THE QUEST FOR ACCESS TO MEDICINES AND THE EFFECTS OF THE TRIPS AGREEMENT: AN APPRAISAL OF THE NIGERIAN SITUATION BALANCED AGAINST OTHER STATES.

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ABSTRACT

The objective of this thesis is to find solutions to the access to medicine problem in Nigeria whilst still complying with the TRIPS Agreement. The study reveals that apart from the high prices of medicines, there are other major domestic factors such as the lack of social amenities, the failure of the pharmaceutical industry to become self reliant, counterfeit drugs and lack of recognition for traditional medicines which have contributed to the lack of medicines for HIV/AIDS and other opportunistic diseases that are a major public health problem in Nigeria.

In fulfilling the objective of this study, the thesis notes that many Nigerian laws are based on the British legal system; a historical analysis of the patent system in Britain and indeed Europe is therefore carried out. The historical analysis is relevant in recognizing how the patent concept developed and evolved into becoming one of the most powerful components of the multi-lateral trading system and why developing countries like Nigeria have struggled with the concept.

The HIV/AIDS epidemic in Nigeria, neglected diseases and counterfeit drugs are also examined with key emphasis on the Nigerian governments' position on tackling the access to medicines problem. In that section an examination of the human rights approach to confronting the access to medicines crisis is conducted with a view of encouraging the respect and protection of fundamental human rights whilst still complying with the TRIPS Agreement.

Ultimately a comparative analysis of the Nigerian and Indian pharmaceutical industry is carried out in order to extract lessons which may be useful to the Nigerian government when initiating public health policies and amending its intellectual property laws which are presently out-of-date. In the end the thesis stipulates ways in which Nigeria can take advantage of the flexibilities of compulsory licenses and parallel importation within the TRIPS Agreement to gain access to medicines.

To my father and mother Zegetar and Torkwase Iyortyer

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I once read a PhD candidate's acknowledgement who said it is customary to begin such acknowledgements with a bout of name dropping, so I choose to begin mine with Friedrich Nietzsche quote "what does not destroy me makes me stronger".

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Most earnestly thank you God for making everything possible in my life

CONTENTS

LIST OF ACRONYMS

AAIN	ActionAid International Nigeria
ACHPR	African Commission on Human and Protection Rights
ACP	African, Caribbean and Pacific
ACTA	Anti Counterfeiting Trade Agreement (ACTA
AFPAC	Armed Forces Programme on AIDS Control
AIDS	Acquired Immuno-deficiency Syndrome
AIPO	African Intellectual Property Organisation
AITIC	Agency for International Trade Information and Cooperation
APEC	Asia-Pacific Economic Cooperation
APIN	AIDS Prevention Initiative in Nigeria
APOC	African Programme for Onchocerciasis Control
ARIPO	African regional intellectual property organization
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
ASINFAR	Association of Colombian Pharmaceutical Industries
BCPW	Bengal Chemical and Pharmaceutical Works
BFAD	Bureau of Food and Drug
BIRPI	Bureaux for the Protection of Intellectual Property
CAFC	Court of Appeals for the Federal Circuit
CAFTA	Central American Free Trade Agreement
CBD	Convention on Biological Diversity
CBOs	Community-Based Organizations
CDC	Centre for Disease Control and Prevention (US)
CEDAW	Convention on the Elimination of Discrimination Against Women
CHAN	Christian Health Association of Nigeria
CIDA	Canadian International Development Agency
CISNHAN	Civil Society Network for HIV/AIDS in Nigeria
CSO	Civil Society Organizations

DALE	Disability adjusted life expectancy
DCG	Donor Coordination Group on HIV/AIDS
DFID	Department for International Development
DIGEMID	Directorate of Medicines, Supplies and Drugs
DMA	Danish Medical Agency
DNDi	Drugs for Neglected Diseases initiative
DPCO	Drug Price Control Authority
DPHC	Department of Primary Health care
DRC	Democratic Republic of Congo
ECJ	European Court of Justice
ECOSOC	Economic and Social council
ECOWAS	Economic Community of West African States
EDL	Essential Drug List
EFCC	Economic and Financial Crimes Commission
EPA	Economic Partnership Agreement
EPO	European Patent Office
EU	European Union
FBOs	Faith-Based Organizations
FCT	Federal Capital Territory
FDI	Foreign Direct Investment
FERA	Foreign Exchange Regulation Act
FHI	Family Health International
FLE	Family Life Education
FMIGA	Federal Ministry of Inter-governmental Affairs
FMOE	Federal Ministry of Education
FMOH	Federal Ministry of Health
FTA	Free Trade Agreement
GAAP	Greater Access to Affordable Pharmaceuticals Act
GATT	General Agreement on Tariff and Trade
GDP	Gross Domestic Product

GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GHAIN	Global HIV/AIDS Initiative Nigeria
GIPA	Greater Involvement of People Living With HIV/AIDS
GMP	Good Manufacturing Practices
HAART	Highly Active Antiretroviral Therapy
HAF	HIV/AIDS Fund
HEAP	HIV/AIDS Emergency Action Plan
HHS	Health and Human Services
HIV	Human Immuno-deficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IIPA	International Intellectual Property Alliance
ILO	International Labour Organization
ILPIC	Industrial Licensing Policy Committee
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
INVIMA	National Institute for the Supervision of Foods and Medication
IPC	Intellectual Property Committee
IPMG	International Pharmaceutical Manufacturers Group
IPRs	Intellectual Property Rights
JAAIDS	Journalists Against AIDS
LACA	Local Action committee on AIDS
LASUTH	Lagos State University Teaching Hospital
LDC	Least Developed Countries
LGA	Local Government Authorities
MAP	Multi-country AIDS Program
MDGs	Millennium Development Goals
MNCs	Multinational Corporations
NACA	National Action Committee on AIDS
NAFDAC	National Agency for Food and Drug Administration and Control

