pharmaceutical industry.[91] Ostry comments that,

> As the Uruguay Round negotiations proceeded, the message in Brasilia and New Delhi became clearer: given a choice between American sanctions or a negotiated multilateral arrangement, an agreement on TRIPS (Trade-related intellectual property) began to look better.[92]

The imbalance in negotiating powers of the TRIPS Agreement between the North and the South has led to it being one of the more controversial agreements within the WTO framework.[93] The following chapter shall discuss this agreement and attempt to analyse the effect it has on the access and affordability of essential medicines in particular to ARV drugs in developing countries where the AIDS Epidemic has the most devastating effect.[94]

---

[90] '*Do Corporations Rule?*' Walden Bello and Philippe Legrain, BBC Who Runs your world? Series 2005, Available at http://news.bbc.co.uk/1/hi/magazine/4201516.stm Note 'Big Pharma' is a colloquial term used to describe the main pharmaceutical companies in the industry.

[91] The Agreement on Trade-Related Aspects of Intellectual Property, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

[92] Supra note 88

[93] Haochen Sun, *The Road to Doha and Beyond: some reflections on the TRIPS Agreement and Public Health*, European Journal of International Law 2004 15(1):123-150

[94] 70% of the world's population living with HIV live in Sub-Saharan Africa. UNAIDS 2008 Annual Report pg 7 available at http://data.unaids.org/pub/Report/2009/jc1736_2008_annual_report_en.pdf

## Chapter 3 The TRIPS Agreement and its Interpretation

### 3.1 Intellectual Protection before the WTO

This chapter hopes to analyse the provisions of the original TRIPS Agreement and the initial impact on the production of ARV's. The more recent amendments to the TRIPS Agreement shall also be considered.

The TRIPS Agreement which came into force in 1994 was an attempt to harmonise the various IP rights around the world and was aimed at setting minimum standards of protection that each member state must afford to the nationals of other members.[95] The term nationals is defined as,

> ...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.[96]

Legal persons are taken to include companies and corporations and their legal personality simply means the organisations ability to enter into legal transactions.[97]The TRIPS Agreement thus requires member states to ensure that the intellectual property rights enshrined within the Agreement are afforded to companies and corporations that are incorporated in other member states. The non-discrimination principles of MFN and NT must also be adhered to in the application of the TRIPS Agreement.[98]

TRIPS set out a minimum standard of rights that must be guaranteed to nationals of other members and must be provided for domestically within the legal framework and state practice.[99]Unlike the Paris Convention previously discussed above the TRIPS Agreement was the first international agreement that actually required states to enforce intellectual property rights domestically.[100]

The objectives of the TRIPS Agreement can be seen in Article 7,

---

[95] TRIPS Agreement Article 1(3)
[96] Notes accompanying Article 1(3) TRIPS Agreement
[97] Under English law for example see Halsbury's Laws of England from LexisNexis - Corporations (Volume 9(2) and Companies (Volume 14(2) (2009) 5th Edition
[98] Ibid Articles 3 and 4
[99] TRIPS Agreement Article 1(1)
[100] Joseph, Sarah, *Pharmaceutical Corporations and Access to Drugs, 'The Fourth Wave of Corporate Human Rights Scrutiny*, Human Rights Quarterly, Vol. 25, No. 2 (May, 2003), pp. 425-452

> 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.[101]

Thus, the Agreement in principle aims to strike a balance between the competing rights of pharmaceutical patents and access to medicines or in essence a balance between the rights of the patent holder and the interests of the user. The right to health and access to essential medicines could thus fall under the obligation to ensure IP protection is 'conducive to social and economic welfare'. This seems further qualified by the guiding principles that are explained in Article 8,

> 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 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.[102]

The articles above are also strengthened when the preamble of the TRIPS Agreement is considered. The preamble sets out the ideals that members should recognise, for example to

> to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;
>
> along with also recognising,
>
> the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;[103]

The TRIPS Agreement is also supported by the preamble of the founding Agreement of the WTO which was discussed in Chapter II above and reminds members of the objectives of raising standards of living and also to recognise,

---

[101] TRIPS Agreement Article 7
[102] Ibid Article 8
[103] Ibid Preamble

> that there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development.[104]

In recognising different capabilities between developed, developing and least developed countries member states were given different deadlines reflective of their development status to bring their national policies in intellectual property law inline with the TRIPS provisions. Developed member states were given one year from the date of enforcement (1995). Developing countries and transition economies had until 2000 [extended to 1st January 2005] and the Least Developed Countries had until 2006 [now extended to 2016 for pharmaceutical patents][105] to conform to the agreement. Developing countries that did not provide patent protection in a particular area, for example pharmaceuticals, were given 10 years to bring their legal regimes in line with the requirements of TRIPS,[106]

Article 27.1 defines what may be patentable,

> 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.[107]

The inclusion of the words 'all fields of technology' brought pharmaceutical processes and products under the scope of patent protection which all member states now have a duty to respect. Prior to the Agreement states were free to choose which industry sectors would be afforded patent protections and often the pharmaceutical industry was excluded. Under the TRIPS Agreement WTO Member states can no longer place blanket exclusions on pharmaceutical products from receiving patent protection. This was a huge step forward in favour of intellectual property rights and meant many countries, like India and Brazil, would have to amend their national legislation if they were to comply with the agreement. In recent years India has been known as the 'pharmacy of the developing world' because it has been providing cheap generic drugs to much of the developing world, as pharmaceuticals were out-with their patent protection system.

---

[104] Preamble to the Marrakesh Agreement Supra note 91

[105] Intellectual Property – Protection and Enforcement Available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

[107] TRIPS Agreement Article 27.1 Supra note 91

> In the postwar pre-TRIPS period some developed and developing countries chose either not to permit patenting of essential goods such as medicine...or to create laws where compulsory licensing of medicines was legitimised in the public interest. This permitted reverse engineering of medicines by generic companies...In a globalised world, particularly one that has glorified competition, the existence of interchangeable alternative medicines costing a fraction of the price of patented versions, was seen as a threat.[108]

Now that 2005 has passed, developing countries like Brazil and India are under a legal obligation to provide patent protection to all new pharmaceuticals. They must provide patent protection for entirely new medicines and therefore generic manufacturers previous freedom in developing affordable versions is no longer available. They must wait until the patent expires or they must obtain the patent owner's permission.

The production of generic drugs by these countries previously allowed for a sharp reduction in the price of many HIV/AIDS related medicines. MSF maintains that:

> Competition among producers is the tried and tested way to bring prices down. Competition among generic manufacturers is what helped bring the cost of AIDS treatment down from $10,000 per patient per year in 2000 to $130 per patient per year today.[109]

Effectively the TRIPS Agreement under Article 28, allows for patent holders to have the power to make, use and sell or import that product or process exclusively. Third Parties have no rights to use the product or process without consent of the patent holder and under TRIPS Article 33 patent protection must last for 20 years.

In an attempt to mitigate the effects of the potential conflict between the right to access affordable medicines and the right to patent protection for pharmaceuticals and possible monopoly, the TRIPS Agreement incorporated certain flexibilities. According to the WTO, the Agreement is able to benefit all exactly because such flexibilities are built into the system:

> Society benefits in the long term when intellectual property protection encourages creation and inventions, especially when the period of protection expires and creations and inventions enter the public domain. Governments

---

[108] Heywood, Mark, *Drug Access, Patents and Global Health: 'Chaffed and Waxed Sufficient'*, Third World Quarterly, Vol. 23, No.3, Global Health and Governance: HIV/AIDS (Apr.2002) pp.225

[109] MSF, Q&A on patents in India and the Novartis case http://www.msf.org/msfinternational/invoke.cfm?objectid=A05B02CF-5056-AA77-6CA9A174A5C4E2F7&component=toolkit.article&method=full_html

> are allowed to reduce any short term costs through various exceptions, for example to tackle public health problems.[110]

These exceptions which will be analysed shortly however have become controversial since the TRIPS Agreement's enforcement and there has been great confusion in how to implement and interpret the vague provisions. One immediate failure of the exceptions was thus the lack of guidelines for Member states to follow.

