The Right to Health in the Global Economy: Reading Human Rights Obligations into the Patent Regime of the WTO-TRIPS Agreement

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

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November 2001

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I List of Abbreviations

AAI	Accelerating Access Initiative
AIDS	Acquired Immune Deficiency Syndrome
ACHPR	African Charter on Human and Peoples' Rights
ACHR	American Convention on Human Rights
AI	Amnesty International
ARIPO	African Regional Intellectual Property Organisation
ARVs	Anti Retrovirals
ASIL	American Society of International Law
AU	African Union (formerly the Organisation of African Unity – OAU)
AZT	Zidovudine (formerly Azidothymidine)
CEDAW	Convention on the Elimination of Discrimination of All Forms against Women
CERD	Convention on the Elimination of All Forms of Racial Discrimination
CESCR	Committee on Economic, Social and Cultural Rights
CNN	Cable News Network
CRC	Convention on the Rights of the Child
CCSA	Constitutional Court of South Africa
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
EPC	European Patent Convention
ESC	European Social Charter
EU	European Union
GATT	General Agreement on Trade and Tariffs
HDR	Human Development Report
HIV	Human Immuno-Deficiency Virus
HRW	Human Rights Watch
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IHRL	International Human Rights Law
IMF	International Monetary Fund
IP	Intellectual Property
IPRs	Intellectual Property Rights
MSF	Medecins Sans Frontieres
NGO	Non-Governmental Organisation

OAPI	African Intellectual Property Organisation
OECD	Organisation for Economic Co-operation and Development
R & D	Research and Development
SAPs	Structural Adjustment Programmes
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Agreement on the Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organisation
WTO	World Trade Organisation
UDHR	Universal Declaration on Human Rights
UN	United Nations Organisation
UNDP	United Nations Development Programme
UNHCHR	United Nations High Commissioner for Human Rights
USA	United States of America
USTR	United States Trade Representative

II Acknowledgements

I would like to express my gratitude to Dr. J. Oloka-Onyango under whose supervision this work was prepared for his support and expertise which proved invaluable. Thanks are also due to Professor Fredrick Abbott, Professor Frank J Garcia, Professor Viljoen, Robert Lettington, Lirette Louw and to all those who have provided their valuable time and input in various ways over the period that has preceded the completion of this work. I am also grateful to the management and staff of Centre for Human Rights, University of Pretoria and the Human Rights and Peace Centre, Faculty of Law, Makerere University.

1. INTRODUCTION

1.1 Background to the Study

> "We live at a time of new discovery, with the mapping of the human genome, enormous structural shifts in the way science is carried out and unprecedented networking and knowledge sharing opportunities brought about by falling costs of communication. But it is also a time of growing public controversy on issues ranging from the possible risks of transgenic crops to providing access to lifesaving drugs for all who need them." Mark Malloch Brown, Administrator UNDP in the foreword to the *Human Development Report 2001.*

Virtually no area of human existence today is free from the varied consequences of globalisation. Increasingly, policy makers and ordinary people are turning to technology for solutions to the world's socio-economic and development problems. Today's technological transformation is pushing forward the frontiers of medical research, communications, agriculture, and energy and is seen as a source of dynamic growth.[1] In the medical and pharmaceutical industry in particular, major technological advances have been witnessed. There have been dramatic developments in medical science such as 'Dolly' the Sheep, the mapping of the human genome, advances in stem cell research and a vast number of developments including anti-retroviral therapy and second line treatments for tuberculosis (TB) and malaria. These developments in medical research provide increasing hope for the realisation of the right to health. Yet, the reality is that curable and preventable diseases continue to kill and maim millions in Africa and other developing regions of the world.[2] In this context, globalisation can be seen as having created new opportunities as well as challenges for the protection and promotion of human rights.[3]

It is against such a paradoxical background that questions have arisen with regard to the role and benefits of medical and pharmaceutical technology in an expanding global economy. Access to health care is today widely accepted as a core component of efforts to

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1 UNDP, *Human Development Report 2001: Making New Technologies Work for Human Development (2001)* 95.

2 The Cable News Network's (CNN) programme "CNN Perspectives" tacitly summed up the paradox in a special feature on HIV/aids by titling it *The Dream Deferred.* The ravages of disease have shattered the dream that the twenty first century would be the century for Africa.

3 R Howse & M Mutua "Trading in Human Rights: The Human Rights Obligations of the WTO" ICHRRD (April 2000).

promote and protect the right to health.[4] At the same time, the health sector is one of the newest fields of commercial activity in the global economy.[5] As a result, there now exists unacceptable inequalities in the health status of people particularly between developed and developing countries as well as within countries. We live in a society in which there are great disparities in wealth; a world where millions of people are living in deplorable conditions which are made worse by great degrees of poverty.[6]

1.1.1 Privatisation and Liberalisation in the Health Sector

In the wider debate about globalisation, one of the areas of considerable controversy is the issue of trade liberalisation. The current thinking and health policy in developing countries is greatly oriented towards privatisation and liberalisation. The result is that hospital care, ambulance services; care for the aged, telemedicine and other health care services have been privatised and liberalised. The consequences are several including the increased cost of hospital and other forms of health care.[7] The focus has shifted to 'effective demand' for medical and pharmaceutical services.[8] It follows that the health needs of people in Africa and other developing regions of the world must now be backed by hard cash in a health sector that is commodified, privatised and globalised.

The market perspective regards health as a commodity to be sold like any other good and not as a public good to be distributed equally to all.[9] Consequently, there is an emphasis on a reduced role for the state, the privatisation of public enterprise and the continuous

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

5 A Bertrand & L Kalafatides "The WTO and Public Health" (1999) *The Ecologist.* Available at <http://www.aidc.org.za/archives/wto_health_bertrand_kalafatides.html> accessed on 15 March 2001.

6 The Judgment of Chaskalson, P in *Soobramoney v. Minister of Health (KwaZulu-Natal)* Case CCT 32 OF 1997 Judgment of 27 November 1997 CCSA, para 8. Available at <http://www.concourt.gov.za> accessed on 21 August 2001.

7 J Oloka-Onyango & D Udagama *Globalisation and its Impact on the Full Enjoyment of Human Rights* (July 2001) para 43.

8 D Smith "What Does Globalisation Mean for Health?" (June 1999) *Third World Network*. Available at <http://www.globalpolicy.org/globaliz/special/health/html.> accessed on 11 March 2001.

9 VA Leary "Implications of a Right to Health" in KE Mahoney and P Mahoney (eds) *Human Rights in the Twenty-first Century* (1993) *481*, 482.

deregulation of the economy.[10] One of the most serious effects of the economic liberalisation policies has been the constraint placed on the provision of essential medicines. The concept of essential drugs, which was aimed at ensuring that all essential drugs are available to all people free of charge or at reasonable prices, has suffered serious drawbacks. In addition, promotional activities traditionally undertaken by governments have been reduced affecting crucial activities such as immunisation.[11] Although there is no consensus on how trade liberalisation affects human rights, at the very least, it should be understood that privatisation and liberalisation of the health sector cannot relieve the state of the obligation to use all available resources to promote adequate access to health care particularly for the poorer segments of the population.[12]

1.1.2 *Intellectual Property Rights (IPRs) and Access to Medicines in the Global Economy*

Within the context of the privatisation and liberalisation of health care services under the structural adjustment programmes (SAPs) of the World Bank and the International Monetary Fund (IMF), came the signing of the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994.[13] The Agreement introduced important dimensions to the field of intellectual property (IP) with far reaching implications for health delivery, in particular access to essential medicines. By accepting to be bound by the requirements of the TRIPS Agreement developing and least developed countries in particular undertook to substantially review, expand and strengthen their IP legislation. The strengthened and expanded patent protection covering pharmaceuticals products has meant that with the emergence of new diseases such as HIV/AIDS and the growing resistance to drugs of old diseases such as malaria and TB, effective medicines are increasingly patent protected. Indeed, few issues have more dramatically illustrated the tensions between human rights law and WTO law than the relationship between IP protection and access to essential medicines. Today, intellectual property rights (IPRs) lie at

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10 Oloka-Onyango & Udagama (n 7 above) para 4.

11 In Zimbabwe, the implementation of the SAPs led to a fall in the level of immunisation. See Smith (n 8 above).

12 Toebes (n 4 above) *666.*

13 The TRIPS Agreement was part of the Final Act establishing the WTO commonly referred to as the 'Marrakech Agreement'.

the heart of a highly polarised debate on technology and development.[14] The measures of economic reform coupled with the strict regime of patent protection under the WTO have therefore substantially impacted on the progressive realisation of the right to health.[15]

Drugs and therapies are an integral part of the realisation of the right to health. Indeed, drugs and techniques for therapeutic, diagnostic and prevention of diseases are essential factors in guaranteeing human health in general. The cost disparity restricting access coupled with reduced government spending on health care has therefore virtually guaranteed that most sufferers of HIV/AIDS and other tropical diseases have little or no access to the best available treatments. In the main the increased protection of IPRs in a privatised and liberalised health sector has created controversy over the issue of access to new and mostly expensive technologies with enormous potential to alleviate suffering and improve the living conditions of millions of people. From a rights perspective, the interplay between the protection of health and the protection of IPRs has become a critical area of focus in the ongoing debates about the benefits of globalisation. As the principal duty bearers in human rights law states therefore face a new challenge as they implement the TRIPS Agreement; the obligations under the Agreement may undermine or usurp their prior obligations under human rights instruments.

While developing countries have to conform to the minimum standards under TRIPS, there is a wide scope to fashion appropriate national strategies within this multilateral framework.[16] Indeed, the ultimate impact of the Agreement will largely depend on how countries use these implementation strategies. The Agreement contains a number of provisions such as those on compulsory licensing and government use, exhaustion and other exceptions such as the early working exception designed to permit countries to take measures to protect their public priority objectives including health. While there is continuing debate about the adequacy of these provisions, the most important issue is the one concerning the implementation and interpretation of these provisions. While the Agreement leaves the questions of implementation and interpretation largely in the hands of states, differentials in power, influence and resources clearly place limitations on how the room for manoeuvre can be utilised by developing countries.[17] A single set of minimum rules may seem to create a level

14 HDR 2001 (n 1 above) 102.

15 Oloka-Onyango & Udagama (n 7 above) para 24.

16 HDR 2001 (n 1 above) 104.

17 Oloka-Onyango & Udagama (n 7 above) para 21.

playing field but the game is hardly fair when the players are of such unequal strength, both economically and institutionally.[18]

1.2 Statement of Research Problem

The implementation of the TRIPS Agreement, within the wider context of globalisation, has brought about a conflict between the obligation of states to promote and protect health and the achievement of economic goals pursued under the WTO regime. Since trade is the driving engine of globalisation, it is imperative that, at the very least, rules governing it do not violate human rights but rather promote them. The problem of IP and the right to health therefore lies in ensuring that the integration of economic rules and institutional operations in relation to IPRs coincide with states' obligations to promote and protect public health.

1.3 Focus and Objectives of the Study

This study centres on the specific debate about health and IPRs in the context of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the WTO rules on IP protection. In terms of a human rights approach to the TRIPS Agreement, the ICESCR has been chosen for several reasons. First, the ICESCR specifically recognises both the right to health and the right to the protection of inventions in clearer terms than any other human rights instrument. Secondly, at least 111 of the state parties to the ICESCR are also members of the WTO including a large number of developing countries.[19] Thirdly, if one sees the ICESCR as a vehicle for the fulfilment of the obligation to promote and protect human rights under the United Nations Organisation's (UN) Charter, it can be argued that in line with article 103, the implementation and interpretation of TRIPS by all UN members states must take into account basic human rights.[20] However, even with primary focus being on the ICESCR, most of the discussion on practical issues will focus on the experiences in Sub-Saharan Africa because the inequalities and problems of access to health care are most dramatically played out in this part of the world.

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18 HDR 2001 (n 1 above) 105.