NASCP	National AIDS and STDs Control Program
NASCP	National HIV/AIDS/STI Control Programme
NASSRA	National Assembly Response to AIDS
NEACA	National Expert Advisory Committee on AIDS
NEDL	Nigeria's Essential Drugs Policy
NEEDS	National Economic Empowerment and Development Strategy
NEPAD	New Economic Partnership for Africa Development
NEPWHAN	Network of People Living with HIV/AIDS in Nigeria
NERB	National Ethical Review Board
NERDC	Nigerian Educational Research and Development Council
NGO	Non-Governmental Organization
NHIS	National Health Insurance Scheme
NIPRD	National Institute for Pharmaceutical Research and Development
NNMDA	Nigeria Natural Medicine Development Agency
NNRIMS	Nigerian National Response Information Management System
NOP	NNRIMS Operational Plan
NPC	National Planning Commission
NQCL	National Quality Control Laboratories
NSF	National Strategic Framework
NUP	Nigerian Union of Pharmacist
OCP	Onchocerciasis Control Program
OECD	Organization for Economic Cooperation and Development
OEPA	Onchocerciasis Elimination Program for the Americas
OI	Opportunistic Infections
OPS	Organized Private Sector
OVC	Orphans and Vulnerable Children
OVD	Optically Variable Devices
PEPFAR	President's Emergency Plan For AIDS Relief
PhRMA	Pharmaceutical Research and Manufacturers of America

PIJIP	Program on information Justice and Intellectual property
PLWAs	People Living With AIDS
PLWHA	People living with HIV and AIDS
PMA	Pharmaceutical Manufacturers' Association
PMTCT	Prevention of Mother-To-Child Transmission
PSN	Pharmaceutical Society of Nigeria
PSRHH	Promoting Sexual and Reproductive Health for HIV/AIDS
Reduction	
R&D	Research & Development
RFID	Radio Frequency Identification Technology
RTIs	Reverse Transcriptase Inhibitors
SACA	State Action Committee on AIDS
SACU	Southern African Customs Union
SECURE	Standards Employed by Customs for Uniform Rights Enforcement
SEEDS	State Economic Empowerment and Development Strategy
SNR	Strengthening the National Response to HIV/AIDS
STA	State Trading Corporation
STIs	Sexually Transmitted Infections
STOP	US Strategy on Targeting Organised Piracy
SUS	Sistema Único de Saúde
SWAA	Society Women and AIDS in Africa
TB-DOTS	Tuberculosis Direct Observation Treatment Scheme
TRIPS	Trade Related aspects of Intellectual Property Rights
NOTAP	National Office for Technology Acquisition and Promotion
UAFTA	US-Australia Free Trade Agreement
UDHR	Universal Declaration of Human Rights
UN	United Nations.
UNAIDS	Joint United Nations Programme on AIDS
UNCTAD	United Nations Conference on trade and Development
UNDP	United Nations Development Programme

UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USFDA	US Food and Drug Administration
VCT	Voluntary Counselling and Testing
WCO	World Customs Organisation
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organisation

LISTS OF DIAGRAMS, CHARTS AND TABLES

DECLARATION

In accordance with the Regulations for Higher Degrees by Research, I hereby declare that the whole thesis now submitted for the candidature of Doctor of Philosophy is a result of my own research and independent work except where reference is made to published literature. I also hereby certify that the work embodied in this thesis has not already been submitted in any substance for any degree and is not being concurrently submitted in candidature for any degree from any other institute of higher learning. I am responsible for any errors and omissions present in the thesis.

Candidate_____

Hembadoon Iyortyer

1. INTRODUCTION

1.1 The Problem

On most days when you open the newspapers in Nigeria, there is always some news about the lack of medicines in the country. The difficulty of access to medicines in Nigeria has been compounded by numerous factors which have made the search for a solution more complicated. Some of these problems include inadequate infrastructure, high rates of morbidity and mortality due to diseases, lack of technical assistance to existing laboratories and guidance on setting up new laboratories for improved medical/ scientific research and diagnosis in the country, lack of funding for the treatment of major diseases such as HIV/AIDS, tuberculosis and malaria, lack of human and institutional capacity which has affected the quality of healthcare delivery, lack of political will, the presence of counterfeit medicines in the Nigerian market and indeed around the globe, weak traditional medicine practice and an underdeveloped pharmaceutical industry. All these factors have presented a very gloomy picture in the quest to finding a solution for access to medicines in Nigeria.

Other domestic issues that have contributed towards the lack of access to medicine are the lack of electricity, telephone, water and transport. Indeed one Nigerian commentator wrote "If we can't get electricity right, forget Nigeria". Such proclamations are a regular occurrence in the daily newspapers of Nigeria and they signify the high level of disappointment that the indigenes feel about the inability of the Nigerian government to provide basic utilities that are essential for the major sectors of the Nigerian economy to function effectively. Indeed the same commentator wrote that Nigeria "lacks the collective will, to provide uninterrupted power supply to meet her domestic and industrial needs [and may therefore lose] her locus standi as a modern nation".[1] As a matter of

[1] Tunde Fagbenle. If We Can't Get Electricity Right, Forget Nigeria. http://www.nairaland.com/nigeria/topic-232182.0.html 7 February 2009

fact every aspect of a modern industrialized world needs a steady supply of electricity if it is to thrive.

The problem of access to medicines is further compounded by Nigerian's large population and the fact that the Nigerian government is genuinely struggling to meet the healthcare needs of its population; a problem which has been inflamed by the government's failure to increase its national health expenditure. The last Nigerian population census result which was produced in March 2006 showed that Nigeria has a population of over 140 million people, nevertheless a report released by Actionaid showed that Nigeria is among the world's 25th poorest nations and over 69 million of its people live in abject poverty.[2] Without financial assistance from the national government and other international organisations and charities around the world the future for many Nigerians in accessing life saving medicines seem pretty bleak.