### 3.2 TRIPS Safeguards

There are three main exceptions outlined in the Agreement for derogation from affording patent protection. The interpretation of Article 6 (relating to the exhaustion of intellectual property rights), Article 30 (dealing with exceptions to patent rights) and Article 31 (concerning 'other use without authorization of the patent holder) of the TRIPS Agreement aim to provide certain solutions to the problem of access to essential medicines. However despite their appeal on paper, in practice these safeguards are less effective for a variety of reasons.

#### 3.2.1 Article 6 and the concept of parallel imports

Article 6 of the TRIPS agreement concerns the exhaustion of the patent holders' rights and relates to the issue of parallel imports. The exhaustion of rights happens when the patent holder has sold a batch of the product; the patent holder no longer has an input into what happens with that batch and the buyer of the product is free to do as it wishes with the product. There are two types of exhaustion, firstly national exhaustion which involves the holder of the patent marketing the product in the national and therefore exhaust the paten right in same market and then there is international exhaustion which is a little more complex.

International exhaustion is a contested topic and Hestermeyer summaries the issue that it boils down to as follows;

> ...does the TRIPS Agreement provide that a patent holder can prevent the importation of a product where the product has been placed on a foreign market by the patent holder itself or with its consent (parallel import)?[111]

The definition of parallel imports are explained by the WTO as,

---

[110] Understanding the WTO, World Trade Organisation, Chapter 2. The Agreements, pg 39

[111] *Hestermeyer*, Supra note 4 pg 230

> These are products marketed by the patent owner...or with the knowledge of the patent owner's permission in one country and imported into another country without the approval of the patent owner.[112]

Parallel imports affect the patent holder's profits as pharmaceutical companies charge strikingly different prices in different markets reflective on which markets will allow high prices. This is only possible however if there is a separation of the markets. If the concept of parallel imports are allowed the advantage is that if a product is sold in country A at one price and sold in country B at a lower price, importers can be buy in country B at the lower price and import to country A undercutting the original price there.[113] The cheaper price effectively leaks from the lower priced market into the higher priced one, making the product more affordable. The WTO's view on the legality of parallel imports is,

> The TRIPS Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved.[114]

Providing that parallel imports conform to the provisions in the TRIPS Agreement, they are legal and can provide affordable access to medicines if a country that has no production capacity. At first glance it would seem that this removes any barriers to accessing affordable medicines, yet this is not quite true for developing countries. Although the parallel import is able to be sold at the cheaper price it is unlikely to be vastly cheaper, thus parallel imports maybe appropriate in helping the developed west gain access to medicines but it won't solve the affordability problem of medicines in the developing world.[115] There is also controversy over the exhaustion of rights concept and whether it can be applied internationally or not, the WTO has left the decision to member states to determine how to interpret the doctrine under their own legislation; under a national exhaustion state policy parallel imports are not allowed whereas

---

[112] WTO Fact sheet on Patents Available at http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

[113] Supra note 4 pg 231

[114] WTO Obligations and Exceptions Available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#parallelimports

[115] Commission on Intellectual Property Rights, Study Paper 2a '*WTO TRIPS Agreement and Its Implications for Access to medicines in Developing Countries*' Frederick M. Abbott pg 44

under an international exhaustion policy they are.[116] Many developed countries such as the US permit a national exhaustion only but others such as South Africa allow an international rights exhaustion policy.[117]

In allowing members to determine their own policy in relation to the concept of exhaustion of rights, the WTO allows to an extent, members to balance the right to health with the right to intellectual property protection. However as the issue is still controversial and many developed countries are opposed to international exhaustion policies parallel imports do not provide the most effective answer in striving to achieve that balance.

### 3.2.2 Art 30 – Exceptions to Rights Conferred

One safeguard enshrined within the TRIPS Agreement is Article 30 which states that,

> 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.[118]

The Article allows for 'limited exceptions' where the TRIPS Agreement may be derogated from. However this is qualified by saying that these exceptions should not conflict significantly with the usual exploitation of the patent, nor should they unreasonably discriminate against the legitimate interests of the patent holders against legitimate third party interests. This means that a member state cannot unreasonably discriminate against the intellectual property rights of the patent holder against the health rights of third parties.

One common example of the use of Article 30 is to allow research and development of the patented drug before the patent expires and without the authorisation of the patent holder. The second common use of Article 30 is known as the Bolar Exception. Gupta explains,

---

[116] Final Report to World Intellectual Property Organisation 2001 'Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries' Keith Maskus available at http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf

[117] Ibid Makus also comments that during the negotiations of the TRIPS Agreement the USA tried to include a global national exhaustion policy but failed.

[118] TRIPS Agreement Article 30 Supra note 91

> This exception allows generic manufacturers to start the approvals process from public health authorities for marketing generic versions of the patented drugs before the patent expires to ensure that the generic drug is ready to market as soon as the patent expires.[119]

The advantages of the Bolar exception are generally understood to be that when generic medicines are released onto the market, drugs prices fall and therefore are more affordable. The earlier generics are allowed onto the market the greater number of patients will have access to affordable medicine. The Bolar exception is only really therefore of any use once the patent expires.

The vague wording of Article 30 seemingly gave great scope for interpretation in favour of the Right to Health and access to essential medicines. When read alongside Articles 7 and 8 of the TRIPS Agreement, 'limited exceptions' could be understood to include public health emergencies such as the HIV/AIDS pandemic. The WTO have confirmed that the use of a Bolar exception is permitted under the TRIPS Agreement but it was disappointing to see that the WTO Panel in a dispute between Canada and the EC interpret Article 30 restrictively dispelling a greater flexibility of the exception.[120] The case involved a complaint from the European Communities against a Canadian regulation that allowed the manufacture and storage of products before the expiry of those patented products. Hestermeyer comments;

> ...the narrow interpretation of the provision...would not permit an exception under Article 30 that could meaningfully enhance access to medicine in the developing world, such as governmental non-commercial use - permitting the government to produce the medicine and to provide it to large parts of the population.[121]

Whilst providing some relief to the problem of access to essential medicines, Article 30 does not appear to provide a sustainable solution especially in the context of HIV/AIDS epidemic. In the treatment of HIV the majority of ARV's were only developed a few years ago and they are constantly discovering new combinations with less side effects. These combinations are therefore still going to be under patent

---

[119] Gupta, Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS provide a solution? 2004 2 Buff.Intell.Prop.L.J.127

[120] Canada – Patent Protection of Pharmaceuticals WT/DS114/R available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

[121] *Hestermeyer*, Supra note 4 at page 239

protection for many years to come and those who need affordable access to ARV's now will be unable to benefit.[122]

### 3.2.3 Art 31 - Compulsory Licensing

The compulsory licensing exception under Art 31 is possibly the most controversial and complex of the TRIPS safeguards. The Agreement does not actually refer to 'compulsory licensing' as such, instead Art 31 discusses 'other use without authorization of the patent holder'. It allows for governments, during certain situations, namely 'situations of national emergency or other circumstances of extreme urgency' to grant the use of the patented product or process without the consent of the patent holder. This exception is heavily armed with various conditions and constraints and many member states have been reluctant to use the exception. Essentially compulsory licenses are intended to allow generic medicines to be made despite the fact they are under patent protection. The concept satisfies the need to provide access to affordable medicines for the developing world yet the Article is riddled with limitations and therefore the effectiveness is drastically reduced. The licence for example; is only to be provided for on a case by case basis, it is non-exclusive so will not affect the patent in other countries, it is not assignable, it is predominantly for the domestic market, the patent holder is entitled to some remuneration and it is seen as a temporary measure.[123]

Member States that have attempted to implement compulsory licensing such as South Africa and Brazil have in particular faced fierce opposition and pressure from pharmaceutical companies and developed member states alike.[124] Thailand was also subjected to trade threats from the USA in light of its generic drugs policy. The USA threatened to put Thailand on the "priority watch" list which names countries that are

[122] For example the combination ARV pill containing lamivudine + nevirapine + stavudine, which is listed on the WHO's most recent essential medicine list see supra note 7, was granted a patent in the US under Patent Number 20080108586 and filed on the 5th September 2007 available at http://www.patentstorm.us/applications/20080108586/fulltext.html
Under Article 30 of the TRIPS Agreement, the bolar exception will not be able to be used effectively for this ARV until 2027.