19 See the Report of the UNHCHR on the Impact of TRIPS on Human Rights (June 2000).

20 Art 103 of the UN provides that 'In the event of conflict between the obligations of Members under the Charter and their obligations under any other international agreement, their obligations under the Charter shall prevail.' For a fuller discussion of art 103 implications on WTO law see Howse & Mutua (n 3 above).

The objective of the study is to examine the relationship between the obligation of states to progressively realise and guarantee the right to health, and the IP rules under the TRIPS Agreement. The specific objective is to examine the relationship between the exceptions under the TRIPS Agreement and the obligation to protect health and the identification of a consistent way of achieving a convergence between the implementation and interpretation of the rules of the two regimes in the area of health.

1.4 Significance of the Study

IPRs are playing an increasingly more important role in the economic development of nations. While further technological advancement necessitates the protection of exclusive exploitation rights, which IPRs ensures, the maintenance and improvement of human health must be considered within the context of the IP regimes that states establish. The World Health Organisation (WHO), other UN bodies and national governments have expressed increasing concern over the impact of the TRIPS Agreement on the provision of healthcare and a scheme systematically identifying and contextualising how the obligations under the right health condition, both positively and negatively, the room for manoeuvre when implementing the Agreement needs to be agreed upon.[21] This study is contribution intended to help states and other institutions ensure that both innovators and consumers, in a rights sensitive context, share the benefits of medical technology.[22] It is also hoped that the study will inform the post-Doha debates on the issue of access to medicines.[23]

It is also important to note that although the question of access to medicines and related issues regarding the ravages of HIV/AIDS and other diseases in Africa and other developing regions of the world is a critical question, most traditional human rights NGOs including

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21 There are of course significant on-going studies by UN bodies and experts and other international organisations such as the ASIL project (in conjunction with the George Town Law Center, World Trade Institute and the Max Planck Institute) on International Trade and Human Rights lead by professor Frederick Abbott.

22 Already the issue of IPRs and health has been a subject of litigation including in a rights context. At the WTO the case between the US and Brazil was partly on this subject and the pharmaceuticals case and the on-going case by TAC in South Africa raise constitutional issues of the subject.

23 Doha the capital of Qatar is where the WTO Fourth Ministerial Meeting took place from 9 - 14 November 2001.

Amnesty International (AI) and Human Rights Watch (HRW) continue to treat the right to health and other socio-economic rights with scant attention.[24]

1.5 Hypotheses/Research Questions

This study conceptualises the regimes for the protection of IPRs and specifically for the protection of the right to health not as mutually exclusive but as potentially reinforcing. The main thesis of the study is that the obligation to protect and promote the right to health requires in the first instance states to incorporate the flexibility provided by TRIPS into national legislation and policy. Secondly, that the obligations under the right to health limit the manner in which states can exercise the flexibility within the patent regime of the TRIPS Agreement. The study therefore systematically seeks to answer the following question: *To what extent do the obligations imposed on states with respect to the right to health positively and negatively condition the manner in which states can utilise the flexibility under the TRIPS Agreement?*

1.6 Literature Review

Since the coming into force of the TRIPS Agreement, numerous studies have addressed the issue of the protection of IPRs and its implications for public health.[25] There are however very few studies that have sought to identify and analyse the relationship between IP rules and the norms regarding the realisation of the right to health.[26] Even fewer studies have conceptualised the debate in a 'state obligation context'. The most advanced studies in this area have been studies by UN bodies and experts.[27] These studies have among other issues, sought to examine the relationship between the right to health and the protection of IPRs in an effort to ensure that humanity benefits from scientific advancement.[28] The obligations have however mainly been used to show that states must take advantage of the flexibility under the TRIPS Agreement. No particular study has sought to systematically

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24 See current annual reports.

25 See G Velasquez & P Boulet *Globalisation and Access to Drugs: Perspectives on WTO/TRIPS Agreement* (1999) and together with the Annotated Bibliographies.

26 Most of the studies including the HDR 2001, the reports of the UN Special Rapporteurs on globalisation and other articles have addressed this issue as part of broader studies on globalisation.

27 See various reports at <http://www.unhchr.ch> on the subject.

28 See the Report of the UNHCHR (n 19 above).

demonstrate how the human rights obligations limit the manner in which states can exercise the flexibility within the TRIPS Agreement.

1.7 Summary of Chapters

The study is divided into five chapters. Chapter one provides the context in which the study is set, the focus and objectives of the study, its significance and other preliminary issues including the hypothesis and the literature review. Chapter two first seeks to delimit the meaning, content and the resultant obligations under the right to health. In the second part the traditional concept of IPRs as well as the reward-benefits dichotomy in article 15 of the ICESCR is reviewed. Chapter three provides a brief overview of the IP regime under the TRIPS Agreement and the exceptions to exclusive patent rights in the context of the balance of interests concept. Chapter four, which covers the largest part of the main debate in this study, first examines the exceptions in the context of the obligations to protect the right to health identified in chapter two. Secondly, the chapter examines some of the other mechanisms that have been suggested either as complementary to or substitutes to the exceptions under TRIPS such as tiered pricing. The fifth and final chapter of the study seeks to draw some conclusions and give recommendations on how a convergence can be achieved between the goals of IPRs under the TRIPS Agreement and the obligation to protect health under international human rights law (IHRL).

2. LINKING CONCEPTS: THE RIGHT TO HEALTH AND THE CONCEPT OF IPRs UNDER IHRL

The linking of concepts related to the right to health and the conceptual underpinnings of IPRs has particular practical implications for the understanding of the debate in this study. Both the right to health and the right to the protection of the inventions are recognised by the Universal Declaration on Human Rights (UDHR) and the ICESCR.[29] It is therefore necessary to put these two rights into context and examine their relationship at this level before proceeding to deal with the debate on health and trade related aspects of IPRs under the TRIPS Agreement.

2.1 Delimiting the Content of the Right to Health

Despite the fact that the right to health is solidly embedded in international, regional and national human rights instruments, there remains a fair deal of disagreement about its precise meaning and the resultant obligations. It is therefore necessary to address some definitional problems as well as some implementation practices and issues.

2.1.1 The Normative Framework

The right to health is recognised in various international and regional human rights instruments and the Constitution of WHO. Various national bills of rights also recognise the right.[30] At the international level, the starting point is article 25 of the UDHR. It recognises the right of 'everyone … to a standard of living adequate for the health of himself and his family, including food, clothing, housing and medical care and necessary social services.' The concept of health under the UDHR contains sub-rights. These sub-rights are enumerated in article 11 of the ICESCR. The concept incorporates the determinants of health or what in current human rights literature is commonly referred to as the underlying preconditions of health. The preamble to the constitution of the WHO conceptualises health as ' a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'.[31] The Declaration of Alma–Ata adopts the same definition.[32]

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29 See arts 27 and 15 respectively.

30 See for example art 27 of the South African Constitution and art 13 of the Colombian Constitution.

31 The Constitution of the World Health Organisation, 14 U.N.T.S 186 reproduced in *Basic Documents of the WHO* (1981).

While article 12 of the ICESCR is modelled on the UDHR provisions, it provides a more comprehensive definition and is more specific.[33] Article 12.1 of the Covenant recognises 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. Article 12.2 provides a non-exhaustive illustrative list of the steps that are necessary to achieve the full realisation of the right. Other international instruments that recognise the right to health on similar lines include the Convention on the Elimination of all Forms of Racial Discrimination (CERD),[34] the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW),[35] and the Convention on the Rights of the Child (CRC).[36] Several instruments in the three regional human rights regimes also recognise the right to health roughly along the same lines.[37] It can therefore be concluded that, at least at the normative level, the right to health is firmly embedded in IHRL.[38]

2.1.2 Critical Elements of the Right to Health

The right to health as conceptualised under article 12.1 of the ICESCR can be viewed as an inclusive right extending not only to timely and appropriate health care but also incorporating the underlying determinants of health. The right in that sense contains certain critical elements. Consequently, the right to health must be understood as a right to the enjoyment of a variety of essential facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health. The basic elements of the right to health are availability, accessibility, acceptability and quality.[39] The focus of this study as is probably already apparent is on availability and accessibility although certain elements of acceptability are a necessary corollary. According to the Committee on Economic, Social and Cultural Rights (CESCR) availability connotes functioning public and health care

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32 Declaration adopted at the International Conference on Primary Health Care, Alma-Ata, USSR (September 6-12, 1978). Reproduced in G Bekker (ed) *A Compilation of Essential Documents on the Rights to Health Care* (2000) *62*.

33 See para 4 of CESCR General Comment 14 (July 2000).

34 Article 5 (e).

35 Articles 11.1 (f) and 12.

36 Article 24.

37 See articles 11 of the ESC, 16 of the ACHPR and articles 11 of the American Declaration and article 10 of the San Salvador Protocol to the ACHR.

38 A Hendricks & B Toebes "Towards a Universal Definition of the Right to Health" (1998) *17 Medicine and Law 319, 321.*

39 For a discussion, see CESCR (n 33 above) para 12.

facilities, goods and services including relevant programmes. The precise nature of the facilities, goods and services will however vary from state to state and depend on a variety of factors, including the level of development. On the other hand, the concept of accessibility is said to have four dimensions, namely, non-discrimination, physical accessibility, economic accessibility and information accessibility, the most important being economic accessibility. The concept of accessibility therefore connotes a situation where there is equitable access and rational use of essential health care facilities, goods and services.

Economic accessibility, that is affordability, presupposes that health facilities, goods and services must be affordable for all. According to the CESCR, payment for health care services and underlying determinants of health should be based on the principle of equity, which demands that poor households should not be disproportionately burdened with health expenses as compared to richer households.[40] The affordability requirement would also mean that privatisation and liberalisation in the health sector should not constitute a threat to the affordability of health care services.[41] The concept of accessibility therefore underpins the fundamental right to health care to all people. For example, without anti-retrovirals (ARVs) which have restored seropositive people to health in the west and removed the terrifying spectre of AIDS, the millions infected in Sub-Saharan Africa face illness and early death.[42]

2.1.3 Obligations of States and Third Parties

The ICESCR obligates states as primary duty bearers to take steps aimed at attaining the highest level of socio-economic rights. The notion of the highest attainable standard of health in human rights instruments therefore presupposes the progressive realisation of the right and acknowledges the limitations and constraints of resources in ensuring the realisation of the right. This does not however mean that the right is devoid of any real content. The broad definition of the right implies that the right does not merely require states to provide a comprehensive health care delivery and insurance system. The right also entails a duty to undertake measures to promote health, prevent disease and to eliminate other

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40 CESCR (n 33 above) para 12.

41 Toebes (n 4 above) 667.

42 DG McNeil Jr. "Prices for Medicines are Exorbitant in Africa, Study Says" *The New York Times*, 17 June 2000. Available at <http://www.nytimes.com/library/world/Africa/061700africa-medicine> accessed on 18 June 2001.

external causes of morbidity and mortality, reduce health inequalities and improve the underlying conditions of health.[43] In that sense the right to health can be said to embrace two main parts, namely, elements related to health care and elements concerning the underlying preconditions of health, with the first embracing the core content of the right to health. Guaranteeing the core content of the right to health and enhancing its overall realisation therefore imposes a number of clear obligations on states.

(a) Progressive Realisation: Unwillingness versus Inability

The notion of the highest attainable standard of health in article 12.1 of the ICESCR and other human rights instruments takes into account both the individual's biological and socio-economic preconditions and a state's available resources.[44] The human rights framework in this sense accepts that it cannot solve all society's health woes overnight, but it must continue trying to resolve these problems.[45] While the ICESCR provides for progressive realisation and acknowledges constraints due to the limits of available resources, the Covenant imposes obligations upon states that are immediate.[46] The progressive realisation of the right to health should therefore not be interpreted as depriving states parties' obligations of any meaningful content. On the contrary, progressive realisation means that states have specific continuing obligations. In determining violations of the right to health it is therefore critical that a distinction is made between inability and unwillingness of the state to fulfil its obligations.