Another major problem which has contributed to the lack of access to medicines in Nigeria is the fact that intellectual property is still not a well developed area, thus there is no up to date legal framework on the subject of intellectual property law. Indeed I spoke to many legal practitioners in Nigeria during the course of my research that struggled with the concept and had little knowledge about the law in this area. It follows that although the Nigerian government is aware of the need to develop the law in the area of intellectual property if it is to compete with other countries who through their intellectual property laws have been able to develop their pharmaceutical industry to the level of producing and manufacturing medicines for its population, it must be acknowledged that there is still a very long way to go in making this aspiration a reality.

[2] Ayegba Isreal Ebije, "69 million Nigerians in Abject Poverty". Daily Trust, Wednesday, November 26, 2008.

Another complex issue which has compounded the access to the medicines problem is the fact that the TRIPS Agreement which has been in force since 1995 introduced global minimum standards for the protection and enforcement of nearly all forms of intellectual property rights, including those on patents. The TRIPS Agreement requires all WTO members (to which Nigeria is a party) to implement the Agreement with different implementation deadlines depending on each country's economic development. Nigeria like many other developing countries had a deadline of 2005 to become TRIPS compliant. Being TRIPS-compliant includes granting pharmaceutical patents for both process and products, however Nigeria has not yet amended its intellectual property laws to meet the required standards. Some of the reasons for this shortcoming include the fact that the growth and development of intellectual property rights in Nigeria has been slow when compared to countries like India or Brazil; lack of institutional capacity and the absence of appropriate IP-related technical assistance.[3] The complexity however lies in that it is important for Nigeria to adapt its intellectual property laws to become TRIPS compliant if it is to take advantage of the flexibilities within the TRIPS Agreement and ensure that its populace have access to medicines in the short and long term.

Some of the flexibilities within the TRIPS Agreement that WTO members can take advantage of, which have also been affirmed by the Doha Declaration in 2001 include: (i) compulsory licences which permits 3rd parties to use an invention, without the patents holder's consent (ii) government use which allows government agencies to use an invention for public non-commercial purposes (iii) parallel import which allows the importation and resale of patent products in other countries; other flexibilities which the government can take advantage of include making use of measures such as (iv) the Bolar exception and the (v) Paragraph 6 system which allows import and export of generic

[3] The pharmaceutical industry in Nigeria can gain from lose intellectual property rights laws and reverse engineer many medicines than stricter intellectual property rights. India was able to take advantage of this before the TRIPS Agreement came into place.

medicines under compulsory licences. The importance of incorporating these flexibilities into the Nigerian national law is that they will allow a degree of elasticity for the Nigerian government to accommodate their own patent needs, intellectual property systems and developmental need. If on the other hand Nigeria does not comply with the TRIPS Agreement or in becoming TRIPS-compliant uses words inappropriate in the national legislation it may be forced to initiate TRIPS-Plus measures in the form of Free Trade Agreements (FTAs)[4] or the inclusion of data exclusivity into the Nigerian legislation.[5]

Thus a state begins to set off TRIPS-Plus measures when it carries out activities that are aimed at giving right holders a level of protection that is higher than what is stipulated in the TRIPS Agreement. Such measures have the effect of reducing the ability of developing countries to protect their public interest. Such measures can be adopted at the multilateral, plurilateral, regional or national level. Sometimes they have the effect of impacting adversely on the healthcare delivery system by delaying the introduction of cheap medicines. This in the long term compounds the already existing problem of access to medicine which is a major problem in many developing countries. It is with this backdrop at the forefront that this thesis finds its purpose and mission in seeking to find a solution to the access to medicines issue in Nigeria.

1.2 Statement of Purpose

The primary quest of this thesis is to find ways of conquering the access to medicine problem in Nigeria by finding ways of ensuring that the government

[4] Note that some commentators have suggested that what the USA cannot accomplish through trade policies and behind the scene trade threats it tries to accomplish through technical assistance provided by USAID and by WIPO. In See Brook K Baker. Pharma's Relentless Drive for Profits. Health GAP. December 10, 2002. http://www.globalpolicy.org/component/content/article/209-bwi-wto/43688.html

[5] Note that data exclusivity is a means of preventing generic competition, which greatly restricts access to medicines. The TRIPS agreement does not refer to data exclusivity at all. It only refers to data protection against "unfair commercial use".

in becoming TRIPS compliant makes full use of all the flexibilities within the Agreement. This thesis will show that the Nigerian government need to adopt national policies that will develop the local pharmaceutical industries if it is to eradicate the access to medicine problem. In order to accomplish the foregoing, this thesis will analyze specific subject matters that shed light on the complexity of the issues stated above. It will conduct an in-depth analysis of other developing countries that have successfully initiated the TRIPS Agreement and draw on their experiences and struggles in a bid to ensure that the Nigeria government can improve its own intellectual property rights policy initiatives in the future. This thesis is consequently divided into three main parts.

Part I will provide a historical and jurisprudential background that is essential to understanding the key elements that continuously resound throughout the thesis. Chapter Two explores the birth of the TRIPS Agreement and exposes the pressures that developing countries faced throughout the negotiation process in the Uruguay Rounds that lasted between September 1986 and April 1994. It also exposes the initial fears that developing countries had; fears that were based on the belief that a stricter intellectual property system would impact adversely on public health. The chapter also goes further to discuss the gains that developing countries had at the Uruguay rounds, gains that seem very little when compared with those of the bloc of developed countries. The comparison is essential in appreciating the suitability of the multilateral trading system in our modern day society.