[123] TRIPS Agreement Article 31 Supra note 91

[124] For example see US- Brazil WTO dispute Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm

thought to be committing intellectual property violations and this would adversely affect Thailand's trade status.[125]

Member States that have limited or no manufacturing capacity, including the majority of African countries such as Rwanda, are excluded from benefiting from Article 31, as under 31(f),

> any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;[126]

Therefore they cannot be assisted by other member states as the supply should only be for domestic market. The word 'predominantly' would seem to provide some sort of assistance for countries to export generics to other members by interpreting the phrase to mean that the domestic market should be the priority and then supply to other members may be permitted after this.[127] This is however very much dependant on the exporting state and as can be seen from Article 31(f) the grant of a compulsory licence for the sole purpose of importing to another member state is not allowed. The various trade pressures and sanctions threatened by developed members as discussed above, arguably discourages member states from exporting generics under Article 31 to those members with manufacturing capacity problems. This was a huge stumbling block in the fight against HIV/AIDS and the task of achieving 'as close to universal access as possible by 2010'.[128]

The WTO realised that the exceptions of TRIPS were not working and the issue was brought to the fore at the 2001 Doha Ministerial Conference where, after great debate an agreement on TRIPS and Public Health was reached.

### 3.3 The Doha Declaration on TRIPS and Public Health

The Doha Declaration on TRIPS and Public Health was created with the aim to provide more guidance upon the TRIPS exceptions and the relationship to human health. The Declaration was an important step forward in recognising the severity of

[125] WTO Summit: Don't undercut AIDS Drugs Access available at http://www.hrw.org/press/2001/11/wto-aids1107.htm
[126] TRIPS Art 31(f) Supra note 91
[127] Supra note 4 Chapter V Part II
[128] Ibid

the HIV/AIDS epidemic and in recognising that members must take steps to protect public health. It also noted that there is a need for the TRIPS Agreement,

> to be part of the wider national and international action to address these problems [of public health][129]

In this regard the Declaration acknowledges that the TRIPS Agreement does impact on health and assist in helping to alleviate them. Paragraph 4 of the Declaration states,

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[130]

The Declaration went on to confirm that compulsory licensing was a legitimate way to solve the problem of accessing essential medicines such as ART in need in HIV control. This was a positive step for member states that have manufacturing capacity; for example India, China and Brazil were able to progress with their health programmes without fear of further confrontation from pharmaceutical companies or developed members disputing the legality of compulsory licensing. In allowing Members right to decide it also confirms the right to interpret the exhaustion of rights concept as an international one and thus allows for parallel imports. In confirming that public health was a purpose of the Agreement the Declaration implies that members and WTO dispute settlement must respect and be supportive of that.[131]

Whilst the Declaration may have given guidance on how to interpret the TRIPS safeguards in line with public health commitments it failed to address the pressing issue of what is now known as the paragraph 6 problem.

---

[129] Doha Declaration on the TRIPS Agreement and Public Health Available at http://www.who.int/medicines/areas/policy/tripshealth.pdf

[130] Doha Declaration Ibid Para 4

[131] Correa, C, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organisation 2002

> 6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[132]

In reality a decision was not reached until the 30th August 2003 at the Ministerial Conference in Cancun.

### 3.4 30th August Decision 2003

The decision reached on 30 August 2003 by the WTO General Council waives the obligations under Article 31(f) and permits countries to export generic drugs to those member states that lack the capacity to manufacture their own. The WTO promote the decision as removing the 'final patent obstacle to cheap drug imports' and the Director General at the time, Supachai Panitchpakdi, said,

> The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people.[133]

If taken at face value, in theory all the conflicts between patent rules and the problems in accessing medicines to treat people in the developing world are solved. However in practice the debate is far from over. The Doha Declaration on TRIPS and Public Health and the 30th August Decision can be said to be gifts bound in bureaucratic red tape. The procedures for implementing the decision for an exporting member are extremely burdensome. Equally so are the conditions that the recipient country must meet. This has led to many countries with a manufacturing capacity to shy away from using the purported flexibility of the 30th August Decision. The Decision is available to all member states, but twenty three countries have thus far indicated they will not use the system to import cheaper pharmaceuticals from other member states.[134] They believed that the decision could lead to an abuse of patent

---

[132] Doha Declaration Ibid Para 6

[133] WTO Decision removes final patent obstacle to cheap drug imports, Available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

[134] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. Available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

laws. In response to this the Chairperson of the General Council issued a statement to alleviate such concerns;

> Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.[135]

Several countries[136] qualified that they would only use the flexibilities if there was an emergency or an extremely urgent situation. These countries include China and Mexico, both large manufacturers of generic medicines. The waiver of Article 31(f) under the conditions of the Decision is not permanent; it was simply a temporary measure until a more suitable agreement to amend the TRIPS is reached.

### 3.5 The 2005 Amendment Article 31bis

In 2005 it was decided that a direct translation of the waiver in the form of what is known as Article 31bis would be included along with an annex to the TRIPS Agreement. The 2003 Decision was only a temporary solution and therefore needed to be formally included in the TRIPS Agreement.[137] The provision will come into force once two thirds of the WTO members accept it. The initial timeframe for acceptance of this amendment was the 1st December 2007 but the WTO issued a statement on the 21st December that year to announce the deadline had been pushed back and member states now had until the 31st December 2009 to accept the amendment – or possibly later if the Ministerial Conference decides differently. The reason given sheds no light on why the deadline has been extended merely:

> *Noting* that acceptance of the Protocol by two thirds of the Members in accordance with paragraph 3 of Article X of the WTO Agreement is taking longer than initially foreseen;[138]

---

[135] The General Council Chairpersons Statement 30th August 2003 available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

[136] Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.
http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

[137] 'Members OK amendment to make health flexibility permanent' 6 December 2005 available at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm

[138] Amendment of the TRIPS Agreement – Extension for the Period of the acceptance by Members of the Protocol Amending the TRIPS Agreement WT/L/711 21 December 2007 Available at http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

In a decision taken on the 17th December 2009, the deadline was yet again extended, this time to 31 December 2011.[139]No further reasoning than was given in the 2007 statement was made.

There is already a worrying trend emerging in TRIPS plus Agreements, negotiated independently of the TRIPS Agreement, in the form of Free Trade Agreements or Bilateral Investment Treaties. Several of these agreements place even more stringent patent protection and request developing members not use the flexibility provisions within the TRIPS Agreement.[140] They are increasingly being drafted by developed members in particular the USA. This is a future problem that the WTO must address.

It can be seen from the progress and changes the WTO has made to TRIPS since the 2001 Doha Development round that an emphasis has been placed upon using Article 31 and compulsory licensing as a solution to the access to medicines problem. The threat of using compulsory licensing is a powerful bargaining tool against pharmaceutical companies in trying to force them to reduce their prices. This was recently seen in Thailand after the government threatened to issue a compulsory licence for the drug Kaletra, manufactured by Abbot. Abbot offered to reduce its cost of treatment per month from $347 to $167. This is indeed a positive result, but it will only work if governments are brave enough to use the threats and it does not always achieve such reductions.[141]

The other exceptions available within the TRIPS Agreement appear to have been lost in the frenzy surrounding the interpretation and amendment of Article 31.[142]In searching for another end, is it possible to use the conflict of human rights and

---

[139] 'Members accepting amendment of the TRIPS Agreement' 25th January 2010 available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

[140] For example the EU Free Trade Agreement with South Africa maintains that 'South Africa shall ensure adequate and effective protection for patents on biotechnological inventions. South African must also implement "highest international standards" of IPR protection and undertake to go beyond TRIPS standards of IPR protection' available at http://www.grain.org/rights/tripsplus.cfm?id=68

[141] 'Abbott offers price cut to thwart Thai compulsory license on Kaletra' http://www.aidsmap.com/en/news/08E18120-7D15-4E1C-98DC-145C515EFBAC.asp

[142] For an interesting view on how Article 30 could be more effectively used in comparison to Article 31 see Gupta, Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS provide a solution? 2004 2 Buff.Intell.Prop.L.J.127

intellectual property rights to show a hierarchy in human rights which may help rectify the current imbalance in the TRIPS Agreement?