Article 2.1 of the ICESCR refers to states taking necessary steps to the maximum of available resources. Read in the context of 'the highest attainable state of health', the test is whether a state has made every effort to ensure realisation of the right to health. Where this has not been done then it is a situation of unwillingness, which is inexcusable. Put another way, the dependency on resources limits the right with the only implication being that an unqualified obligation is incapable of being fulfilled.[47] A state therefore has to show that every effort has been made to use available resources to satisfy, as a matter of priority, its

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43 See Hendriks & Toebes (n 38 above) 325.

44 CESCR (n 33 above) para 9.

45 See Madala J in *Soobramoney* (n 6 above) para 43.

46 CESCR (n 33 above) para 30.

47 See Chaskalson P's Judgment in *Soobramoney* (n 6 above) para 11.

obligations.[48] Indeed Justice Sachs in his concurring opinion in the *Soobramoney* case argues that the rationing of access to life-prolonging resources is regarded as integral to, rather than incompatible with, a human rights approach to health care.[49] The obligation of states to take progressive measures to realise the right to health therefore requires much more than merely abstaining from health harming activities.

(b) Non-Retrogression Approach

There is also a strong presumption that retrogressive measures taken in relation to the right to health are not permissible. Retrogressive measures in relation to socio-economic rights refers to measures that result in the overall level of protection to fall below the level that existed when the state took on the obligation to progressively realise the right. It follows therefore that if any deliberately retrogressive measures are taken then the state is prima facie in violation of the right. Such measures are only justifiable where they are necessary and no less harmful alternatives exist.[50]

(c) Core Obligations and Non-Derogability

In the context of the debate on the justiciability of socio-economic rights a view has emerged that each socio-economic right has a core content imposing core obligations, which are non-derogable.[51] In General Comment 3 the CESCR reiterated that states have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights of the Covenant.[52] In relation to the right to health, the CESCR argues that under no circumstances, including resource limitations, can a state justify its non-compliance with core obligations which are non-derogable.[53]

In the analysis of the human rights obligations of states, a distinction is commonly made between the obligation to protect, to fulfil and to respect.[54] The obligation to protect requires

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48 CESCR (n 33 above) para 47.

49 N 6 above para 52.

50 CESCR (n 33 above) para 32.

51 See CESCR (n 33 above) para 47.

52 See also CESCR (n 33 above) para 43.

53 CESCR (n 33 above) para 47.

54 See CESCR (n 33 above) para 33.

states to take measures to prevent third parties from interfering with the right while the obligation to fulfil requires the facilitation, provision and promotion of the right. The obligation to respect requires the state to refrain from interfering directly or indirectly with the enjoyment of the right. Conceptualised in relation to the right to health, the obligation to respect includes the duty of the state to refrain from any action that would hamper individuals in their access to health care or activities resulting in harm to an individuals' health.[55] The obligation to protect requires the state to take measures to prevent health harming activities by third parties, while the obligation to fulfil would require the state to take measures aimed at ensuring opportunities for the individual to realise the right to health.

The core content of social human rights is taken to mean those essential elements without which the right would lose meaning.[56] Concerning the right to health, it is important to recognise the broad character of the right covering the underlying conditions of health and the core content of the right. Article 12.2 of the ICESCR provides specific generic examples of measures to be undertaken in relation to the right to health. The examples given illustrate the specific content of the right. In particular, article 12.2 (c) requires steps to be taken to prevent, treat and control epidemic, endemic, occupational and other diseases. The control of diseases refers to a states' efforts to make available technologies, using and improving epidemiological surveillance and data collection on a disaggregated basis, and the implementation or enhancement of immunisation programmes and other strategies to control infectious disease.[57] Article 12.2 (d) requires the creation of conditions that would assure to all medical service and medical attention in the event of sickness. The obligation here is to ensure the provision of equal and timely access to basic preventive, rehabilitative health services and appropriate treatment for prevalent diseases, illnesses, injuries and disabilities as well as the provision of essential drugs.[58]

In General Comment 3 the CESCR further recognised the obligation of states to take steps individually and through international assistance and co-operation, especially economic and technical assistance, towards the full realisation of the rights recognised in the Covenant.[59] In addition, the UN Charter has as its purpose the achievement of international co-operation

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55 Hendriks & Toebes (n 38 above) 328.

56 Hendriks & Toebes (n 38 above) 325.

57 CESCR (n 33 above) para 16.

58 CESCR (n 33 above) para 17.

59 CESCR General Comment 3.

in solving international problems of an economic, social, cultural, or humanitarian character and in promoting and encouraging respect for human rights and fundamental freedoms for all.[60] In the context of the debate on the implementation and interpretation of the TRIPS Agreement this would, at a minimum, mean that other states parties to the ICESCR would not require another state to implement the TRIPS Agreement in an ICESCR inconsistent manner.

On the basis of the wording of ICESCR article 12 and a review of the *travaux preparatoires,* the CESCR has concluded that the core obligations resulting from the right to health include at least the following: Obligation to ensure access to health facilities, goods and services; to ensure access to minimum essential food, basic shelter, housing and sanitation and adequate supply of safe and potable water; to provide essential drugs; to ensure equitable distribution of health facilities, goods and services and the adoption and implementation of a national public health strategy and plan of action.[61] Violation of the right to health therefore includes the formal repeal or suspension of legislation necessary for the continued enjoyment of the right or the adoption of legislation and policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.[62] Violation could also include failure to take measures necessary to safeguard persons within a state jurisdiction from infringements of the right to health by third parties. The CESCR concludes that this category of violation includes such omissions as failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others.[63] Further violations could also include failure to adopt or implement a national health policy designed to ensure the right to health, insufficient expenditure or misallocation of public resources and the failure to take measures to reduce the inequitable distribution of health facilities, goods and services.[64]

The implementation of the TRIPS Agreement to fulfil the higher minimum standards of IP will for most developing countries require the enactment of new legislation. In particular, the envisaged patent law reform, which has been the area of most contention in the access debate, will require legislation and policies that at least, on the face of it, are manifestly

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60 See art 1.3 of the Charter.

61 CESCR (n 33 above) para 43.

62 CESCR (n 33 above) para 48.

63 CESCR (n 33 above) para 50.

64 CESCR (n 33 above) para 52.

incompatible with pre-existing international legal obligations relating to the realisation of the right to health.

2.2 The Conceptual Underpinnings of IPRs

The notions of IP date as far back as the Chinese Zhou dynasty in the eighth century AD when concern for commodity identification arose.[65] By AD 835, it is said that the Wenzong emperor barred the unauthorised reproduction of documents, calendars, and other items related to prognostication. In the west, IPRs (at least in the form of patents) came into existence around 1500 in Venice and spread to most of the major European powers by 1550.[66] Gradually governments recognised the right of ownership over ideas. In subsequent years, states adapted their IP regimes to accommodate the increasingly expansive growth of technological innovation. In the era of the UN human rights regime, the claim to IPRs evolved from a state granted right to a universal human right.[67]

IPRs fall within the realm of property rights, which by their very nature allow holders to exclude others from exploiting the resource. During the period of protection, the patent holder has a market advantage, which might allow higher prices for access to technology depending on market conditions. The concept of IP protection is therefore based on exclusivity of exploitation. Patent protection therefore means that the inventor is granted exclusive control over the object, with the resultant exclusion of others, control of output and the establishment of monopoly prices within the limits that the product demand will allow.

2.2.1 The Traditional Concept of IPRs

The theoretical justification for intangible property has traditionally been grounded on two main theories of property. The first is John Locke's labour theory of property.[68] The second is the utilitarian doctrine. The basic concept of the modern patent system in particular is

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65 RL Ostergard "Intellectual Property: A Universal Human Right?" (1999) 21 *Human Rights Quarterly* 156, 157.

66 Ibid.

67 See art 27 UDHR and 15 ICESCR.

68 Ostergard (n 65 above).

however predominantly based on the utilitarian theory.[69] The utilitarian theory is rooted in the traditional western view of property, which emphasises private property and its importance in development. The conventional justification of the patent system based on this approach is that the inventor and investors are rewarded for their time, work and risk of capital by the grant of a limited but strong monopoly of exploiting the invention. The system guarantees a limited exclusive term in return for the inventor's disclosure of the details of the invention.[70] The approach is seen as benefiting society by stimulating investment, creating employment and ensuring supply of technology based goods and services. In addition, the system is seen as ensuring a continuous process of knowledge creation and data building which is crucial for technological advancement.

In the pharmaceutical industry, the accumulated knowledge is considered invaluable as a basis for further research in the continuing efforts to deal with the persistent and emerging challenges in disease management. The Canadian philosopher Will Kymlicka suggests that utilitarianism conforms to our inner sense of social responsibility; that is, the idea that the well-being of humans matters, and moral rules must be subjected to tests for their consequences to human beings.[71] The utilitarian approach weighs the long-term development of society against the short-term drawback of assigning exclusive exploitation rights to the inventor.[72]

It is true that IPRs can induce creativity and the production of some intellectual products, increasing the immediate availability of products, particularly in the fields requiring long training and/or high research costs.[73] However, this does not necessarily imply a long-term benefit of economic progress. If the purpose of IPRs were simply to induce creativity and production, then this is easily achieved. However, a system based on such assumption would say nothing about the rights of other people to use this information except under the monopoly conditions. If the purpose of the system is to make the lives of people better, then

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69 The details given are required to be sufficiently comprehensive so that a person skilled in the particular art would be able to make practical use of the invention. Disclosure is a central prerequisite for the grant of a patent. See Grove, J in *Young v. Rosenthal* (1884) RPC 29, 31.

70 PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (1999) 323.

71 Ostergard (n 65 above) 163.

72 Ibid.

73 Ostergard (n 65 above) 165.

one must look at the effects that the grant of IPRs has on all people. Consequently, although an inventor's rights must be recognised in any IPRs scheme, the rights must be juxtaposed with the interests of society.[74] In short, one must ask whether the institution of IPRs is just when it provides benefits to a select few. In the global economy access to advantages produced by IP protection is based on financial resources, which one would naturally expect in a competitive economy.[75] Such a system is satisfactory when one is concerned about the distribution of non-essential items, that is, objects that do not affect people's well - being. Traditionally the patenting of inventions such as chemicals, food products and pharmaceuticals has however been associated with high prices.

2.2.2 The Reward-Benefits Dichotomy under Article 15 of the ICESCR

Historically, property in one form or the other has been at the centre of many struggles for fundamental rights.[76] The Magna Carta, the US Declaration of Independence, the French Declaration of the Rights of Man and Citizens have all recognised property rights.[77] In modern human rights law, the UDHR in addition to recognising the right to own real property also recognises IP as a human right.[78] Article 27.1 provides that, 'Every one has the right to the material protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author." Article 15 of the ICESCR is modelled on the UDHR provision but is more detailed and broader. Article 15 first recognises the right of everyone to take part in the cultural life, to enjoy the benefits of scientific progress and its application and 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. The rest of the article covers the undertakings of the state parties. The intellectual property regime as conceptualised under the UDHR and ICESCR therefore requires that a balance be struck between the promotion of public interests in accessing technology and in protecting the interests of inventors.

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74 Ostergard (n 65 above) 162.

75 Ibid.

76 Ostergard (n 65 above) 158.

77 Ibid. See also the US Constitution which empowers congress to 'promote the progress of science and useful arts, by securing limited times to authors and inventors exclusive rights to their respective writings or discoveries' (article 1 & 8).

78 See arts 17 & 27 respectively.

The protection of IPRs as a human right means that the inventor has the right to the ownership of their ideas, creations and inventions.[79] The patent therefore does not grant the patentee the right to own or use the invention, as the patentee possesses this right; a patent grants only the right to exclude others from using the invention.[80] The implication is that where one does not seek patent protection he or she cannot be compelled to disclose the invention.

When conceptualising IPRs in the context of article 15 of the ICESCR, the emphasis must therefore not be exclusively placed on the producers of technology; IPRs must also be conceptualised from the perspective of consumers and state welfare.[81] There must be some focus on the states obligation to fulfil the citizen's basic needs, which in today's world are largely dependent on technologies and processes that are protected by IPRs. In a situation where certain individuals or corporations have the exclusive control of technologies, others may be deprived of basic products that contribute to their welfare. When rights by their very nature are shared and inter-dependent however, striking appropriate balances between the equally valid entitlements or expectations of a multitude of claimants should not be seen as necessarily imposing limits on those rights, but as defining the circumstances in which the rights may most fairly and effectively be enjoyed.[82] The rest of this study is concerned with determining how the right to health and the right to protection of inventions can be fairly and effectively enjoyed in the global economy.