Chapter Three expounds a jurisprudential examination of the patent regime and its historical heritage in Europe. The importance of this chapter to the entire structure of this thesis is it seeks to analysis the importance of the patent system and how it came into being. The different justifications of the concept of owing knowledge, inventions and ideas are developed in this chapter, whilst

the advantages and disadvantages of intellectual property rights as a whole are also explored here. The aim of the foregoing is to set the scene towards understanding the usefulness of patents as an incentive to driving Research and Development (R&D) into new discoveries for innovative new medicines. Chapter three is also useful in showing that the concept of patents has evolved for centuries in Europe and taken shape, whilst on the contrary the idealisms and principles of patents are not so established in many countries in the sub-Sahara where ownership is based on communal ownership. For example in many parts of Africa, knowledge is seen more as a communal commodity rather than a product belonging to a particular individual. This reveals certain aspect of why developing countries have encountered many obstacles in accepting and implementing the TRIPS Agreement. The chapter further explores the theory of natural rights, incentive to invent and investments as a foundation to the justification of intellectual property rights which are key issues in the access to medicine debate.

Part II then follows by providing a revision of wide-ranging aspects of human rights as it relates to TRIPS and the access to Medicines debate. Chapter four gives a general overview of the origins of human rights, the interaction between human rights and trade, the human rights obligations of Multinational Corporations (MNC) and developed/ countries in alleviating the public health crisis of lack of medicines in developing countries. Chapter four is also significant as it examines the development of international law with regards to UDHR, ICESCR and the ICCPR in a bid to shade more light on the quest of access to medicines.

Chapter five focuses specifically on HIV/AIDS as a human rights issue in Nigeria; it analyses the problem of HIV/AIDS in the country with an in-depth examination of how the Federal Government of Nigeria has responded to the problem. It examines the efforts that have been made by the government in

procuring antiretroviral medicines in the past and whether such programs have been successful or not. The chapter discusses the Nigerian government's national response in tackling the HIV/AIDS crisis through grass root support and international projects. The Nigerian's Agency for the Control of AIDS is particularly examined with major emphasis on how it has partnered with other international donors such as HEAP, Global funds, DFID, FHI and PEPFAR to pay for the high prices of medicines. The chapter also goes further to provide an insight into how a few other countries including Uganda, Brazil, and South Africa has handled its HIV/AIDs epidemic and how Nigeria can draw lessons from it.

Chapter six examines other important issues that shed more light on access to medicine as an important human rights issue. These issues include 'neglected diseases' and the refusal of the pharmaceutical industry to invest in producing medicines for diseases that affect mainly poor people who cannot afford to pay for their own medication. The chapter goes further to establish the link between diseases, development and terrorism as an urgent matter that needs immediate attention from the international community. Another important human rights issue that is further tackled in this chapter is drug counterfeiting. The trade in counterfeit drugs has continued to grow and not only does it affect countries like Nigeria, but industrialised countries as well. The trade in counterfeit medicines has caused the deaths of many unsuspecting victims and many human rights activist have called upon the international community to recognise that the trade in counterfeit medicines that causes grievously bodily harm (GBH) or death is a clear violation of human rights under Articles 3, 5 and 25 of the UDHR.

Part III subsequently provides a comparative analysis, with Chapter seven presenting a comparative analysis of the way that the UK and US have used the flexibilities within the TRIPS Agreement: namely compulsory licenses and

parallel importation to gain access to cheaper medicines. The chapter also evaluates the successes and limitations of the Doha Declaration with a view of ascertaining what progress has been made since 2001 when the Declaration was announced. The Chapter concludes by evaluating whether in becoming TRIPS complaint Nigeria is at risk of becoming TRIPS-plus.

Chapter eight concludes by conducting a comparative analysis of the pharmaceutical industry in Nigeria with India. Although much of the discussion is focused on India, the chapter presents a historical analysis of the pharmaceutical industry in both India and Nigeria .The analysis seeks to show that with the right policies Nigeria has the potential to increase the production of medicines for its populace thereby improving access to medicines. The chapter concludes by asserting that traditional medicines are the way forward for the development of the pharmaceutical industry in Nigeria.

1.3 Scope of Study

Although Nigeria is ultimately the central focus of this thesis, other countries play a very important role in the study. The reason for this are listed below: Nigeria has not yet developed its intellectual property rights laws, therefore it is necessary to discuss how other states have developed their intellectual property rights laws to ascertain if there are specific policies or lessons that Nigeria can adopt when attempting to develop its own intellectual property rights policies and legislations. Another reason why the scope of this thesis extends to analysing intellectual property laws in other countries is so to establish that the TRIPS Agreement is not only harmless; but if implemented in the right way can promote the transfer of technology and FDI which will inadvertently impact positively on the public health sector of Nigeria in the long run.

The scope of the study extends to cover a historical analysis of the patent system in Europe. The importance of carrying out a historical analysis on the evolution of the patent system in Europe lies in the fact that the concept of patents originated in Europe and spread throughout the world. It is therefore important to understand why the principle was established in the first place and what it intended to achieve. This will enable one to determine whether patents as a whole fit into our modern day economy or not. The historical analyses of patents are also important because patents are a central theme of this study and they have been blamed for higher prices of medicines.

A discussion of the Indian pharmaceutical industry also occupies a large section of this study. The usefulness of this lies in the fact that India has a similar history to Nigeria. They are both former colonies of Britain; they both have huge populations, rich cultures and a history of using traditional medicines (in the case of India -ayurveda medicines). Whilst India has developed its pharmaceutical industry to become one of the most prominent suppliers of generic medicines, Nigeria is still lacking behind. The importance of this analysis is for the Nigerian government to learn from India how to succeed in implementing policies that have promoted their pharmaceutical industry and adopt the same strategy if possible. Indeed India played a very important role at the Uruguay and has always been at the forefront of the fight for access to medicines; they provide the cheapest ARVs and have saved many lives through its unwavering efforts in promoting access to medicines.