## Chapter 4 Conflicts of International Norms

### 4.1 The Conflict between the Right to Health and the Right to Intellectual Property

The very nature of international law and the way in which it has developed has undeniably led to the possibility of conflicts between individual laws or principles. There are over 190 states, with a vast array of cultures and ideals and international law has been shaped in such a way as to find the common ground between them. The fragmentation of international law is a result of the various law makers and regulators attempting to reach for example a Convention agreeable to every state. Thus many international norms are left unclear or are broadly defined and this has inevitably led to confusion and conflict about the correct interpretation of international law norms and the obligations engendered by them conflicts between the laws have inevitably arisen.[143] Pauwelyn notes that,

> ...the more states join a regime, the more difficult it becomes to agree on explicit conflict clauses dealing with the question of how the regime relates to other rules of international law and, hence the more conflicts that remain potentially unsolved.[144]

This is exactly the situation that has resulted from the TRIPS Agreement and the conflict between the right to health and the right to intellectual property protection. The types of conflicts in international law can be numerous; for this chapter, the focus will be on how a state should act when two international norms, for example two obligations under the ICESCR and the TRIPS Agreement, both of which the state is a party to, seemingly engender conflicting obligations.

It may be helpful to define what I mean by the term 'conflict' Jenks provides us with a definition of what would constitute a conflict between treaties as follows;

> A conflict in the strict sense of direct incompatibility arises only where a party to the two treaties cannot simultaneously comply with its obligations under both treaties.[145]

---

[143] On the fragmentation of International Law see for example the works of the International Law Commission website available at http://www.un.org/law/ilc/

[144] J. Pauwelyn, Conflict of Norms in Public International Law, Cambridge University Press 2004 pg 13

[145] W Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 BYIL 401

In the context of access to affordable medicines I shall compare the provisions of the ICESCR and the TRIPS Agreement.

The two rights involved differ markedly, making it difficult to find an agreeable solution. Chapter I of this thesis ascertained that access to affordable medicines is an international human right. Human Rights theory holds that such rights are fundamental rights automatically held by every single human being by virtue of being human.[146]Intellectual Property Rights as found within the TRIPS Agreement and discussed in Chapters II and III above, in comparison are temporary rights, held by individuals, and in the case of patents only upon application. Philippe Cullet clarifies,

> Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being humans. This is in contrast to property rights, which can always be ceded in voluntary transactions.[147]

The right to health is set out in Article 12 of the ICESCR; of the WTO members, 123 have ratified the Covenant.[148]A reminder of Article 12.2(c) states how access to medicine relates to the right to health;

> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;[149]

In ratifying the Covenant, these Member States agreed to take on the obligations entrenched within and to respect, protect and fulfil them. However the TRIPS Agreement also places obligations upon the member states who have ratified it. It is an agreement that places the obligation of achieving a minimum standard of intellectual property protection which (as I have demonstrated in Chapter III) potentially conflicts with the right to health by impacting negatively upon the availability of affordable medicines. Currently various states interpret the conflict in

---

[146] Philippe Cullet Patents and Medicines: the relationship between TRIPS and the human right to Health pg 140 Available at http://www.blackwell-synergy.com/doi/abs/10.1111/1468-2346.00299?journalCode=inta

[147] Ibid

[148] ICESCR Available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm

[149] Ibid

different ways dependant on their needs and resources. For example developed members are pushing for stronger intellectual property protection based on commercial interests, whilst developing members are desperate to find a balanced system that still allows them to address their grave public health problems that require access to essential medicines.[150]Under the WTO system the Doha Declaration confirmed that Member States are deemed to be the primary mechanism in finding a balance between trying to achieve, on one hand, the realisation of the right to health, whilst, on the other, also implementing the provisions of the TRIPS Agreement.[151]

The question to be answered therefore is how should a state determine how to strike such a balance and where can the state government look for guidance? The 1969 Vienna Convention provides for the means to interpret treaties in Articles 31-33.[152] Article 31 asserts that a treaty should be interpreted in 'good faith' and 'in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.[153]Article 30 explains that where there is a conflict between two treaties which concern the same subject matter the later treaty is deemed to prevail over the first.[154]This approach is only true if states are a party to both treaties and providing there is no provision to the contrary.[155]

If human rights, including the right to health are fundamental then they should perhaps carry more weight than intellectual property rights. A fundamental right, such as the right to health could be seen as a provision to the contrary that a latter treaty trumps the right. However intellectual property rights can also be found within human rights instruments. As previously mentioned in Chapter I the ICESCR derived Article 15(c) from Article 27.2 of the UNDHR, Article 15 (c) states,

> The States Parties to the present Covenant recognize the right of everyone:
>
> (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[156]

---

[150] See Chapter III above at pg 27
[151] Doha Declaration on the TRIPS Agreement and Public Health Paragraph 4
[152] Vienna Convention on the Law of Treaties 1969 available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf
[153] Ibid Article 31(1)
[154] Ibid Article 30
[155] Ibid Article 3 (a) and (b)
[156] ICESCR Article 15 Available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm

To assume that this puts intellectual property rights on a level par with the right to health would however be a gross misunderstanding of the drafter's intention. It is imperative that Article 15(c) is read with Article 15 (a) and (b) in order to appreciate the context of the Article. They state that,

> The States Parties to the present Covenant recognize the right of everyone:
> (a) To take part in cultural life;
> (b) To enjoy the benefits of scientific progress and its applications;[157]

There seems to be great consideration given to end users of 'scientific progress' i.e. the consumers of medicines and not primarily the inventors. Knowledge and scientific progress is often referred to as a social good and therefore should be for the benefit of society and not merely the inventor.[158] This interpretation also conforms to a treaty interpretation approach laid out in Article 31 of the Vienna Convention, the object and purpose of the ICESCR can be seen in the preamble where states,

> [realise] that the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant.[159]

Philippe Cullet enhances upon this when he explains,

> From the point of view of human rights, the link between the two fields [Intellectual Property rights and human rights] was considered in the drafting of human rights treaties, when,...it was concluded that the interests of the community at large should generally prevail over those of individual authors. This does not imply a rejection of the interests of the author but rather their subordination to broader goals.[160]

International Law in practice does not advocate a hierarchy of rights.[161]One exception, albeit a controversial one, is seen within the doctrine of Jus Cogens. There does seem to be some awareness that perhaps not all human rights are equal. The doctrine of *jus cogens* supports the idea that certain human rights are so fundamental they take precedence over others and they may not under any circumstances be derogated from.[162]They are described as pre-emptory norms. The International Law

---

[157] Ibid
[158] Cullet, Philippe, Supra note 146 pg 155
[159] ICESCR Preamble Supra note 148
[160] Supra note 146
[161] International Law Commission works on fragmentation of International Law Supra note 143
[162] See Dimitrijevic V *'Customary Law as an Instrument for the Protection of Human Rights'* Working Paper No 7, 2006 ISPI Istituto per Gli studi di Politica internazionale

Commission included the concept in the Vienna Convention on the Law of Treaties under Article 53;

> For the purposes of the present Convention, a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.[163]

International Courts have also understood the concept of jus cogens norms; the Barcelona Traction, Light and Power Co Case in the 1970's emphasised this in the judgement where it was held,

> Such obligations [jus cogens] derive, for example, in contemporary international law, from the outlawing of acts of aggression, and of genocide, as also from the principles and rules concerning basic rights of the human person, including protection from slavery and racial discrimination. Some of the corresponding rights have entered into the body of general international law; others are conferred by international instruments of a universal or quasi-universal character.[164]

I discussed the right to health and the right to life in Chapter 1 above and explored the possibility of linking access to medicines as a pre-condition to the right to life. HIV patients require access to ARV's if they are to survive, in this way it is possible to argue a hierarchy over intellectual property rights. The right to life is enshrined in Article 6(1) of the ICCPR, 'Every human being shall have the right to life'.[165] In maintaining that the right to life under the ICCPR is a jus cogens norm evidence can be seen from the ICCPR itself which lists that certain articles are not to be derogated from even in times of emergency.[166]The Human Rights Committee that monitors compliance with the ICCPR noted in its General Comment No 24 that states may also not make reservations to treaty articles that contain jus cogens norms.