79 Ostergard (n 65 above) 175.

80 E Ackiron "Patents for Critical Pharmaceuticals: The AZT Case" (1991) 17 *American Journal of Law and Medicine* 145, 148.

81 Ostergard (n 65 above) 157.

82 See Sachs J's concurring opinion in *Soobramoney* (n 6 above) para 54.

3 READING HUMAN RIGHTS INTO THE TRIPS AGREEMENT

The balance between public and private interests under article 15 of the ICESCR is one familiar to the concept of IPRs. Traditionally, states have granted rights over new inventions as a means of providing an incentive for innovation and for ensuring public access to technology. Consequently, there is a degree of compatibility between the human rights approach embodied in article 15 of the ICESCR and the traditional concept of IPRs. Indeed, the whole WTO system is also based on concepts familiar to human rights. The system is based on the principles of equality and non-discrimination.[83] The question, however is how do you ensure the critical balance between rights and interests?

IPRs have increased private investment in industries such as pharmaceuticals, agri-business and software by enabling the gains of research and investment to be recouped and thereby leading to higher profits.[84] Indeed, the number of international patent applications has risen dramatically over the years, and particularly in the late 20th century. For example, the number of international applications rose from just 7,000 in 1985 to 74,000 by 1994 when the WTO came into being.[85] The strategic use of patents has also become more aggressive, because increasingly patents are viewed as key business assets. Unfortunately, patent protection often results in monopoly pricing once a successful product is put on the market.[86] In the normal course of things, this is viewed as unavoidable in an incentive system that encourages costly R & D. However, the implementation of the TRIPS Agreement in developing countries has led to widespread public outcry as it is seen as only rewarding the inventors, but not ensuring access to pharmaceutical technology. The controversy has brought into sharp focus the balance that patent law seeks to reach between *ex ante* incentives intended to ensure that products are brought to the market, and *ex post* inequities created by the resulting monopoly pricing.[87]

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83 The principles of national treatment and the most-favoured-nation that prohibit discrimination.

84 HDR 2001 (n 1 above) 103.

85 Id.

86 Ackiron (n 80 above) 145

87 Ackiron (n 80 above) 179.

(a) Patents, Prices and Medicines

Without much argument, medicines can be classified as an important factor to the improvement of people's physical well - being.[88] Often the demand of a particular medicine is inelastic, meaning that people cannot find alternatives and they must purchase the product even if the cost escalates. If they cannot afford the price, they must do without the product and live with the result, which in many cases is death. The problems associated with HIV/AIDS treatments in Sub-Saharan Africa illustrate this point most starkly. It has however been argued by the pharmaceutical industry and others that the issue of access to medicines is not an IPR issue but rather an issue of social welfare policies.[89] In fact, other arguments suggest that it is the burden of the government to provide health care at whatever cost.[90] If the argument is taken to its logical conclusion, it means that the state has to provide financial assistance to people who cannot afford medicines because the state granted a monopoly on the production of the medicines. This approach is fiscally impossible especially in poor countries where diseases are prevalent. Even the USA and Canada with all their resources and elaborate health insurance systems recently found it difficult to purchase large quantities of Cipro at Bayer's monopoly price to treat anthrax in the face of bioterrorism.[91] The result of an unmitigated strengthening of IP protection for developing and least-developed countries may be the foregoing of products that are necessary in sustaining economic development. Expressing his views in a slightly different context, Justice Madala of the South African Constitutional Court (CCSA) in his concurring opinion in the *Soobramoney* case summarises the dilemma thus;

> [T]he appeal before us brings into sharp focus the dichotomy in which a changing society finds itself and in particular the problems attendant upon trying to distribute scarce resources on the one hand, and satisfying the designs of the Constitution with regard to the provision of health services on the other. It puts us in a very painful situation in which medical practitioners must find themselves daily when the

88 Ostergard (n 65 above) 169.

89 "'Patents are not the Problem,' says Harvey Bale of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)" *Financial Times* 20 June 2001 12. See also A Attaran & L Gillespie-White "Do Patents Constrain Access to AIDS Treatment in Poor Countries? Antiretroviral Drugs in Africa" 17 October 2001 *JAMA.*

90 Ostergard (n 65 above) 170.

91 D Alexander "'Duplicated' drugs life-line for millions in Africa: US anthrax scare renews debate on generic drugs law" *The Monitor* 1 November 2001, 15 and D Kimani "AIDS Drugs: Kenya Must Capitalise on Expiring Patents" *East African,* Magazine Section 19-25 November 2001, VII.

question arises: " Should a doctor ever allow a patient to die when the patient has a treatable condition?"

The debate about patents, drug prices and access is therefore not an academic debate or a conflation of issues as concluded by Attaran and Gillespie-White.[92] The debate has serious practical consequences for the implementation and interpretation of the IP rules in the context of essential life-saving medicines for the poor.

3.1 An Overview of the IP Regime of WTO

On 15 April 1994, representatives of 125 governments signed the Final Act embodying the results of the Uruguay Round of trade negotiations in Marrakech, Morocco. While the previous negotiations within the framework of GATT were largely concerned with the elimination of trade barriers, the Uruguay Round was more oriented towards the harmonisation of trade policies. The most ambitious of this harmonisation drive occurred in the area of IP.[93] Today, IP protection requirements have been tightened worldwide. Developing countries now have to enforce national IP systems based on an internationally agreed set of minimum standards. Before the TRIPS Agreement under the WTO framework, the regulation and protection of IP at the international level, was mainly managed by the World Intellectual Property Organisation (WIPO).[94] The WIPO system continues to co-exist with the TRIPs system.

The TRIPS Agreement covers both categories of intangible property envisaged under the ICESCR, that is, literary and artistic works and industrial property including patents, trademarks, geographical indications, trade secrets and industrial designs. The Agreement requires that member states provide certain minimum standards in the field of IP as detailed in the Agreement and that they provide procedures and remedies for the enforcement of these rights. In relation to the rights protected, the Agreement requires the application of the basic GATT principles of national treatment and most-favoured-nation (MFN) treatment.

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92 See Attaran (n 89 above).

93 Velasquez & Boulet (n 25 above) 12.

94 WIPO is one of the 16 Specialised Agencies of the UN with the mandate to promote the protection of IP worldwide. Currently WIPO has 177 members and administers 21 treaties in the field of IP including protection system treaties, classification treaties and administration treaties. Some provisions of treaties administered by WIPO such as the Paris Convention have been incorporated into the WTO system. See <http://www.wipo.org> accessed on 19 November 2001.

3.1.1 The Challenge of Reading Rights into a Concession Based Trade Regime

Although the WTO is essentially different from GATT, it is still based on the GATT system of concessionary trade negotiations. Expert commentators, including active participants in the Uruguay negotiations, have discussed the negotiating history of the TRIPS Agreement extensively and it is generally accepted that developing and least developed countries were placed under great political and economic pressure to accept terms that did not necessarily take into account their specific interests.[95] As a result, many of the provisions of the Agreement reflect the views and demands of countries with powerful industrial lobbies.[96] In particular, it is understood that although the obligations established by the TRIPS Agreement were likely to have substantial impact on prices and access to medicines, there was very limited participation by public health experts in the negotiating process.[97] In contrast, pharmaceutical industry players played a major role in pressing for the conclusion of the Agreement. Indeed, IPRs were included in the agenda of the Uruguay Round on the initiative of developed countries, following pressure from a variety of economic groups.[98] In addition, as a natural consequence of the isolation between human rights law and trade law, the trade negotiators who put together the WTO would not have been expected to consider the human rights impact of the various instruments. In the post-WTO era, there have also been instances of threat and/or realisation of trade sanctions creating substantial economic and political insecurity.[99]

From a human rights perspective, the concessionary system that is susceptible to economic and political pressure raises several difficulties. First, the question arises as to whether the internal constitutional treaty ratification processes are democratic in many of the developing countries. The lack of democratic treaty ratification procedures in weaker states makes it all the more easier for the economic and political pressure to weigh-in. The second difficulty, which is more important for the debate in this study, is whether states parties to the ICESCR

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

96 See Howse & Mutua (n 3 above).

97 Abbott (n 95 above).

98 Velasquez & Boulet (n 25 above) 38.

99 Abbott (n 95 above) 30. See also R Elliott "WTO needs reminding we all deserve health care" *Toronto Star* 11 November 2001 A 13.

could make concessions that effectively negate their obligations under the Covenant. The acceptance of TRIPS by most developing and least-developed countries was based on apparent concessions in other areas such as agriculture and textiles. While in general countries are free to trade off certain rights for other benefits in a multilateral trading system such concessions are presumed to be for the welfare of society. Fundamental rights are the basis of society and it cannot therefore be in the interest of society to trade them off.

3.1.2 TRIPS' Concept of a Balance of Interests: A review of Articles 7 and 8 and Related Provisions

In a world of great disparities in technology and wealth, technologies designed for the interests of Europe, Japan or the US will not necessarily address the needs, conditions and institutional constraints existing in developing countries.[100] Therefore, without an effective way of co-ordinating the latent demand and capturing the external benefits of technology, neither private investors nor national public agencies will be motivated to invest in innovation at socially optimal levels.[101] In an apparent recognition of this fact, the TRIPS Agreement attempts in various ways, to strike a balance between developed and developing/least-developed countries needs and interests and between the public and private interests in the various economic settings at the national level. However, this balance has not translated into any significant success.

The TRIPS Agreement envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology. The balance can be gleaned from several provisions of the Agreement. The most important of these provisions at least in the context of this study are the provisions on the objectives and principles of the Agreement, the provisions relating to transfer of technology and the provisions covering exceptions to exclusive rights. The basic concept of balance under TRIPS is found in the objectives and principles of the Agreement. The objective of the IP system under the Agreement set out in article 7, 'is to promote technological innovation and the transfer and dissemination of technology to the mutual benefit of innovators and consumers and in a manner conducive to social and economic welfare, and to the balance of rights and obligations'. The principles upon which the balance is to be achieved are stated in article 8 of

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100 HDR 2001 (n 1 above) 103.

101 HDR 2001 (n 1 above) 96.

the Agreement. First, states in formulating or amending their laws may adopt measures necessary for the protection of public health and nutrition and measures to promote public interests in sectors of vital importance to socio-economic and technological development.[102] Second, members may adopt appropriate measures to prevent the abuse of IPRs by right holders or the resort by right holders to practices that unreasonably restrain trade or adversely affect the international transfer of technology.[103]

The Agreement therefore recognises that there are underlying national public policy objectives that must be taken into account when implementing it at the national level. Article 8.1 of TRIPS in particular should be read as an interpretive principle in favour of the adoption of internal measures deemed necessary for the protection of health.[104] Indeed the Preamble to the WTO Agreement, which establishes the entire framework of the WTO system, does not make free trade an end in itself.[105] Rather, it establishes the objectives of the system as related to the fulfilment of basic human values, including the improvement of living standards for all people and sustainable development.

Read in the context of the objectives of the WTO and the TRIPS Agreement in particular, the granting of patents should be seen as involving a balance between the public interest in accessing a larger pool of inventions, and the private interests in wealth generation.[106] In the view of the US Supreme Court,

> Whilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectively guarded. Considerations of individual emolument can never be permitted to operate to the injury of these.[107]

The other provisions attempting to balance interests are the provisions relating to transitional periods and technology transfer incentives. In partial recognition of the social and economic adjustments that developing and least developed members would have to make to provide

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102 Art 8.1.

103 Art 8.2.

104 See Abbott (n 95 above) 31. Also see the WTO Ministerial Declaration on the TRIPS Agreement and Public Health made in Doha, Qatar at the Fourth Session of the Ministerial Conference WT/MIN (01)/ Dec/W/2 14 November 2001 para 5 (a).