The scope of the thesis also extends to other countries such as Brazil, South Africa, Kenya, USA, Liberia, China and other Asian and South American countries. It attempts to touch on other countries in order to deduce lessons for Nigeria to follow so that it can make full use the flexibilities of the TRIPS Agreement in the fight for access to medicines.

1.4 Conclusion

At the end of this thesis the reasons why Nigeria has faced problems with regards to gaining access to medicines and whether it should become TRIPS compliant will become clear. The TRIPS Agreement is a very important part of the struggle for access to medicines in the sense that it increases the prices of some medicines, but what will also become clear is that there are other domestic issues that have contributed to making medicines inaccessible in many developing countries including Nigeria. Although the concluding chapter will be geared towards making recommendations in the sphere of legally inclined policies and laws; the thesis will ultimately end with making suggestions that I believe is the way forward for the Nigerian government in its quest for access to medicines.

PART I

2 THE TRIPS AGREEMENT ACCESS TO ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES: AN OVERVIEW

2.1 Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS)[6] is the most important International Intellectual Property Agreement of the 21st century for the following reasons: it extends the principles underpinning the world trading system to intellectual property rights and it ensures that there is adequate enforcement for it. However it remains the most controversial agreement in international commercial jurisprudence.[7] In the access to essential medicine debate the criticisms against the TRIPS Agreement are essentially that it is a product of duress by powerful and developed states against the weak and under-developed states, rather than a bargain struck by equal sovereigns. The Agreement has also been condemned by some as being part of a hard bargain in which developing countries received very few reciprocal gains, thereby giving more to developed countries than they got in return.[8] Some commentators have questioned whether developing countries really understood the implication of the TRIPS Agreement before agreeing to it. Indeed others have asserted that the US use of Special 301 contributed in coercing developing countries to agree to the TRIPS Agreement regardless of their reluctance.[9] And thirdly the implementation of the TRIPS

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[6] Hereinafter called The TRIPS Agreement, TRIPS or the Agreement.
[7] See: Drahos P and Braithwaite J (2002) *Proceedings of the 2002 Access to Medicine in the Developing World: International Facilitation or Hindrance?* 25 Hous. J. Int'l L. 229.
[8] Finger J. Michael (2007) *Implementation and imbalance: dealing with hangover from Uruguay Round. Oxford Review of Economic Policy* 23(3):440-460; doi:10.1093/oxrep/grm020
[9] See Matthews, D (2002) *Globalising Intellectual Property Rights: The TRIPS Agreement* (London: Routledge)

Agreement has been castigated for impacting adversely on the economies and health care delivery systems of developing countries.[10]

The TRIPS Agreement stipulates the transition periods for all member states of the World Trade Organisation (WTO) to ensure that their national laws adhere to minimum standards of intellectual property protection by specific deadlines. For developed countries, they had to adapt to the minimum standards of intellectual property as early as 1995. Accordingly the transition periods as stipulated in the TRIPS Agreement varies for each member state depending on the sort of obligation in question and the level of development of that country. Interestingly the WTO does not have a definition for "developed" and "developing" countries. Members announce for themselves whether they are "developed" or "developing" countries. [11] Although it is important to note that being a developing country brings with it certain rights such as the ability to receive technical assistance.[12] Nevertheless the World Bank prefers to group all low- and middle- income countries as "developing". For example in 2008, all countries with a GNI per capita below US$11,905 were grouped as developing. The UN on the other hand defines (LDCs) as a group of states that are deemed to be 'highly disadvantaged in their development process (many of them for geographical reasons), and facing more than other countries the risk of failing to come out of poverty'.[13]

As such the initial date set for developing countries to adhere fully with the TRIPS Agreement was 1 January 2000; this was later postponed to 1 January

[10] Note that in Nigeria, health care delivery (which means health care provision) is the responsibility of the federal, state and local government. The federal government responsibility is to the university teaching hospitals, whilst the state government manages the general hospitals. The local government is in charge of the dispensaries. Note also that private providers of health care are active in the delivery of health care in Nigeria.
[11] Note that, this announcement is subject to being accepted by all WTO bodies, also note that other members can challenge the decision of a member to make use of provisions available to developing countries. http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm
[12] Ibid
[13] http://www.unctad.org/Templates/Page.asp?intItemID=3618&lang=1

2005. Least-developed countries (LDC) on the other hand had until 31 December 2005 to comply fully with the TRIPS Agreement, this date was later extended by 11 years (that is until) 2016.[14]

With regards to the access to medicine debate, critics argued that insisting that developing countries adhere to the TRIPS Agreement in 2005 negatively affected public health and stalled their quest to halt the spread of HIV/AIDS and other opportunistic diseases. The way that it did this was by further putting antiretroviral (ARV) medicines out of the reach of majority of people living with HIV/AIDS in many developing countries. ARVs are very expensive and for most people living with HIV/AIDS in developing countries (PLWHA), there are no drug assistance programs and community resources do not pay for the cost of treatment. For example in the UK, the National Health Services (NHS) provides healthcare for all UK citizens based on their need for healthcare rather than their ability to pay for it. Although the NHS in funded by taxes, it ensures that people who cannot afford to pay for very expensive treatments receive the care that they need. Unfortunately, such systems do not exist in many parts of the developing world. The problem is further compounded by the fact that pharmaceutical companies charge extremely high prices for bringing new drugs unto the market which they blame on the high cost of R&D. The costs for R&D include clinical testing on both people and product developments have been identified as one of the driving factors for the prohibitive prices of new drugs.[15]

[14] In the event that a member state ceased to be a LDC, it had to comply fully with the TRIPS Agreement depending on which date came first.