> Reservations that offend peremptory norms would not be compatible with the object and purpose of the Covenant. Although treaties that are mere exchanges of obligations between States allow them to reserve *inter se* application of rules of general international law, it is otherwise in human rights treaties, which are for the benefit of persons within their jurisdiction. Accordingly, provisions in the Covenant that represent customary international law (and a fortiori when they have the character of peremptory norms) may not be the subject of reservations. Accordingly, a State may not

[163] Supra note 152 Article 53
[164] Barcelona Traction, Light and Power Co Case para 34 (DJ Harris, Cases and Materials on International Law pg 632
[165] Article 6 ICCPR Available at http://www2.ohchr.org/english/law/ccpr.htm
[166] Ibid Article 4 paragraph 2

> reserve the right to engage in slavery, to torture, to subject persons to cruel, inhuman or degrading treatment or punishment, to arbitrarily deprive persons of their lives...[167]

This statement from the Human Rights Committee clarifies that the right to life is indeed a jus cogens norm and as such is a non derogable right, which by its very nature takes should arguably take precedence over a conflicting obligation.

### 4.2 A Human Rights Approach in Context

In the context of the TRIPS Agreement the Sub Commission on Human Rights in 2001 issued resolution 2001/21, whereby in paragraph 3 the resolution, the Committee,

> 3. *Reminds* all Governments of the primacy of human rights obligations under international law over economic policies and agreements, and requests them, in national, regional and international economic policy forums, to take international human rights obligations and principles fully into account in international economic policy formulation; [168]

They also issued a report whereby one of the recommendations was;

> The requirements under the TRIPS Agreement for the grant of patents - novelty, inventive step and industrial applicability - are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge under article 15 [of the ICESCR].[169]

The Sub Committee whilst recognising the right of inventors therefore stressed again the broader outlook of the public interest to benefit from such knowledge. The Committee on Economic, Social and Cultural Rights also provided a statement on Human Rights and intellectual property, the Committee appears to favour a human rights based approach on the issue.

---

[167] Human Rights Committee, General Comment 24 (52), reservations to the ICCPR, U.N. Doc. CCPR/C/21/Rev.1/Add.6 (1994). Available at http://iilj.org/courses/documents/HRCGeneralComment.pdf

[168] Resolution 2001/21 Intellectual Property and Human Rights Available at http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument

[169] Sub Commission for the Promotion and Protection of Human Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13
27 June 2001 Available at
http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa023802566870051 8ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf

> reserve the right to engage in slavery, to torture, to subject persons to cruel, inhuman or degrading treatment or punishment, to arbitrarily deprive persons of their lives...[167]

This statement from the Human Rights Committee clarifies that the right to life is indeed a jus cogens norm and as such is a non derogable right, which by its very nature takes should arguably take precedence over a conflicting obligation.

### 4.2 A Human Rights Approach in Context

In the context of the TRIPS Agreement the Sub Commission on Human Rights in 2001 issued resolution 2001/21, whereby in paragraph 3 the resolution, the Committee,

> 3. *Reminds* all Governments of the primacy of human rights obligations under international law over economic policies and agreements, and requests them, in national, regional and international economic policy forums, to take international human rights obligations and principles fully into account in international economic policy formulation; [168]

They also issued a report whereby one of the recommendations was;

> The requirements under the TRIPS Agreement for the grant of patents - novelty, inventive step and industrial applicability - are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge under article 15 [of the ICESCR].[169]

The Sub Committee whilst recognising the right of inventors therefore stressed again the broader outlook of the public interest to benefit from such knowledge. The Committee on Economic, Social and Cultural Rights also provided a statement on Human Rights and intellectual property, the Committee appears to favour a human rights based approach on the issue.

---

[167] Human Rights Committee, General Comment 24 (52), reservations to the ICCPR, U.N. Doc. CCPR/C/21/Rev.1/Add.6 (1994). Available at http://iilj.org/courses/documents/HRCGeneralComment.pdf

[168] Resolution 2001/21 Intellectual Property and Human Rights Available at http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument

[169] Sub Commission for the Promotion and Protection of Human Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13
27 June 2001 Available at
http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf

> A human rights-based approach focuses particularly on the needs of the most disadvantaged and marginalized individuals and communities. Because a human right is a universal entitlement, its implementation is evaluated particularly by the degree to which it benefits those who hitherto have been the most disadvantaged and marginalized and brings them up to the mainstream level of protection. Thus, in adopting intellectual property regimes, States and other actors must give particular attention at the national and international levels to the adequate protection of the human rights of disadvantaged and marginalized individuals and groups...[170]

If states are to adhere to a human rights based approach, it seems competent that in the case of the TRIPS Agreement states should be allowed to ensure that the right to health is upheld for disadvantaged individuals and groups such as those suffering from HIV/AIDS. The current flexibilities in the TRIPS Agreement as was shown in chapter III above do not really fully afford states this option; if a more rights based approach was used the story could be somewhat different. In determining what action to take when confronted between the potential conflict of the right to health versus patent rights this chapter has aimed to show that states should be mindful of their fundamental human rights obligations and of the concept of jus cogens and non derogable rights.

> Overall, there appears to be a substantive difference between intellectual property rights, and the fundamental and universal entitlements called human rights. The former are temporary rights granted by the state that can be revoked and transferred, while the latter are alienable and timeless.[171]

The final chapter in this thesis shall look to the future and to possible solutions towards the conflict and failures of the TRIPS Agreement. A solution within the WTO framework shall be discussed alongside the positive steps that the Pharmaceutical Companies and civil society itself may take in striving to achieve the Millennium Declaration Goal Number Six of halting and reversing the spread of the HIV/AIDS virus by 2015.

---

[170]Committee on Economic, Social and Cultural Rights, Human rights and intellectual property, E/C.12/2001/15 para 8
Available at http://www2.ohchr.org/english/bodies/cescr/docs/statements/E.C.12.2001.15HRIntel-property.pdf

[171] Philippe Cullet, Supra note 146 pg 152

## Chapter 5 - Solutions towards solving the conflict

### 5.1. Solutions within the WTO

Essentially this debate involves a conflict between World Trade regimes and human rights, more specifically between the TRIPS Agreement and the right to health. The previous chapter aimed to show there is an apparent trend towards society believing that human rights should – morally at least – be on an equal footing with other international norms or even take precedence over such norms. This chapter shall firstly suggest that the most appropriate solution would be to use the WTO system to achieve the right balance between intellectual property rights and human rights.