105 Howse & Mutua (n 3 above)

106 Abbott (n 95 above) 5.

107 In *Kendell v. Winsor*, 62 U.S. (21How.) 322, 329 quoted in Ackiron (n 80 above) 149.

patent protection for pharmaceutical products and processes, the TRIPS Agreement provided for transition periods for those members which did not provide patent protection for pharmaceuticals.[108] Article 66.1 therefore provides that,

> In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPs shall, upon duly motivated request by a least-developed country member, accord extensions of this period.[109]

A distinction is therefore made between developed countries, developing countries that already protected pharmaceuticals and those that did not protect pharmaceutical inventions and least-developed countries. In the interim however there is the so called 'mailbox' system, where developing countries that did not provide protection are required to establish mechanisms for receiving and preserving priority in regard to pharmaceutical patent applications and allowing for the grant of exclusive distribution rights when prescribed conditions are satisfied.

On incentives, article 66.2 provides that,

> Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technological transfer to least-developed country Members in order to enable them to create a sound and viable technological base.[110]

The provision therefore recognises that commercial enterprises are unlikely to invest in certain technologies and in certain regions of the world without economic incentives.

The third category of provisions representing the balance in TRIPS are the provisions relating to the exceptions to exclusive rights envisaged under article 28.[111] It is these provisions that are the primary focus of this study. These include the provisions on

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108 See Abbott (n 95 above) 2. Under art 65 developing countries, which already had protection for pharmaceuticals, had up to January 1, 2000. Developing countries such as India, which did not have protection for pharmaceuticals, have until January 1, 2005 and least developed countries originally had until January 1, 2006 but this has been extended to 2016 by the Doha Declaration (n 104 above) para 7.

109 Also, see the Doha Declaration (n 104 above).

110 Id.

111 The grant of a patent confers upon the patent holder the exclusive rights to make, import, offer for sale, sell and use the product.

exhaustion of rights,[112] patentability requirements,[113] the general exception provision[114] and the provisions on other uses of the patent not authorised by the patent holder.[115]

Strictly speaking, however, the TRIPS Agreement was not designed to promote the balance envisaged under article 15 of the ICESCR concerning access to medicines. The exceptions to patent rights such as compulsory licensing and government use, the early working exception and freedom to establish a suitable exhaustion regime are based on the traditional concept of IP and national constitutional principles that predate the ICESCR. That fact notwithstanding, the balance under the Agreement can be conceptualised and interpreted from a human rights perspective albeit at a theoretical level. If article 7, 8, 65 and 66, the various provisions covering exceptions and the clarifications and commitments made at the Fourth Ministerial Conference are read in the context of article 31 of the Vienna Convention on the Law of Treaties, human rights obligations can be read into the Agreement. The Vienna Convention provides that 'a treaty shall be interpreted in good faith'.[116] The ordinary meaning of this provision in relation to the protection of human rights would be that member countries that had prior human rights obligations understood the balance in TRIPS to coincide with the fulfilment of such obligations. In essence therefore, while the TRIPS Agreement does not explicitly base the balance of interests on a human rights framework, it contains exceptions that permit states to promote and protect human rights including the right to health.

112 Art 6.

113 Art 27.

114 Art 30.

115 Art 31.

116 Art 31.1. The Appellate Body of the WTO has indeed emphasised on several occasions that art 31 of the Vienna Convention is a fundamental reference point for WTO dispute settlement and therefore an acceptable rule of interpretation. For further discussion, see Howse & Mutua (n 3 above).

3.2 An Overview of the Exceptions to Exclusive Patent Rights under TRIPS

3.2.1 Compulsory Licensing and Government Use

A compulsory license refers to a license granted by an administrative or judicial body, upon application, to a third party to exploit the invention without the authorisation of the patent holder. This type of license is commonly referred to as a non-voluntary license connoting the lack of authorisation. The concept of compulsory licensing itself has a long history. One of the earliest legal documents to incorporate the concept was the UK Statute of Monopolies of 1623, which allowed the taking of a patent for lack of working.[117] At the international level compulsory licenses were recognized and provided for in the Paris Convention of 1883.[118] Under this Convention, subject to certain limitations, member countries could grant compulsory licenses for refusal to deal or non–working. Indeed the substantive law on compulsory licensing in the IP system of the WTO remains the Paris Convention. The Convention's provisions relating to compulsory licenses among others are incorporated into TRIPS by reference.[119] By 1994 when the negotiations on TRIPS were being finalised, compulsory licensing had become a typical feature of patent laws worldwide.[120] Under TRIPS, countries can use compulsory licenses in a number of circumstances including public emergency, high prices and as a measure to remedy anti-competitive practices.[121] Article 31 implicitly recognizes these as grounds for the issue of compulsory licenses.

Where a member state chooses to have compulsory licensing within its IP regime article 31 contains detailed conditions, which must be fulfilled. These include the need to grant licenses on a case-by-case basis, evidence of unsuccessful prior request of voluntary license, non-exclusivity of the license and the requirement for compensation. There are also conditions for terminating the license and restrictions on assignment of the license to third

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117 CM Correa "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing countries" (1999) *Trade – related agenda, development and equity (T. R. A. D. E) Working Papers 5,* 1

118 See art 5A.2 of the Paris Convention which provides that, 'Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work'. For a discussion of US law, see Ackiron (n 80 above) 54-55.

119 See art 2 of TRIPS

120 Correa (n 117 above) 2.

121 See art 31 TRIPS read together with art 5 of the Paris Convention.

parties. Notwithstanding these conditions however, the Agreement still leaves considerable room for flexibility in legislating on compulsory licenses.

Government use is a variant of compulsory licensing and the general rules under article 31 apply. The main distinction is that governmental use relates to a situation where the government grants itself, or a third party as its agent, a license to exploit a patented invention.[122] Government use provisions are therefore akin to a taking under the eminent domain doctrine. The most common situation where this power is exercised is in cases of public emergency. In practice, government use has also been predominantly a public non-commercial activity.

3.2.2 Parallel Imports

A parallel import exists where a third party imports a foreign manufactured product put on the market abroad by the patent holder or his or her licensee in competition with imports by the patent owner or his or her licensee.[123] The practice is based on the first sale doctrine which rests on the principle that the first sale of a product by the patent holder or a licensee exhausts the exclusive rights over that product and consequently he or she loses his or her legal control over the commercial exploitation of the product thereafter. The basic justification for the first sale doctrine is that the inventor has been rewarded through the first sale of the product and his or her further control over the resale of the product would unreasonably restrain trade. Parallel importation is therefore seen as preventing market division and price discrimination.

The first sale doctrine turns on the principle of exhaustion of IPRs. Historically, various countries have approached the issue differently. Under TRIPS, article 6 provides that the issue of exhaustion is excluded from the matters for which the Agreement's dispute settlement procedures may be used to resolve. The only exception is where such a dispute concerns issues of national treatment or most-favoured nation status. Article 6 read together

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122 RJL Lettington and SF Musungu "In Defence of Kenya's Health: Proposed Amendments to the Industrial Property Bill 2000" (2000) 31.

123 A crucial distinction therefore exists between parallel imports and counterfeit products. For further discussion of the distinction, see Lettington & Musungu (n 122 above). Also see FM Abbott " First report (final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation", (1998), *Journal of International Economic Law*, 607.

with article 28 therefore maintains the status quo, as it existed before TRIPS. The question of exhaustion was deliberately left to the discretion of each state or subject to other bilateral or multilateral arrangements outside the WTO framework.[124] WTO member states can therefore choose to adopt national or international exhaustion.[125]

The principle of exhaustion has been applied either on the national or international scale. A variant of the latter approach is the regional exhaustion.[126] Under the former practice, the first sale of a patented product exhausts the rights of the patent holder as far as the resale is within the territory of the country where the first sale occurs. National exhaustion is therefore based on the principle of patent territoriality. In the leading case *of Boesch v. Graff* the court held that a sale by the importer of patented burners in the US was an infringement of the rights of the holder of the US patent covering the same burners and that that the right to use or resell must be understood to mean use or resale within the US being the territory that the patent covers.[127] On the other hand, international exhaustion relates to the opposite practice. The underlying theory being that once a right holder authorises the entry of a product onto the market anywhere in the world his or her exclusive rights to use or sell the product are exhausted and he or she cannot exercise further control over the resale of the product abroad.

3.2.3 Patentability and New Use Pharmaceutical Patents

Article 27.1 of TRIPS establishes the general rule that where a product or process fulfils the requirements of novelty, non-obviousness and usefulness it must be protected. There is no specific requirement for protection of new uses as such. The grant of new use patents therefore expands the scope of patentable subject matter beyond the strict requirements of TRIPS. The practice is however known to exist in several jurisdictions. For example, under the European Patent Convention (EPC) article 54 recognises new use patents. The US also allows new use patents although the US law is more restrictive and such patents are

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124 For example, the European Union states adopt the same approach as a matter of EU law.

125 See arts 6 & 28 of TRIPS read together with para 5 (b) of the Doha Declaration on TRIPS (n 104 above). See also Abbott (n 95 above) on the US position and the counter arguments and the decision of the Swiss Supreme Court in *Kodak SA v. Jumbo-Markt AG,* 4C.24/1999/RND.

126 The best example is the EU, which is taken as a single market.

127 133 U.S 697, 703, 10 Sect. 378, 380, 33 L.Ed 787 (1890). See also the decision of the Supreme Court of Kenya in *Beecham Group Ltd v. International Products Ltd & Anor* [1968] EA 398.

confined to a particular method of use where the patent does not encompass protection of a new product as such. New use patents have also been routinely granted in the African Regional Intellectual Property Organisation (ARIPO) and the African Intellectual Property Organisation (OAPI).[128]

New use patents are justified on the basis that the discovery of a new use may require the same level of investment and creativity as in the case of a new product. In the pharmaceutical sector, new uses are either first pharmaceutical use (also referred to as first medical indication) or second pharmaceutical use (second medical indication).[129] The former case relates to a situation where a new pharmaceutical use is discovered for a product with no previously known pharmaceutical use. Under this scenario, the product will be put to new use in the pharmaceutical industry for the first time. In the latter case, a product already known to have one or more pharmaceutical uses is discovered to have a further pharmaceutical use although unrelated to the earlier known use(s). The classical example of second medical indication is the case of Azidothymidine (AZT).[130] Protection for first pharmaceutical use poses fewer problems. Protection of the second pharmaceutical uses poses a greater challenge for access to medicines.[131] Such protection has been seen as an anti-competitive practice mainly intended to extend the patent period.[132]

3.2.4 Article 30 Exceptions and the Early Working (Bolar) Exception

Article 30 of TRIPS establishes the general bases for exceptions to the exclusive rights envisaged under article 28. The essence of the criteria is that exceptions to the patent rights must be limited; should not unreasonably conflict with the normal exploitation of the patent

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128 ARIPO was established by the Lusaka Agreement of 9 December 1976 while the Bangui Agreement of 1977 established OAPI.

129 Grubb (n 70 above) 217-218.

130 The drug was first discovered in 1964 at the US National Cancer Institute Laboratory as a cancer treatment. However, due to problems of toxicity, it was not used and the patent eventually expired. In 1984, the Institute invited companies to submit compounds for testing as possible AIDS drugs and Burroughs Welcome submitted AZT. For a detailed discussion of the AZT case, see Ackiron (n 80 above).

131 Despite the fact that US government funding was available for the research and that a fast track procedure was used in the clinical trials, the R $ D argument has been used to justify the high cost of AZT.

132 Lettington & Musungu (n 122 above) 58.

and should not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Although not explicitly mentioned in the Agreement, the early working exception is the most widely accepted exception under article 30.

The early working exception relates to a situation where a potential competitor uses an invention without the authorisation of the patent holder. However, such use is only for purposes related to research and other acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. In the pharmaceutical and related industries such as in the agro-chemical industry, the purpose of the exception is to permit the performance of technical activities necessary in obtaining regulatory approval and securing capital.[133] On all fours, this type of provision fully complies with the criteria of article 30. Under the exception, generic producers are not allowed to commercially exploit the invention before the expiration of the patent term and there is therefore no prejudice to the legitimate interests of the patent owner.