[15] Love J, (2008) *Prizes, not prices, to stimulate antibiotic R&D*. http://www.scidev.net/en/health/antibiotic-resistance/opinions/prizes-not-prices-to-stimulate-antibiotic-r-d-.html (Accessed 23 June 2008) . See also Adams CP, Brantner VV (2006) *Estimating the cost of new drug development: is it really 802 million dollars*? Health Affairs, 25(2):420-8.

2.2 Cost of R&D

The figures for the actual cost of R&D for producing a new drug differ and unfortunately there is no way of being certain what the actual cost is. Thus according to the pharmaceutical industry's trade group Pharmaceutical Research and Manufacturers of America (PhRMA), in the 1990's US and foreign drug companies spent a staggering $139.8 billion on domestic R&D.[16] In order words for every new drug developed pharmaceutical companies claim to have spent $163 million on R&D. The Tufts Centre for the Study of Drug Development came up with a different figure, stating that the average total cost of R&D for new drugs in the late 1990s was $897 million;[17] a figure much lower than PhRMA's estimates. Another report by the Public Citizen puts the price much lower at $107 million before tax.[18] Interestingly after the Public Citizen report was released, PhRMA released new figures putting the total cost of R&D at $771 million.[19] A figure much lower than it had initially published.

Needless to say that even if the cost of R&D is $107 million per drug as the Public Citizen Report asserts, pharmaceutical companies are not charity organisations, they have to make a profit if the industry must flourish. Profits mean charging the users of the drugs for consumption. It therefore seems common sense that they should be allowed to recover the money invested into R&D if they must continue to find new drugs for the various ailments and diseases that plague the world today. The question however remains how can society strike a balance between what seems ethical (pharmaceutical companies' responsibility of saving lives and working for the public good) and

[16] Pharmaceutical Research and Manufacturers of America, "Annual Survey 2000," List of Tables, 2001, http://www.phrma.org/publications/publications/profile00/. (Accessed 26 June 2007)
[17] Mark Moran. (2003) *Cost of Bringing New Drugs to market rising Rapidly*. Health Care Economics. *Psychiatric News* Vol 38, No 15
[18] *Rx R&D Myths: The Case Against the Drug Industry's R&D "Scare Card"*. Public Citizen Congress Watch, July 2001. http://www.citizen.org/documents/acfdc.pdf
[19] Bob Huff. (2001)*What Does R&D Really Cost.* http://www.thebody.com/content/art13514.html (Accessed 30 March 2008)

the need to promote innovation by allowing pharmaceutical companies to reap the full benefits of their investment through profit making (if pharmaceutical companies are prevented from making profit the industry will die away, thereby eliminating the wealth of lifesaving drugs capable of curing sickness and disease around the world).

Before the TRIPS Agreement came into being, developing countries were able to avoid paying the expensive prices charged by pharmaceutical companies for purchasing branded medicines. They could easily gain access to generic equivalents at a lower price. Generic medicines have the advantage of being less expensive when compared to branded medicines because they do not have all the risks and costs associated with R&D for manufacturing new medicines. Indeed generic companies essentially focus on the production of existing generic compounds and concentrate on finding which patents protection have expired rather than developing new medicines that are classified as new chemical entities (NCEs). When countries such as India who are the biggest supplier of cheap generic medicines to developing countries (with 67% of its exports going to developing world)[20] had to comply with the TRIPS Agreement in 2005 they had to begin recognizing both product and process patents. This changed the entire landscape for access to cheap medicines all over the developing world. After the Indian Patents Act 1970, India excluded pharmaceutical products from being patented, this made it easier for their manufacturers to sometimes reverse engineer medical products cheaply and sell them at a cheaper price than their branded manufacturing counterparts. It was not until 2005 that they began to introduce product patents again. Critics have therefore argued that the TRIPS Agreement brought with it the "transfer of benefits from the hands of the consumer, in the form of consumer surplus,

[20] Oxfam Press Release .*(* 11/15/2006) *Rich countries betraying their obligations to help poor countries protect public health*. http://www.payvand.com/news/06/nov/1179.html (Accessed 5 July 2007)

into the hands of inventors, in the form of profits".[21] Indeed India's national sentiment was best captured by Indira Gandhi's statement at the World Health Organisation in 1982 when she said "The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."

2.3 The TRIPS Agreement

The TRIPS Agreement is a fundamental part of the constitution establishing the World Trade Organization (WTO). It is one of the multilateral trade agreements which have a binding effect on all its members. The WTO has 153 members and requires all its members to provide a higher level of protection for intellectual property than otherwise would have been required.[22] The TRIPS Agreement also stipulates minimum standards to be adopted for the protection of Intellectual Property Rights (IPRs) for countries which are members of the WTO. These standards are considerably detailed, particularly in the patent field. The TRIPS agreement can only operate through the laws of individual countries as it is not an automatic universal law. It therefore needs the co-operation and commitment of individual national governments to be dedicated to the full implementation of the Agreement for it to be effective. The key directive with regards to patent can be found in article 27:1, it requires member states to make patents available for all inventions including products or processes in all fields of technology.[23] This means that apart from the areas where the Agreement specifically exempts the granting of patents,[24] member states must grant patent protection as required by the TRIPS Agreement. This

[21] Lanjouw, Jean O (1996) *The Introduction of Pharmaceutical Product Patent in India" 'Heartless Exploitation of the Poor and Suffering?* NBER Working Paper No6366.
[22] See http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm
[23] Article 21:1 states that subject to paragraph 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application
[24] Article 27:2 allows members to exclude inventions from patentability on broad grounds of public order or morality and an exclusion for diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Article 27:3(b) permits members to exclude plants and animals other than micro-organisms and biological processes for the production of plants or animals other than non-biological processes.