The WTO monitors the compliance of its member states and the TRIPS Agreement. and it is the organization that has the power to enforce penalties for non-compliance with that agreement.[172] It has been shown that the TRIPS flexibilities are not working effectively in aiding developing members provide affordable access to antiretroviral HIV/AIDS medicines. If the WTO gave more of a precedence and greater guidance on human rights under the TRIPS Agreement, a similar binding provision to the GATT XX general exception in respect of human rights, would be of great benefit to the conflict. Ideally the WTO should place stronger emphasis on the realisation of human rights within the WTO system, especially in light of the TRIPS Agreements disputes between human rights and patent rights. Taking a human rights approach to the problem of the hierarchy of rights as was discussed above in Chapter 4 would be a possible example of this. Under the WTO Dispute Settlement Framework, decisions within the system are binding upon the members to that dispute and these decisions set clear guidelines for other members who are required to follow them. However the Dispute Settlement System can currently only be used to settle disputes on the covered WTO agreements,[173]therefore it has no jurisdiction to incorporate international human rights within its ambit unless explicitly stated within the WTO Agreements. The system does recognise that international human rights law can be used to aid and interpret the WTO Agreements[174] but as Hestermeyer notes,

[172] Understanding on Rules and Procedures Governing the Settlement of Disputes, Article 22
[173] Ibid Article 1
[174] Ibid Article 3(2)

> Full integration of human rights law would imply that the human rights provisions could be enforced by WTO dispute settlement.[175]

A move in this direction would certainly provide the WTO with a stronger weapon of human rights enforcement however it would be a controversial one, and possibly a move too far and out with the scope of the WTO ambit. The WTO preferably needs to take a stronger stance in permitting the use of the TRIPS Safeguards to allow access to medicines. The WTO should also remind Member States of their human rights obligations. Developing countries need to feel they can use safeguard options without the fear of trade sanctions from developed member states. A close eye should be kept on the bilateral and multilateral trade agreements that include so called TRIPS plus provisions which put an even greater pressure on developed and developing states to provide stronger intellectual property protection than is required by the TRIPS Agreement.

### 5.2. Responsibility of Pharmaceutical Companies

The responsibilities of third parties (i.e. Multinational Corporations like pharmaceutical companies) in relation to human rights instruments are often called into question. Traditionally states are thought of as having the obligation to protect and abide by and enforce human rights instruments however the process of globalisation has seen a shift in this thinking. The world stage is no longer only inhabited by states; large multinational corporations are beginning to play a more dominant role. Many MNC's now have a greater yearly sales figure than the GDP of a state. This stark contrast was shown by Hestermeyer when he writes;

> Corporate power has grown to rival that of states: in 2002 the corporation with the largest sales figure, Wal-Mart at $217,799m, outdid Austria's 2002 GDP, the twentieth biggest national GDP of the world, and was not that much smaller than the whole of Sub Saharan Africa ($319,288m).[176]

However does this mean that corporations like the Big Pharma have a responsibility to respect and promote human rights? The attitude from Bernard Lemoine, the Director General of France's National Pharmaceutical Industry on the matter was shown when he declared, 'I don't see why special effort should be demanded from the pharmaceutical industry. Nobody expects Renault to give cars to people who

[175] *Hestermeyer*, Supra note 4 pg 287
[176] Ibid pg 94

haven't got one.'[177]Clearly the consumption of pharmaceuticals such as ARV's are extremely different to commodities such as a Renault car amongst others because 'consumers of prescription drugs are often a captive rather than a willing market.'[178] Morally it seems justifiable that pharmaceutical companies should have obligations to respect and promote the rights contained in international human rights instruments. However, it is much more difficult to link the legal obligations of International human rights instruments directly to corporations. The ICESCR and the ICCPR are directed at states.[179]A General Comment of the Human Rights Council acknowledged that,

> ...it does not seem that the international human rights instruments discussed here [such as ICESCR and ICCPR] currently impose direct legal responsibilities on corporations. Even so, corporations are under growing scrutiny by the international human rights mechanisms. And while states have been unwilling to adopt binding international human rights standards for corporations, together with business and civil society they have drawn on some of these instruments in establishing soft law standards and initiatives. It seems likely, therefore, that these instruments will play a key role in any future development of defining corporate responsibility for human rights.[180]

One key instrument is the United Nations Global Compact which is an initiative that encourages businesses in 'aligning their operations and strategies with ten universally accepted principles in the areas of human rights, labour, environment and anti-corruption.'[181]The Compact is composed of ten principles. Principles 1 and 2 relate specifically to human rights and states:

> Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and
> Principle 2: make sure that they are not complicit in human rights abuses.[182]

The Global Compact is however not binding and interestingly none of the big pharma are parties to the Compact.[183] In any case there needs to be a greater dialogue

---

[177] As quoted in Jeffrey Robinson, *Prescription Games* 2001 at pg 20, found in Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Security*, Human Rights Quarterly, Vol. 25, No. 2 (May 2003) pg 436

[178] Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Security*, Human Rights Quarterly, Vol. 25, No. 2 (May 2003) pg 436

[179] ICESCR Article 2, ICCPR Article 2

[180] Human Rights Council, Implementation of General Assembly Resolution 60/251 of 15th March entitled 'Human Rights Council', Report of the Special Representative of the Secretary-General (SRSG) on the issue of human rights and transnational corporations and other business enterprises Available at http://www.business-humanrights.org/Documents/SRSG-report-Human-Rights-Council-19-Feb-2007.pdf

[181] United Nations Global Compact Website available at http://www.unglobalcompact.org/

[182] United Nations Global Compact Principles 1 and 2

between all the parties involved – from human rights academics, to WTO members, to NGO's and pharmaceutical companies for a solution to be reached. Public pressure has proved to be one of the most effective ways to make an impact and ensure that access to medicine is a priority consideration in many disputes. In 2001 a case involving 39 International pharmaceutical companies against South African patent laws saw the companies back down after immense protests from the Treatment Action Campaign, Oxfam and the MSF.

> ...the court case was adjourned at the request of the pharmaceutical companies in order to prepare a response to TAC's challenge. In granting their request the judge ruled that they must reply to all the points raised by TAC. Any point they refused to answer would be taken as proven. Unwilling to discuss their pricing policies and provide details of research funding that underlies their huge profits, the companies, led by trans-nationals such as GlaxoSmithKline and Merck, backed down.[184]

Public pressure on pharmaceutical companies and their actions can bring bad publicity via the media for a company.[185]Pharmaceutical Companies are also reluctant to disclose details to do with financing and profits, as was seen in the above case. Civil society thus have a role to play in lobbying against pharmaceutical companies taking governments to court over patent issues and in advocating a right to access essential medicines. Organisations like Medecines Sans Frontiers and Oxfam are examples of groups committed to this cause and positive action can be seen from their efforts.[186]In the future big pharma and the WTO forum under pressure from civil society may have to work towards supporting a human rights framework and access to essential medicines policy.

> Re-evaluation of the notion of profit and ownership in crucial areas such as access to health-restoring drugs is necessary in order to close the yawning gap between the haves and have-nots in this world, which is generating misery, instability and hostility.[187]

[183] A Participant search can be done on the website at note 181 above.
[184] South African case ends in climb down by drug corporations 2001 available at http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml
[185] For example 'Thais battle firms over Aids Drugs' available at http://news.bbc.co.uk/1/hi/world/asia-pacific/1166473.stm
[186] See www.msf.org and http://www.oxfam.org.uk/oxfam_in_action/issues/health.html
[187] Supra note 178 above pg 452

## Conclusions

Debate about striking the right balance between the right to health and access to medicines on the one hand, and the effective implementation of the TRIPS Agreement on the other, has taken centre stage at many of the WTO discussions in the past few years. Despite the changes made to the agreement and the acknowledgement that the Agreement must be read and implemented in such a way as to work with and not against public health policies and goals, the world is yet to see a marked improvement to the practical situation regarding access to life saving medicines like ARV's.

The right to health and the right to intellectual property have become more intertwined since the process of globalization gained momentum, the AIDS/HIV epidemic has evolved, and since the establishment of the World Trade Organization and the TRIPS Agreement.

However, the measures provided for in the TRIPS Agreement under Articles 6, 30 and 31 to allow for a more flexible implementation of intellectual property rights in the area of life saving medicines are complex and over burdensome and do not reflect a fair balance between the right to health and the intellectual property rights. The Agreement is construed in such a way as to heavily favour intellectual property protection. Article 6 and the concept of parallel imports are not effective as the price of the parallel import is still unlikely to be affordable to the poor, some countries have laws to prohibit parallel imports and many countries are put off using parallel imports due to the expensive litigation cases that may result from developed members or pharmaceutical companies. The exceptions under Article 30 relating to 'limited exceptions' such as public health emergencies, needs to be interpreted more widely by the members of the WTO and the WTO itself for the Article to have optimum effect. Article 31 and the issue of compulsory licensing is still the most contentious, despite the amendments and waivers to the exception the requirements are still too high and too troublesome to achieve the aims of the safeguard.