The mechanism is intended to ensure that generic versions of the product are available on the market immediately or within a reasonable time of the expiry of the patent.[134] The actual implementation of the exception has differed from country to country. Under the 1984 US Drug Price Competition and Patent Term Restrictions Act, the US introduced this type of provision to protect patent holders for the time lost in the registration and approval process.[135] The US situation is therefore not an early working exception *strictu sensu* but it turns on the same principle and justification. The practice under the US law, which is also the practice in Israel, effectively extends the patent term for up to 5 years.[136] Other countries such as Argentina, Canada, Australia, and Thailand on the other hand provide for the early working exception to generic manufacturers.

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

134 Lettington & Musungu (n 122 above) 65.

135 Ackiron (n 80 above) 157.

136 See Grubb (n 70 above) 218. Also, see Lettington & Musungu (n 122 above) 55-56.

4. CONCEPTUALISING THE EXCEPTIONS TO IPRs (TRIPS FLEXIBILITY) WITHIN A HUMAN RIGHTS FRAMEWORK

Two main problems are creating hurdles for the implementation of the TRIPS Agreement in the countries of the geopolitical south. In the first place, a consensus is emerging that IPRs under the system may have gone too far, hampering rather than encouraging innovation and unfairly redistributing the ownership of knowledge.[137] In the second place, there are signs that the cards are stacked against the fair implementation of the Agreement. While experts in the patent and trade fields are in substantial agreement that the role of patent protection in a country varies depending on a variety of factors, including the level of economic growth, development, capacity for innovation and local market size, the US and Switzerland are pressing a one-size-fits-all approach to patents.[138] The US and other western countries have also pressured developing and least developed members to accelerate the adoption of patent protection on pharmaceuticals before the end of the transition periods.[139] In the post-TRIPS era, the US has also threatened trade sanctions against other WTO members when they have sought to grant compulsory licenses, authorise parallel imports or use other exceptions, making the use of these policies difficult.[140] In a rule-based system, which the WTO is intended to be, a human rights approach based on UN law may be a useful basis to deal with most of the controversial issues.

4.1 Implementing the TRIPS Exceptions in the Context of the Right to Health

The pharmaceutical industry was able to grow rapidly not only because its structure evolved in an atmosphere relatively free from close examination, but also because it developed in a unrestricted regulatory setting.[141] The legal protection of patents and the proliferation of brand name products have enabled drug companies to create and sustain leading marketing positions.[142] These factors have operated together to deprive consumers of the opportunity

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137 HDR 2001 (n 1 above) 103.

138 Abbott (n 95 above) 9.

139 There have been reports for example that Uganda is being pressurised to accelerate the implementation of TRIPS on the basis that it will stimulate foreign direct investment. See *The Monitor* 7 November 2001.

140 See Abbott (n 95 above) 7.

141 MT Griffin "AIDS Drugs and the Pharmaceutical Industry: A Need for Reform" (1991) 17 *American Journal of Law and Medicine* 363, 374.

142 Griffin (n 141 above) 369.

to effectuate control over the market and enabled drug manufacturers to sustain their pricing policies. The implementation of the TRIPS Agreement in developing countries will require substantial legal reform that further limits the potential for control over the pricing schemes of companies. The repeal and/or enactment of legislation and the adoption of policies to implement TRIPS has the potential to introduce structures that are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health. A law whose effect would result in unnecessary mortality, such as a law leading to denial or restriction of access to essential health facilities, goods and services, would violate the state's obligations to protect and respect the right to health. It is also important to bear in mind that the most feasible measures to implement the right to health will vary significantly from state to state. In that respect, every state has a margin of appreciation in assessing which measures within the TRIPS regime are most suitable to meet its specific circumstances.[143]

The resulting limitations, either on patent holders or on the public must however be reasonable and justifiable in a democratic society. As observed in Justice O'Connor's concurring opinion in the *Peyote* case, the rule is that the government has to demonstrate that the unbending application of the law is essential to accomplish an overriding governmental interest.'[144]

4.1.1 Compulsory Licensing and Government Use

After January 2006 affordable access to on-patent medicines in developing and least developed countries will become increasingly dependent on compulsory licensing. In general, there is not much controversy as to the right of states to grant compulsory licenses. Much of the current debates focus on the problem of exports and imports under such licenses after 2006. Article 31(f) of TRIPS requires that a compulsory license be granted for the supply 'predominantly' of the local market.[145] With a very limited number of developing and countries having manufacturing capacity, if article 31(f) is interpreted strictly, then compulsory licenses will not make much difference for access to medicines. Abbott argues

143 See CESCR (n 33 above) para 53.

144 *The Employment Division Department of Human Resources of Oregon and Others v Smith* [1990] 494 US 872; 108L Ed 2(d) 876, 898.

145 See the Doha Declaration on TRIPS (n 104 above) para 6. The Ministerial Conference failed to reach an agreement on a solution this problem.

that a legal basis for a voluntary license to export may be based on the concept of comity although he also recognises that a human rights approach may be relevant.[146] Where the two states are both members of the UN and state parties to the ICESCR, a stronger basis for recognition of foreign compulsory licenses can be found in human rights law.

From a human rights perspective, the recognition of compulsory licenses to import is therefore a significant component in the efforts to realise the right to health through improved access to essential medicines. In many instances the size of local markets in developing countries would not justify local manufacture. Local manufacture may also not significantly address the deficiency in supply, where for example production costs are high. Indeed, in many cases such as where large investments are required, where there exist barriers to access operative technology or where there is a need to remedy anti-competitive practices or address public interest considerations, the most effective way of using a compulsory license would be through importation.[147] The right to work a compulsory license through importation is indeed implicit in article 27.1 of the TRIPS Agreement.[148] The Agreement provides that patents shall be enjoyable without discrimination as to whether products are imported or locally produced. The EU has noted that the TRIPS Agreement can be interpreted to allow one WTO member to recognise and give effect to a compulsory license issued by another WTO member, and to authorise local production for export to the other member.[149] Incorporating workable and clear compulsory licensing provisions for import and export into national law is therefore a necessary step in ensuring that the compulsory licensing regime works within a human rights framework.

It can be concluded that compulsory licensing in general and especially for importation represents a rational human rights approach to deal with the current monopolistic nature of the pharmaceutical industry. Consistent with the balance envisaged under article 15 of the ICESCR, the public interest is served by widening availability of drugs through reduced prices. In relation to essential drugs, compulsory licensing would in many cases benefit the public interest by providing access to the only form of therapy available. The private interests

146 See Abbott (n 95 above) 16-17.

147 Grubb (n 70 above) 244.

148 Abbott (n 95 above) 13.

149 The EU Communication at the first TRIPS Council meeting of Access to Medicines quoted in Abbott (n 95 above) 16.

in making profits is protected by the requirement that in each case where a compulsory licence is issued, adequate compensation be paid to the patent holder.

The concept of government use is also very important with regard to the accessibility element of the right to health. This is particularly so where drugs have to be supplied directly by the government. This is the case for the poor in most African countries. A reasonable approach to government use in Africa and other developing regions would however require that the mechanism be restricted to national emergency management and as a public non-commercial activity. By restricting the situations of government use, firstly the requirement of prior request for a compulsory licence is eliminated so that government use becomes a fast track procedure to access technology in the public interest which is critical in emergencies. Secondly, the inventor's only recourse is restricted to the recovery of reasonable compensation from the government and the opportunity for injunction is eliminated. Outside the strict requirements of emergency and non-commercial use, a human rights approach would require that the due process procedures as required for compulsory licensing *strictu sensu* be followed. The foregoing of the opportunity to have government use for other purposes may be required as a legitimate purpose to protect patent holders.[150]

4.1.2 Parallel Imports

Parallel importation is an important policy instrument for mitigating patent price effects and promoting competitive worldwide markets in pharmaceutical products.[151] The situation obtaining under the national exhaustion doctrine amounts to the inventor being repeatedly rewarded for the same product every time the product crosses an international border. In the global economy, the division of markets by patent territoriality is clearly an uncompetitive practice.[152] There is no legitimate governmental purpose served by a system that restricts access to medicines in order to repeatedly reward an inventor. Further, the practice under the national exhaustion doctrine goes against the general objectives of the WTO. The main objective of the world trading system under the WTO is to secure the greatest possible

150 Such protection is usually required in cases of takings under the eminent domain doctrine. Also, see Griffin (n 141 above) 404.

151 Abbott (n 95 above) 20.

152 Bhala and Kennedy *World Trade Law* (1998) 1130.

access to all goods available on the world market.[153] That objective also coincides with a human rights approach to trade in essential products. A state that adopts national exhaustion not only fails to serve a legitimate governmental purpose that the implementation of TRIPS is meant to serve, but also breaches its obligation to ensure the greatest possible access to essential drugs.

One of the justifications for adopting the national exhaustion practice has been to protect and harness comparative advantage.[154] The protection of such advantage can be justified under international human rights law as a legitimate governmental purpose. This restrictive approach however also means that such a market would have some of the most expensive medicines in the world. The question then is whether it is justifiable under human rights law that the citizens and residents of such a state who are entitled to the best attainable state of health shoulder the burden of higher prices. Even if the state were to subsidise the health care for its citizens, the right to health is a right for all people within the states' jurisdiction and not a citizen's right. Secondly, the Medicaid offered for example in the US does not offer unlimited payments for drugs and some have cost ceilings while others require substantial patient contributions.[155]

In Sub-Saharan Africa, largely for historical reasons most countries had hitherto adopted the national exhaustion doctrine.[156] Even South Africa, which in 1997 sought to acquire cheaper treatments to deal with the critical HIV/AIDS situation, parallel importation is prohibited under the Patent Act.[157] This means that Africa with the lowest pharmaceutical manufacturing base, minimal earning capacity and non-existent medical cover and insurance systems for the poor also has the same restrictive approach to parallel importation as the US. The negative socio- economic implications of high drug prices in Sub-Saharan, particularly in the

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153 See Lettington & Musungu (n 122 above) 28. The authors argue that prohibiting parallel imports could in fact contravene article IX of GATT 1994.

154 For example, the US seeks to protect its sophisticated pharmaceutical industry since it has a competitive and absolute advantage.

155 See Ackiron (n 80 above) 168.

156 See Beecham (n 127 above) which represents the situation in ARIPO and OAPI countries. There are now some changes and both Kenya and South Africa have incorporated some form of parallel importation provisions into national law although both legislations have not yet come into force. See sect 58.2 of the Kenya Industrial Property Act 2001 and sect 15 of the South Africa's Medicines and Related Substances Control (Amendment) Act.

157 See section 45 Patent Act 1978 as amended including amendments by Act 38 of 1997.

face of HIV/ AIDS cannot be gainsaid. Clearly, this approach cannot be sustained in the context of the obligations under the right to health. There is no tangible governmental purpose served by such an approach and the governments provide no cushion to mitigate the resultant negative effects. Allowing parallel importation therefore offers an immediate, effective and human rights consistent legal tool to ensure access to essential life–saving medicines. Further, lower drug prices in Sub-Saharan Africa will also mean that governments spend much less in the procurement of drugs freeing the much needed cash for infrastructure development, research and doctor.

4.1.3 Patentability and New Use Pharmaceutical Patents

Minor changes to products at the end of the patent life, especially for medicines, are used to evergreen the monopoly rights.[158] This is done by drawing the original patent claims with great obscurity so that subsequent minor changes appear to be novel. The protection of second medical indications in particular impedes access to medicines and in most cases is used as a restrictive practice.[159] The net effect of this kind of protection is that while the patent protection of a product may have expired, competitors and consumers are prevented from subsequently exploiting the new use of the product, which would affect the freedom to exploit the old use of the product to a considerable degree.