in effect increases the scope of patentable subject matters from what it used to be. Thus the birth of the TRIPS Agreement is a major development in international intellectual property rights protection especially in sensitive areas such as pharmaceuticals which many countries had previously guarded jealously because of public health.[25]

Although article 1 of the TRIPS Agreement indicates that states are not obliged to adopt higher standards or provide greater protection than those set out in the Agreement, thus leaving the modalities for the implementation of the TRIPS Agreement at the discretion of the member states; article 33 of the TRIPS Agreement obliges states to grant patent protection for a minimum of 20 years beginning from the day of filling.[26] This gives patent holders monopoly right over products and processes for a 20 year period with the attendant power to charge whatever price they wish irrespective of the consumer's (in the case of drugs, patient's) ability to pay. [27] Despite the foregoing analysis it is important to note that it can sometimes take 8-12 years to bring a new drug to the market.[28] In such a case, the patent holder only has 8-12 years to charge whatever price they wish.

This has resulted in drug prices not corresponding to the market forces but to the buying power of the rich minority.[29] Whilst 8, 12 or even 20 years may not seem a long term for proponents of a strong patent protection system, commentators have argued that when producers are permitted to charge and maintain prices at a higher cost than the marginal costs of production, even 5

[25] Before TRIPS India did not grant patents in the pharmaceutical field.
[26] Article 33 states that the term of protection available shall end before the expiration of a period of twenty years counted from the filling date
[27] Sell K Susan (2002) *Proceedings of the 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance?* 20 Wis. Int'l L.J. 481
[28] See Y. Richard Wang. (2006) Price Competition in the Chinese Pharmaceutical Market. Int J Health Care Finance Econ 6:119-129
[29]. Nnadozie C Kent (2001) *The Trips Agreement and Access to Essential Medicines in Nigeria", being a Status Report on the IP Regime in Nigeria, Presented to the Coalition of Civil Society Groups on Access to Essential Medicines*, (COCSAEM) in Nigeria.

years is a very long time to discourage generic competitors in such sensitive and fast evolving field such as the pharmaceuticals industry which deals with medicines where availability determines who lives and who dies, considering that HIV/AIDS kills 8,200 people every day[30]

Nevertheless there are flexibilities within the TRIPS Agreement which reduces the harshness of the 20 year patent rule and this include where a country is experiencing a "national emergency" or other situations of "extreme urgency" (such as public health crises, such the HIV/AIDS, tuberculosis, malaria and crisis facing most parts of the sub-Sahara).[31] The TRIPS Agreement makes provisions for such situations by providing countries with the options of issuing compulsory license under Article 31 of the TRIPS Agreement or parallel importation under Article 6 of the Agreement.

Compulsory licensing allows a party to exploit a patented invention without the permission of the patent holder; however the patent holder of the compulsory license is required to pay the patent holder "adequate remuneration". Another flexibility which is line with the WTO rules on TRIPS is the Bolar exemption. The Bolar exemption is a policy that allows generic manufacturers to prepare production and regulatory procedures before a patent expire. The aim of such preparation is to ensure that products are ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process after the patent period expires which may further delay the availability of urgently needed medicines. In my opinion from the foregoing analysis it is fair to say that the TRIPS Agreement has sought to insert flexibilities within the Agreement which allow member states to circumvent

[30] See Dasgupta S and Srivastava Y, (2003) *Public Health Safeguard in TRIPS: A Domestic Legal Response* 43 India Journal of International Law 661 and See Keith E. Maskus (2002). *Proceedings of The 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance? : Panel #4: Access to Essential Medicines and Affordable Drugs: Ensuring Access to Essential Medicines: Some Economic Considerations,* 20 WIS. INT'L. L.J. 563, 564 and 590 .

[31] World Trade Organisation. Fourth Ministerial Conference. Doha 9- 14 November 2001

the harsh effects that the TRIPS Agreement might otherwise have had on public health in developing countries. For that it must be praised, the problem however goes beyond this. The major issue now is whether the flexibilities inserted into the TRIPS Agreement are in reality alleviating the public health crisis confronting the developing world in terms of gaining access to medicines.

2.4 Intellectual Property Rights Before the WTO

Before the TRIPS Agreement came into force in 1995, intellectual property was chiefly governed internationally by two Conventions namely The Paris Convention of 1883 which protects "industrial property" including patents [32] and the Berne Convention of 1886 which protects "every production in the literary, scientific and artistic domain, [and] mode or form of its expression."[33] The problem however remained that multinational pharmaceutical companies were concerned that the Conventions did not do enough to protect intellectual property rights. [34] Thus it was becoming increasingly urgent that intellectual property rights (IPRs) be protected within the GATT, which is a predecessor of the WTO. Two key issues that pushed the TRIPS agenda forward were firstly,[35] the fundamental principle of "national treatment" was found to be lacking in the both conventions because it only worked well for countries that could provide more or less the same level of protection and worked poorly for