The G8 have not met their commitment to achieve 'as close to universal access to HIV/AIDS treatments as possible by the year 2010'. The delay in implementing

Article 31bis was a blow to the target. In relation to the Millennium Development Goals there is slightly more time with just less than 5 years to meet the challenges of halting and reversing the spread of HIV/AIDS. This is simply not possible unless there is a greater access to ARVs at an affordable price.

The conflicts between the norms of human rights law and intellectual property law are clearly apparent. In addressing this conflict a superior function of human rights norms is what is required although this can generally said to be frustratingly absent from international law in practice. If however, the WTO can work toward providing a stronger promotion and enforcement of human rights, the imbalance between the right to health and the TRIPS Agreement could be alleviated, resulting in greater access to medicine. Greater co-operation between pharmaceutical companies, the WTO, member states and civil society is also an essential tool in furthering access to medicines especially antiretroviral drugs needed for HIV/AIDS treatment.
This requires a change in attitudes, especially from pharmaceutical companies and the developed world, in their approach to patents and the right to health which includes access to essential medicines. In continuing the push for stronger IP regimes they are signing a death warrant to millions of people living in the developing world that require affordable access to medicine.

Every day lives are at risk as the debate continues and solutions keep failing. Oxfam estimate that 'Every hour – 300 people die of an AIDS related illness.'[188]As Nelson Mandela aptly said in 2002,

> Concerted action is what is required. Every moment spent in deliberation that does not lead to action is a moment tragically wasted.[189]

Sadly world leaders have not learnt, concerted action has not yet been seen, and flexibilities within the TRIPS Agreement and their amendments are not working. The conflicts of the right to health and the right to intellectual property within the TRIPS Agreement must be more aptly addressed and the time to find that appropriate solution must be now, in 2010.

---

[188] Making health care available for all, available at http://www.oxfam.org.uk/oxfam_in_action/issues/health.html
[189] Nelson Mandela, Johannesburg 2002, found in Unicef. Caring for Children Affected by HIV and AIDS 2006 pg 4

## Appendix 1

## TRIPS Agreement Part II

## Standards concerning the availability, scope and use of Intellectual Property Rights

SECTION 5: PATENTS

*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.[190] 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.

[190] 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[191] 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.

[191] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

*Article 31*

*Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use[192] 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) authorization 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;

[192] "Other use" refers to use other than that allowed under Article 30.

(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-licence 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 32*

*Revocation/Forfeiture*

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

*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.[193]

*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.

[193] It is understood that those Members which 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.

**Appendix 2**

## DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

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

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

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.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

**Amendment of the TRIPS Agreement**

Decision of 6 December 2005

The General Council;

*Having regard* to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

*Conducting* the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

*Noting* the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

*Recognizing*, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

*Recalling* paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

*Having* considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

*Noting* the consensus to submit this proposed amendment to the Members for acceptance;

*Decides* as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of

Article X of the WTO Agreement.

**ATTACHMENT**

PROTOCOL AMENDING THE TRIPS AGREEMENT

*Members of the World Trade Organization;*

*Having regard* to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

*Hereby agree* as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

*Done* at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

## ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

*Article 31bis*

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the

economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

## ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as

an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex;

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves , provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[7] the following information:

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

## APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

## Bibliography

Please note all web materials were accessed and available at the time of writing, (01/2010)

### Primary Sources

#### Cases

Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain) *ICJ Judgement 24 July 1964*

*Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory*, ICJ Judgement 9 July 2004

*Minister of Health et al v Treatment Action Campaign et al* 2002 (5) SA 721(CC) Case CCT 8/02

*Canada – Patent Protection of Pharmaceutical Products* 2000 WT/DS114/R available at www.wto.org

*US- Brazil Measures Affecting Patent Protection* 2000 DS199 available at www.wto.org

#### International Law

International Covenant on Civil and Political Rights 1976
International Covenant on Economic, Social and Cultural Rights 1976
Paris Convention for the Protection of Industrial Property March 20, 1883
Universal Declaration on Human Rights 1948
Vienna Convention on the Law of Treaties 1969

#### WTO Law

The General Agreement on Trade and Tariffs 1947
The General Agreement on Trade and Tariffs 1994
The General Agreement on Trade and Services
The Agreement on Trade-Related Aspects of Intellectual Property
Understanding on Rules and Procedures Governing the Settlement of Disputes
Amendment of the TRIPS Agreement – Extension for the Period of the acceptance by Members of the Protocol Amending the TRIPS Agreement WT/L/711 21 December 2007

### Secondary Sources

#### Books

Burgi, E, Cottier, T, Pauwelyn J, *Human Rights and International Trade*, Oxford University Press London 2005

Correa, C, *Intellectual Property Rights, the WTO and Developing Countries, The TRIPS Agreement and Policy Options*, Zed Books Ltd, Third World Network, 2000

Harris, DJ *Cases and Materials on International Law*, Thomson Sweet and Maxwell, 2004

Hestermeyer, H, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, Oxford University Press London 2007

Pauwelyn, J, *Conflict of Norms in Public International Law*, Cambridge University Press, London 2004
Roffe, P, Tansey, G, Vivas-Eugui, D, *Negotiating Health, Intellectual Property and Access to Medicines*, Earthscan, 2006
Sachs, J, *The End of Poverty, How we can make it happen in our Lifetime*, Penguin Books, London 2005
Stiglitz, J, *Making Globalization Work*, Penguin Books, London 2007
*The Legal Texts, The Results of the Uruguay Round of Multilateral Trade Negotiations*, Cambridge University Press, London 2005
Van den Bossche. P, *The Law and Policy of the World Trade Organization*, Cambridge University Press, London 2005

**E-books**

Pugatch ,M.P, *The International Political Economy of Intellectual Property Rights pg 141-142*

**Journals**

Attaran A, How Do Patents And Economic Policies Affect Access to Essential Medicines in Developing Countries? Health Affairs 23, no. 3 (2004)
Barton J, TRIPS and the Global Pharmaceutical Market, Health Affairs 23, no. 3 (2004)
Chirwa, Danwood, 'The Right to Health in International Law: Its implications for the obligations of state and non state actors in ensuring access to essential medicines'. (2003) 19 SAJHR
Correa, Carlos, 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements, as in Negotiating Health, Intellectual Property and Access to Medicines, Chapter 6
Cullet P, Patents and Medicines: the relationship between TRIPS and the human right to Health Available at http://www.blackwell-synergy.com/doi/abs/10.1111/1468-2346.00299?journalCode=inta
Dimitrijevic V 'Customary Law as an Instrument for the Protection of Human Rights' Working Paper
No 7, 2006 ISPI Istituto per Gli studi di Politica internazionale
Grossman and Lai, International Protection of Intellectual Property, The American Economic Review, Vol. 94, No. 5 (Dec., 2004), pp. 1635-1653 Published by: American Economic Association
Gupta, A, Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS provide a solution? 2004 2 Buff.Intell.Prop.L.J.127
Haochen Sun, The Road to Doha and Beyond: some reflections on the TRIPS Agreement and Public Health, European Journal of International Law 2004 15(1)
Heywood, Mark, Drug Access, Patents and Global Health: 'Chaffed and Waxed Sufficient', Third World Quarterly, Vol. 23, No.3, Global Health and Governance: HIV/AIDS (Apr.2002)
H . Hogerzeil , M . Samson , J . Casanovas , L . Rahmani-Ocora Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? The Lancet , Volume 368 , Issue 9532
Jenks, W 'The Conflict of Law-Making Treaties' (1953) 30 British Yearbook of International Law 401