The TRIPS Agreement only establishes a general criterion for patentablity. The criteria being flexible, the requirements of patentability may be strictly interpreted to limit the grant of new use patents for pharmaceuticals. In deciding whether to grant new use patents a lot of thought must be given to the issue of inventiveness versus adaptation. In the case of second pharmaceutical use it is clearly difficult to draw the line.[160] By insisting that patents are granted only for new drugs representing a major breakthrough, a state fulfils its obligation to protect health as it ensures that no unnecessary restriction not serving the legitimate governmental purpose of protecting inventions is placed on access to medicines. An important component of this obligation is therefore creating administrative mechanisms that ensure that patents meet strict standards.

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158 HDR 2001 (n 1 above) 103.

159 Article 27 TRIPS only requires patent protection only for products and process but not explicitly for new uses.

160 For a fuller discussion, see CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000).

In terms of establishing a technological base however, it is considered that developing countries may have some comparative advantage investing in discoveries of new uses of known products as opposed to investments in R & D for new products. Where this is the case and where the government can cushion against any detrimental effects, protection for first medical indications may pass the test of reasonableness.

4.1.4 Article 30 Exceptions and the Early Working (Bolar) Exception

In the pharmaceutical industry, the conduct of bio-equivalence studies and other procedures necessary for regulatory approval have been known to take up to three years. Without the early working exception, it would mean that after the expiry of a patent it would take at least three years before generics can be available on the market. It is also known that patent holders often increase prices soon after the patent expiration to maximise profits while the branded drug still controls the market to offset losses from the anticipated generic competition.[161] This is an undesirable situation particularly since the introduction of generics can bring down the price of drugs by up to 90%.[162] A human rights approach to such patent protection and implicit in the justification for the grant of patents is that on the expiry of the patent the protected products should be accessible more widely and under non-monopoly conditions. A failure to provide *bolar* provisions in national legislation negates this possibility and is detrimental to the protection and promotion of the right to health.

[161] Griffin (n 141 above) 372.

4.2 The Right to Health and Other Strategies to Improve Access to Medicines

In the on-going debates on IPRs and access to health care, other mechanisms have been suggested either as complementary to or as substitutes to the exceptions provided under TRIPS. The most widely debated mechanisms relate to the question of technology transfer, tiered pricing and the global fund established under the UN.[163] It is therefore important that these mechanisms are also examined to determine their compatibility with a human rights approach to access to medicines particularly where these are suggested as substitutes for TRIPS exceptions.

4.2.1 Technology Transfer

Building technological capacity in developing countries is central to forging long-term solutions to the problems of access to affordable health care because technologies for development have not, cannot and will not be supplied through the current global market place alone.[164] Current global markets continue to drive a technological trajectory that is not suited to the needs of developing countries.[165] Research agendas are driven by the interests of scientists and inventors in research hubs and motivated by the needs and desires of high income consumers in Europe, Japan and North America and the developing world elite. Inadequate national policies and migration of skilled humanpower are partly responsible for the failure of developing countries to adapt existing technologies to their needs, but the lack of supporting global institutions and unfair implementation of global trade rules are creating additional barriers.

While developed nations have argued that patent protection is necessary for technology transfer to developing countries, most studies on patents and innovation have been inconclusive regarding a correlation between patents and technological development.[166]

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162 For example, after the expiry of the Cipro patent in Kenya, generics produced locally and imported costs between $6 and $2 per ten tablets as opposed to Bayer's monopoly price of $38.

163 The fund was established at the April 2001 Abuja Summit on AIDS under the auspices of the UN as a source of money for prevention, treatment and research for AIDS, TB and malaria.

164 HDR 2001 (n 1 above) 97.

165 HDR 2001 (n 1 above) 96.

166 See for example KE Maskus *Intellectual Property Rights in the Global Economy* (2000) referred to in Abbott (n 95 above) footnote 5.

Maskus argues that based on these studies it is demonstrable that it is only as countries have reached higher levels of economic development that they have adopted stronger patent protection. It is in this context that other commentators such as Abbott have argued that there is in fact no demonstrable causal link between patents and invention.[167] It is also for this reason that developing countries accepted the TRIPS Agreement with great reluctance, fearing that the high levels of IP protection would not be appropriate for technology transfer and other social objectives such as availability of essential medicines. [168]

The transfer of technology, as well as innovation, played a key role in the history of industrialisation in the west.[169] Many of today's advanced economies however refused to grant patents throughout the 19th and 20th centuries, or found ways of circumventing them.[170] These economies only formalised and/or enforced IPRs gradually as they shifted from being net users of IP to being net producers. Indeed several of the major European economies with high pharmaceutical production including France, Germany and Switzerland only fully formalised IP protection in the 1960s and 1970s.[171] It is because of this apparent correlation between low levels of IP protection and higher levels of technological growth that technology transfer provisions had to be included in the TRIPS Agreement in an effort to allay the fears of developing countries. The TRIPS Agreement in similar fashion to a number of other international agreements includes technology transfer provisions as a balancing mechanism. In practice however, beyond the negotiating rooms, provisions for technology transfer written into many international agreements have often turned out to be paper promises.[172] While the TRIPS Agreement calls for technology transfer nothing tangible is happening. A number of developing country delegations at WTO have noted that so far there is little evidence that the Agreement is contributing to the transfer and dissemination of technology in a manner conducive to their social and economic welfare, particularly in the field of public health.[173]

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167 See Abbott (n 95 above) 5.

168 See Howse & Mutua (n 3 above).

169 HDR 2001 (n 1 above) 102.

170 Id.

171 Id. The apparent correlation between lack of IP protection and higher levels of progress can also be seen in countries such as India and Brazil which today have a highly developed pharmaceutical manufacturing base.

172 HDR 2001 (n 1 above) 105.

173 See Abbott (n 95 above) 29.

The problem is that although technology may be a tool for development, it is also a means of competitive advantage in the global economy.[174] In the Paris regime of IP, one of the most important technology transfer tools was the local working requirement. It has however been suggested in some quarters particularly by the United States Trade Representative (USTR) that TRIPS prohibits local working requirements.[175] This argument is ostensibly based on article 27.1 which provides *inter alia,* that patent rights shall be enjoyable whether products are imported or locally manufactured. There is however still considerable debate on this point.[176] Suffice it to say however that from the perspective of human rights, local working should still be adopted by developing states as an exception to the requirements of article 27 as it is necessary to promote technological development. Such an exception clearly serves a legitimate governmental purpose to ensure the transfer and dissemination of technology in line with the objectives of TRIPS.

There is also the question of incentives for technology transfer which is an important factor in helping encourage R & D especially on so called neglected diseases of the south. The TRIPS Agreement calls for developed WTO members to 'provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed countries to enable them create a sound and viable technological base'.[177] For developed countries, members of the UN and parties to the ICESCR, apart from the TRIPS obligation, they have an obligation to provide such incentives under human rights law.[178]

The US for example has offered financial incentives to its own enterprises under the 1983 Orphans Drug Act by granting exclusive licenses, tax credits and federal grants for drug development.[179] In enacting this legislation, the US Congress clearly recognised that the pharmaceutical industry needed incentives to undertake R & D in diseases that are similar to neglected diseases. The Orphan Drugs Act approach can be used by the US and other

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174 HDR 2001 (n 1 above) 109.

175 A local working provision under section 68 of the Brazilian patent law was the subject of the now settled trade dispute between the US and Brazil.

176 Correa (n 117 above) 9.

177 See TRIPS art 66.2.

178 There is an international cooperation and assistance obligation under both the UN Charter and the ICESCR. See arts 1.3, 13 and 56 of the UN Charter and art 2 of the ICESCR.

179 For a discussion, see Ackiron (n 80 above) 157-59.

developed countries as an incentive system for R & D on neglected diseases. Such incentives are required under the obligation of states individually and jointly to promote medical research as a component of the core obligations under the right to health.

4.2.2 Tiered Pricing and the Reverse Leakage Debate

Some products of new technologies from pharmaceuticals to computer software are in demand worldwide. However, when they are protected by IP and produced under monopoly conditions, pricing strategies and market division may put them out of the reach of some people. A monopoly producer seeking to maximise global profits on a new technology would ideally divide the market into different income groups and sell at prices that maximise revenue in each market, while always covering marginal costs of production.[180] Such tiered pricing could lead to an identical product being sold for one-tenth or even one-hundredth of the prices in another country irrespective of the differences in levels of development. It is this price discrimination and market division that parallel importation seeks to eliminate. Consequently, one of the main objections raised to the practice of parallel importation is that it will interfere with the strategy of tiered pricing.[181] Already, several initiatives are underway to create tiered pricing for brand name drugs including the Accelerating Access Initiative (AAI) launched in May 2000 by the Joint UN Programme on AIDS (UNAIDS) and five major pharmaceutical companies.[182] However, with the increasing opening of borders, producers in rich countries fear that re-imports of heavily discounted products will undercut the higher prices charged to cover overheads and R & D costs.[183]

While tiered pricing may serve to enable a lowering of costs for essential drugs, the strategy cannot be a substitute for parallel importation. In the first place, in the long term it is difficult to see how tiered pricing is a more reasonable and less restrictive means of ensuring access to affordable medicines than parallel imports. In the second place, it is difficult to see how a prohibition on parallel imports to allow market division can be classified as an overriding governmental purpose when African governments have virtually starved their own populations in the name of opening up borders to trade. In any case even where there is no

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180 HDR 2001 (n 1 above) 96.

181 See Abbott (n 95 above) 26.

182 See HDR 2001 (n 1 above) 106. The companies involved are Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, GlaxoSmithKline and Merck.

183 HDR 2001 (n 1 above) 97.

reverse leakage, there is also the challenge of protecting the rights of consumers in the developed countries. Knowledge about lower prices in other regions may create consumer backlash. The way things are playing out in regard to prescription drug prices between the US and Canada starkly illustrates the point. Except where the high cost is subsidised by governments in the north, tiered pricing may still fail a human rights test from the perspective of developed countries. Why would a consumer in the US be overly burdened than a consumer in Canada or Western Europe?

It is clear that while tiered pricing may result in lower prices in developing country markets it is not a sustainable strategy since there is no legal obligation on the companies and it all depends on good will. Parallel importation on the other hand confers on consumers a legal right to shop globally. In addition, from a human rights perspective it is difficult to justify high prices in developed countries purely on the basis that it is a subsidy for lower prices in other markets.

4.2.3 The Global Fund and Drug Donations Programmes

Good drug donation and similar programmes such as the Global Fund[184] can be highly effective in the fight against diseases in the developing world and it fits as part of the international assistance and co-operation envisaged in the realisation of the right to health and other socio-economic rights. An example of a successful programme is the 1987 Merck programme to provide free 'wherever needed for as long as needed' the drug Mectizan to eradicate river blindness.[185] By 1998 up to 25 million people in 32 countries had been treated.[186] The problem with drug donation programmes is however that they may be seen as a solution to access, when in fact they cannot address the problem adequately.[187] Some drawbacks of drug donation programmes include sustainability issues, inability to deal with large-scale problems such as HIV/AIDS in Sub-Saharan Africa, restrictions and bureaucratic delays. For example, since the announcement of the Global Fund not many contributions have been forthcoming and the target of $10 billion dollars is still far from being realised.

184 N 163 above.

185 HDR 2001 (n 1 above) 101.

186 Id.

187 Id.

There is also already wrangling between the US and the EU on how the Fund will be managed.[188]

Even assuming that large-scale financial assistance is made available by developed countries and the world community through the UN to address the immediate consequences of HIV/AIDS, a human rights approach requires that access to low priced medicines is assured over the long-term. Such long-term assurance may be found more in generic competition through compulsory licensing and parallel importation, technology transfer and other mechanisms than in donations. Hence, while donations and the creation of the global fund represent a proper step in fulfilling the international assistance and co-operation obligation to protect health, it may not be a sustainable approach to ensuring access to essential medicines. Such efforts must be seen as complimentary to other strategies other as than substitutes to them.

188 For a critique of the Global Fund strategy see N Ford & E t'Hoen "The Global Health Fund: Moral Imperative or Industry Subsidy?" *The Lancet* 18 August 2001.

5. CONCLUSIONS AND RECOMMENDATIONS

As we consider the evolution of international trade law and its relationship to the existing legal regime governing the promotion and protection of human rights, we are confronted with difficult dilemmas but few definitive solutions. The challenge of ensuring adequate health care to people in the poor regions of the world and turning today's technological transformations in the pharmaceutical sector to the service of socioeconomic development is indeed tremendous. But it is not an impossible task. While the genius of what can be done through technology is astounding[189] the collective failure such as we are witnessing in relation to access to essential medications is indefensible. As the potential of what can be done to balance the interests continues to unfold, the question remains whether the explosion in pharmaceutical technologies will be matched by policies to ensure that the benefits are well spread to reach those who are most in need. As this study demonstrates, that matching can be found if WTO rules are implemented and interpreted in a way that advances human rights. The balance envisaged under article 15 ICESCR in particular offers a critical basis from which to address the issue of IP and access to essential medicines. There is great potential of realising the right to health if states take into account the critical elements of the right and the resultant core obligations as they integrate the minimum standards of the TRIPS Agreement into national legislation.

While developing countries have to conform to the minimum standards under TRIPS, there is a wide scope of discretion that allows them to fashion appropriate national strategies within this multilateral framework. The flexibility within TRIPS permits countries to take measures to protect their public priority objectives including the realisation of the right to health. In order to ensure that differentials in power, influence and resources do not place limitations on how the room for manoeuvre is utilised by developing countries an appropriate human rights framework is necessary. A single set of minimum rules should create a level playing field even when the players are of such unequal strength, both economically and institutionally. This study has significantly shown how states and other national, regional and international institutions can ensure that both innovators and consumers, in a rights sensitive context, share the benefits of medical technology.

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189 HDR 2001 (n 1 above) 117.

Each country's strategy in the implementation of the TRIPS Agreement should therefore incorporate a clear component concerning the realisation of the right to health. From a human rights perspective, it is necessary that these flexibilities be incorporated into national IP legislation to coincide with the obligation of states to respect, promote and fulfil the right to the highest attainable standard of health. In particular, states must ensure that the legislation includes compulsory licensing provisions allowing import and export, public non-commercial government use as a fast track procedure in cases of emergency and other cases of extreme urgency and that the law permits the international exhaustion principle in respect of exhaustion of IP rights. The Doha Declaration has unequivocally confirmed the legality under WTO law of these flexibilities and the right to use them to address public health.

In addition, states must ensure that proper administrative and technical mechanisms are put into place so that only novel inventions representing a significant advancement to existing knowledge are protected. In addition, states must ensure that their legislation contains reasonable provisions regarding the early working exception to make sure that on expiry of the patent period the protected products should be accessible more widely under non-monopoly conditions. Further, local working conditions should be adopted by developing states as an exception to the requirements of article 27 of TRIPS as it is necessary to promote technological development. Such an exception clearly serves a legitimate governmental purpose to ensure the transfer and dissemination of technology in line with the objectives of TRIPS and consistent with the states obligation to promote medical research. Developed countries should also use the Orphan Drugs Act approach as an incentive for R & D on neglected diseases. As regards drug donation programmes they must be long term and sustainable. Hence, while donations and the creation of the global fund represent a proper step in fulfilling the international assistance and co-operation obligation to protect health, it should not be seen as a substitute to more long-term options under the TRIPS Agreement.

The Doha Declaration on the TRIPS Agreement and public health clearly confirms that the obligations under the right to health must underlie the manner in which states interpret and implement the Agreement. By affirming the right of WTO members to take measures to protect public health, the WTO accepts that the Agreement leaves the interpretation and implementation of the Agreement at the discretion of states and in particular that the right to health conditions the manner in which states can exercise the discretion under the

Agreement. With the commitments made in the Doha Declaration and in line with their obligations under IHRL, states must now establish IP regimes with a human face.

Word count: 17,939 (including footnotes).

6. BIBLIOGRAPHY

A. Books

1. Bainbridge, DI *Intellectual Property* (1999) London: Oxford University Press.
2. Bekker, G (ed) *A Compilation of Essential Documents on the Right to Health Care* (2000) Economic and Social Rights Series Vol. 4, Pretoria: Centre for Human Rights.
3. Brandt, MA "Acquired Immune Deficiency Syndrome (AIDS)" in Kenneth, KF (ed) *The Cambridge World History of Human Disease* (1993) London: Cambridge University Press 549.
4. Bhala, R and Kennedy, K *World Trade Law* (1998) New York: Lexis Law Publishing.
5. Correa, CM *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000) Geneva: South Centre.
6. Correa, CM *Intellectual Property Rights, the WTO and Developing Countries: The TRIPs Agreement and Policy Options* (2000) London/New York: Zed Books & Penang, Third World Network.
7. Grubb, PW *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (1999) London: Clarendon Press.
8. Leary VA "Implications of A Right to Health" in KE Mahoney and P Mahoney (eds) *Human Rights in the Twenty-first Century* (1993) The Hague: Kluwer Academic Publishers.
9. Maskus, KE *Intellectual Property Rights in the Global Economy* (2000) Washington: Institute for International Economics.
10. Melander, G & Alfredsson, G *The Raoul Wallenberg Compilation of Human Rights Documents* (1997) The Hague/London/Boston: Martinuss Nijhoff Publishers.
11. Velasquez, G & Boulet, P *Globalisation and Access to Drugs: Perspectives on WTO/TRIPs Agreement* (1999) Health Economics and Drugs, DAP Series No. 7, Geneva: WHO.
12. Velasquez, G & Boulet, P *Globalisation, Patents and Drugs: An Annotated Bibliography* (2001) Health Economics and Drugs EDM Series No. 9 & 10 Geneva: WHO.

B. Journal Articles

1. Abbott, FM "First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation" (winter 1998), *Journal of International Economic Law,* 607.
2. Ackiron, E "Patents for Critical Pharmaceuticals: The Case of AZT" (1991) *17 American Journal of Medicine and Law 145.*
3. Attaran, A & Gillespie-White, L "Do patents Constrain Access to AIDS Treatment in Poor Countries? Antiretroviral Drugs in Africa 17 October 2001 *JAMA.*
4. Emmert, F "Intellectual Property in the Uruguay Round: Negotiating Strategies of the Western Industrialised Countries" (1990) 11*Michigan Journal of International Law* 1317.
5. Frank, JW & Mustard, JF "The Determinants of Health from a Historical Perspective" *(1995) 123 American Journal of Arts and Sciences.*
6. Griffin, MT "AIDS Drugs and the Pharmaceutical Industry: A Need for Reform" *(1991) 17 American Journal of Medicine and Law 363.*
7. Hendriks, A & Toebes, B "Towards a Universal Definition of the Right to Health" (1998) *17 Medicine and Law 319.*
8. Howse, R & Mutua, M "Trading in Human Rights: The Human Rights Obligations of the WTO" *ICHRRD* (April 2000).
9. Ostergard, RL "Intellectual Property: A Universal Human Right?" (1999) 21 *Human Rights Quarterly 156.*
10. *Toebes, B* "Towards an Improved Understanding of the International Human Right to Health" (1999) *21Human Rights Quarterly 661.*

C. Internet sources

1. Bertrand A & Kalafatides L "The WTO and Public Health" (1999) *The Ecologist* <http://www.aidc.org.za/archives/wto_health_bertrand_kalafatides.html > accessed on 15 March 2001.
2. Smith D "What Does Globalisation Mean for Health?" (June 1999) *Third World Network* <http://www.globalpolicy.org/globaliz/special/health/html> accessed on 11 March 2001.
6. Mc Neil Jr DG "Prices for MEDICINES ARE exorbitant in Africa, Study Says" *The New York Times* 17 June 2000

<http://www.nytimes.com/library/world/africa/061700africa-medicine> accessed on 18 June 2000.

7. World Intellectual Property Organisation <http://www.wipo.org> accessed on 19 November 2001.

D. Newspaper Articles

1. Alexander, D "'Duplicated' drugs life-line for millions in Africa: US anthrax scare renews debate on generic drugs law" *The Monitor* 1 November 2001, 15
2. Elliott, R "WTO needs reminding we all deserve health care" *Toronto Star* 11 November 2001 A 13.
3. N Ford & E t'Hoen "The Global Health Fund: Moral Imperative or Industry Subsidy?" *The Lancet* 18 August 2001.
4. Kimani, D "AIDS Drugs: Kenya Must Capitalise on Expiring Patents" *East African,* Magazine Section 19-25 November 2001, VII.
5. "'Patents are not the Problem,' says Harvey Bale of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)" *Financial Times* 20 June 2001 12.

E. Cases

1. *Beecham Group Ltd v. International Products Ltd &* Anor (1968) EA 398.
2. *Boesch v. Graff* 133 U.S. 697, 703 10sect. 378, 380 33 L.Ed 787(1890).
3. *Employment Division Department of Human Resources of Oregon and Others v Smith* (1990) 494 US 872; 108L Ed 2(d) 876. 898.
4. *Kendell v. Winsor,* 62 U.S. (21How.) 322.
5. *Kodak SA v. Jumbo-Markt AG,* 4C.24/1999/RND
6. *Ono Pharmaceuticals Co. Ltd v. Kyoto Pharmaceuticals Co. Ltd,* Case No. Heisei 10 (JN) 153
7. *Soobramoney v. Minister of Health (Kwa-Zulu-Natal)* Case CCT 32 OF 1997 Judgment of 27 November 1997.
8. *Young v. Rosenthal* (1884) RPC 29

F. Legislation

1. US Drug Price Competition and Patent Restoration Act of 1984
2. US Clean Air Act of 1970
3. The Kenya Industrial Property Act 2001
4. South Africa Medicines and Related Substances Control Amendment Act 1997
5. US Orphans Drug Act 1983
6. South Africa Patent Act 1978

G. International Instruments and Declarations

1. African Charter of Human and Peoples' Rights
2. American Convention on Human Rights
3. Constitution of the World Health Organisation
4. Convention on the Elimination of All Forms of Discrimination against Women
5. Convention on the Elimination of All Forms of Racial Discrimination
6. Convention on the Rights of the Child
7. Declaration of Alma-Ata
8. European Convention of Human Rights and Fundamental Freedoms
9. European Social Charter
10. International Covenant on Civil and Political Rights
11. International Covenant on Economic, Social and Cultural Rights
12. Agreement on the Trade Related Aspects of Intellectual Property Rights
13. United Nations Charter
14. Universal Declaration on Human Rights
15. The Vienna Convention on the Law of Treaties

H. Other Readings

1. Abbott, FM "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference" (September 2001) *Occasional Paper 7*, Geneva: Quaker United Nations Office.
2. Correa, CM "Intellectual property rights and the use of compulsory licenses: Options for Developing countries" (1999) *Trade – related agenda, development and equity (T. R. A. D. E) working papers 5* Geneva: South Centre.

3. Declaration on TRIPs and Public Health, adopted at the WTO Ministerial Conference, Fourth Session, Doha 9-14 November 2001, WT/MIN (01)/Dec/W/2.
4. Lettington RJL and Musungu, SF "In Defence of Kenya's Health: Proposed Amendments to the Industrial Property Bill 2000" (July 2000) a report prepared for the Kenya Coalition for Access to Essential Medicines.
5. Ministerial Declaration adopted at the WTO Ministerial Conference, Fourth Session, Doha 9-14 November 2001, WT/MIN (01)/Dec/W/1.
6. Oloka-Onyango, J & Udagama, D *Globalisation and its Impact on the full Enjoyment of Rights* Progress report by the Special Rapporteurs on Globalisation E/CN.4/Sub.2/2001/10, July 2, 2001. Also available at <http://www.unhchr.ch>.
7. Oloka-Onyango, J "Human Rights and Sustainable Development in Contemporary Africa: A New Dawn. Or Retreating Horizons?" *Human Development Report 2000 Background Paper.*
8. Report of the High Commissioner for Human Rights on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights E/CN.4/Sub.2/2001/13, June 2001. Also available at <http://www.unhchr.ch>.
9. UNDP, *Human Development Report 2001:Making New Technologies Work for Human Development* (2001) New York: Oxford University Press.