Joseph, Sarah, Pharmaceutical Corporations and Access to Drugs, 'The Fourth Wave of Corporate Human Rights Scrutiny, Human Rights Quarterly, Vol. 25, No. 2 (May, 2003)
Ostry, S, The Uruguay Round North-South Grand Bargain: Implications For Future Negotiations, The Political Economy of International Trade Law, University of Minnesota September,2000 available at http://www.utoronto.ca/cis/Minnesota.pdfS
Wade, R 'Which Strategies are viable for developing countries today? The World Trade Organization and the shrinking of 'development space', Review of International Political Economy, Vol 10, No.4, Tenth Anniversary Issue (November 2003)

**United Nations Resolutions, General Comments and Publications**

Atlas of the UN Millennium Development Goals, Map on'Eradicating Poverty and hunger'.
Available at http://devdata.worldbank.org/atlas-mdg/
Declaration of Commitment on HIV/AIDS 2001
Available at http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html
Millennium Declaration 2000
Available at http://www.un.org/millennium/declaration/ares552e.htm
Committee on Economic, Social and Cultural Rights, Human rights and intellectual property, E/C.12/2001/15
Available at
http://www2.ohchr.org/english/bodies/cescr/docs/statements/E.C.12.2001.15HRIntel-property.pdf
Committee on Economic, Social and Cultural Rights General Comment 3 'The Nature of State Parties' Obligations (art 2(1) of the ICESCR) (5th session, 14 December 1990)
Available at
http://www.unhchr.ch/tbs/doc.nsf/0/94bdbaf59b43a424c12563ed0052b664?Opendocument
Committee on Economic, Social and Cultural Rights, General Comment No14 on The Right to the Highest Attainable Standard of Health, UN Doc E/C.12/2000/4(2000)
Available at http://www.unhchr.ch/
Human Rights Committee, General Comment No.6, The Right to Life, UN DOC. A/37/40 Available at
http://www.unhchr.ch/tbs/doc.nsf/0/84ab9690ccd81fc7c12563ed0046fae3
Human Rights Committee, General Comment 24 (52), reservations to the ICCPR, U.N. Doc. CCPR/C/21/Rev.1/Add.6 (1994). Available at
http://iilj.org/courses/documents/HRCGeneralComment.pdf
The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, U.N. Doc. E/CN.4/1987/17
The Maastricht Guidelines January 1997, Available at
http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html
Mission to the World Trade Organization, 2004, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Report of the Special Rapporteur, Paul Hunt E/CN.4/2004/49/Add.1
Available at http://www2.essex.ac.uk/human_rights_centre/rth/docs/WTO.pdf

Resolution 60/224. Preparations for and organization of the 2006 follow-up meeting on the outcome of the twenty-sixth special session: implementation of the Declaration of Commitment on HIV/AIDS
Available at http://data.unaids.org/topics/ungass2003/a60-l43_2005_en.pdf
Resolution 60/251 Implementation of General Assembly Resolution 60/251 of 15th March entitled 'Human Rights Council', Report of the Special Representative of the Secretary-General (SRSG) on the issue of human rights and transnational corporations and other business enterprises
Available at http://www.business-humanrights.org/Documents/SRSG-report-Human-Rights-Council-19-Feb-2007.pdf
Resolution 60/262 Political Declaration on HIV/AIDS
Available at
http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf
Resolution 2001/21 Intellectual Property and Human Rights
Available at
http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument
Sub Commission for the Promotion and Protection of Human Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13 27 June 2001 Available at
http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf
UNAIDS Report 2008
Available at
http://data.unaids.org/pub/Report/2009/jc1736_2008_annual_report_en.pdf
UNICEF Caring for Children Affected by HIV and AIDS 2006, Innocenti Research Centre, Tipografia Giuntina, Florence, Italy 2006
WHO/UNAIDS Epidemic Update 2009 'Impact of Increased Access to Treatment on epidemiological trends'
Available at
http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf

**Other Publications**

Convention establishing the World Intellectual Property Organization, July 14 1967 available at
http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html#P68_3059
Commission on Intellectual Property Rights, Study Paper 2a '*WTO TRIPS Agreement and Its Implications for Access to medicines in Developing Countries*' Frederick M. Abbott available at
http://www.iprcommission.org/graphic/documents/study_papers.htm
Final Report to World Intellectual Property Organisation 2001 'Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries' Keith Maskus available at http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf
Guide to the Application of the Paris Convention for the protection of Industrial Property, Professor G.H.C. Bodenhausen 1968, WIPO Publication.

Overseas Development Institute, '*Poverty and poverty reduction in Sub Saharan Africa: An Overview of the issues*' January 2009, available at http://www.odi.org.uk/resources/download/600.pdf
'*Understanding Patents and Medicine Access, the WTO, Free Trade Agreements and Patent Law*' Kapczynski, Yale Aids Network Presentation Available at www.yale.edu/aidsnetwork/TRIPS%20Teach-In.ppt

**Web Articles**

Abbott offers price cut to thwart Thai compulsory license on Kaletra http://www.aidsmap.com/en/news/08E18120-7D15-4E1C-98DC-145C515EFBAC.asp
'*Do Corporations Rule?*'Walden Bello and Philippe Legrain, BBC Who Runs your world? Series 2005, Available at http://news.bbc.co.uk/1/hi/magazine/4201516.stm
Making health care available for all available at http://www.oxfam.org.uk/oxfam_in_action/issues/health.html
MSF, Q&A on patents in India and the Novartis case available at http://www.msf.org/msfinternational/invoke.cfm?objectid=A05B02CF-5056-AA77-6CA9A174A5C4E2F7&component=toolkit.article&method=full_html
South African case ends in climb down by drug corporations 2001 available at http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml
Thais battle firms over Aids Drugs BBC News 2007 available at http://news.bbc.co.uk/1/hi/world/asia-pacific/1166473.stm
WTO Summit: Don't undercut AIDS Drugs Access available at http://www.hrw.org/press/2001/11/wto-aids1107.htm

**Websites**

Aidsmap www.aidsmap.com
Avert www.avert.org/aidstarget.htm
GlaxoSmithKline www.gsk.com
G8 www.g8.gov.uk
Grain www.grain.org
Human Rights Watch www.hrw.org
International Law Commission www.un.org/law/ilc/
LexisNexis www.lexisnexis.co.uk
Medicines Sans Frontiers www.accessmed-msf.org
Stanford Encyclopdia of Philosophy www.plato.stanford.edu
Oxfam www.oxfam.org
Patent Storm www.patentstorm.us
UNAIDS www.unaids.org
United Nations www.un.org
United Nations Global Compact www.unglobalcompact.org
United Nations High Commissioner for Human Rights www.unhcr.org
World Intellectual Property Organisation www.wipo.org
World Trade Organisation www.wto.org
World Health Organisation www.who.org

**WTO Publications available at www.wto.org**

Understanding the WTO, World Trade Organisation, 3rd Ed, 2005 Geneva
'Members accepting amendment of the TRIPS Agreement' as at 25th January 2010
'Members OK amendment to make health flexibility permanent' 6 December 2005
The General Council Chairpersons Statement 30th August 2003
WTO Decision removes final patent obstacle to cheap drug imports Press Release 30th August 2003

**World Health Organisation Publications**

Boulet & Velásquez, *Globalization and Access to Drugs, Implications of the WTO/TRIPS Agreement*, Health Economics and Drugs, DAP Series No.7, WHO 1998
*Correa, C*, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, 2002
WHO 'Antiretroviral Therapy' available at
http://www.who.int/hiv/topics/treatment/en/
WHO Constitution 1946 available at
http://www.who.int/governance/eb/who_constitution_en.pdf
WHO Model list of Essential Medicines 16th List, March 2009
Available at
http://www.who.int/selection_medicines/committees/expert/17/sixteenth_adult_list_en.pdf
WHO Progress Report 2009 'Towards Universal Access, Scaling up Priority HIV/AIDS interventions in the health sector', Available at
http://www.who.int/hiv/pub/2009progressreport/en/index.html
WHO The 3 by 5 Initiative Available at http://www.who.int/3by5/en/v