[32] Paris Convention for Protection of Industrial Property, March 20, 1883, last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583 ["Paris Convention"].
[33] Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, last revised at Stockholm, July 14, 1967, 828 U.N.T.S. 221.[Berne Convention]
[34] Amy Au, (2000) *National Treatment" and the International Recognition and Treatment of Trademarks* 20 Wis. Int'l L.J.
[35] These persons are referred to as "nationals," but include persons, natural or legal, who have a close attachment to other members without necessarily being nationals. Art 1(3) Marrakesh Agreement Establishing the World Trade Organization, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 [hereinafter TRIPS], reprinted in The Results of the Uruguay Round of Multilateral Trade Negotiations -- The Legal Texts 6-19, 365-403 (GATT Secretariat ed., 1994) [hereinafter Results of the Uruguay Round]. The texts of each of the agreements reached at the conclusion of the Uruguay Round in December of 1993 and the related decisions taken at the same time and those taken at the Ministerial Meeting in Marrakesh in April of 1994, are contained in Results of the Uruguay Round

countries that could not afford to give equal protection to their own citizens. Secondly there was no effective means of enforcement when a party defaulted in not upholding the National Treatment principle, in Article III (1) of the GATT.[36] Indeed Part III of the TRIPS agreement deals with enforcement in the following ways; firstly it states that governments have to ensure that intellectual property rights are enforced under their laws. Secondly the penalties for infringement should be tough enough to deter further violations. Thirdly the procedures must be fair and equitable. Fourthly the procedures should not be unnecessarily complicated or costly. Fifthly that they are no unreasonable time-limits or unwarranted delays, and lastly that people concerned should be able to request that a court review an administrative decision or appeal a lower court's ruling.

2.4.1 The Negotiation Process (1986-1994) From Punta Del Este to Marrakech

The TRIPS Agreement became the chief WTO instrument dealing with intellectual property. The gestation period of the Agreement was a seven year period that began in Punta del Este (in Uruguay) in September 1986 and was concluded at Marrakech (in Morocco) in April 1994.[37] The TRIPS Agreement was concluded as part of the Uruguay Rounds of the Multilateral Trade Negotiations of the GATT. Under the Uruguay Rounds several groups were set up and the "Group of Negotiating on Goods" had fourteen negotiating groups under it. Out of the fourteen groups, intellectual property was discussed under "The Negotiating Group on Trade-Related Aspects of Intellectual Property, Including Trade in Counterfeit Goods".[38]

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[36] Robert J. Gutowski (1999) *Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven?* 47 Buff. L. Rev. 713, 721-23

[37] See Christopher Arup. (2000) The New World Trade Organization Agreements. Cambridge University Press

[38] Ibid

The stages of the negotiation were nevertheless fraught with difficulty and complexity, and one of the reasons why this was the case was the fact that several proposals where put forward by various blocs. The US, the European Community, Japan and the bloc of developing countries all wanted their different agendas and concerns addressed at Uruguay; however the diversity of the agenda resulted in fractions that slowed the entire process down leading to several deadlines being abandoned.[39] The US bloc was unwavering in their position that inadequate intellectual property protection leads to trade distortions and impairment of concession.[40] The European Union had an extra agenda of trying to get geographic indications and appellations of origin included in the TRIPS Agreement; [41] whilst the Japanese were concerned about protecting their domestic computer chip industry.[42] The keenest bloc however was the US who was prepared to use extreme measures such as Special 301 threats to enter into bilateral agreements with individual countries in its ambition to push for stronger intellectual property rights.

The irony however was whilst the US was pushing for stronger international IP protection, she had in the past ran foul of the GATT principles by offering domestic patent holders stronger enforcement procedures than foreign holders.[43] The Mid-term Review of the Uruguay Round held in Montreal in December 1988 highlighted the tension between the positions of developing countries and developed countries.[44] Developing countries led mostly by Brazil and India continued to question the implication of intellectual property as an

[39] For a detailed history of the TRIPS see Emmert, F (1990) *Intellectual Property in the Uruguay Round – Negotiating strategies of the Western Industrialised countries.* Michigan Journal of International Law 11(4), 1317-99.
[40] Blakeney (1996b) Trade Related Aspects of Intellectual Property: A concise guide to TRIPS. Agreement: Sweet and Maxwell. 3
[41] GATT Doc. No. MTN.GNG/NG11/W/26 (7July 1988)
[42] Doane, M.L. (1994) *TRIPs And International Intellectual Property Protection in an Age of Advancing Technology*, American University Journal of International Law an Policy 9, 2: 475
[43] See section 310 U.S.C with regards to seizure of potentially infringing imports into the US markets.
[44] The Japanese Perspective on the Toronto Economic Summit and the Uruguay Round. http://www.g7.utoronto.ca/scholar/kobayashi1988/kobaurug.htm

item on the GATT, and this reinforced their resistance to the terms of the Agreement. The significance of the foregoing in the access to medicines debate must not be lost on the reader, it shows that from the beginning of the negotiation many countries had their own different agenda that they wanted to protect. For many developing countries, their major concern was to ensure that their vulnerable industries were protected, that they still had access to cheaper medicines, and the protection of their public health systems would not vanish.

2.4.2 Resistance from Developing Countries

Initially developing countries resisted the TRIPS Agreement; they were concerned that increased protection of intellectual property rights would lead to adverse changes in their national patent laws. In the end they backed down after much pressure and the TRIPS Agreement was sealed. India and Brazil were particularly interested in protecting its pharmaceutical industry from the repercussions of a stricter IP regime. They feared the TRIPS Agreement would ultimately deny them access to the much needed modern technology that they needed to promote their pharmaceutical industry.[45] Another cause of concern for developing countries was the fear that the TRIPS Agreement would increase the ever widening gap between developed and developing countries; a gap enhanced by the arrival of the knowledge economy era.[46] For the resistant bloc of developing countries, reductions in the transfer of technology and an increase in the cost of pharmaceutical products were concerns that rose suspicions about the benefits of the TRIPs Agreement.

2.5 The Question

If from the onset, developing countries were concerned and possibly aware of the potential repercussions that a stronger intellectual property regime in the

[45] Ibid

[46] OECD. (2004) Knowledge Management. Innovation in the knowledge Economy. Implications for Education and Learning.. The Wikipedia defines knowledge economy as an an economy of knowledge focused on the production and management of knowledge in the frame of economic constraints, or to a knowledge-based economy.

crystallization of the TRIPS Agreement might have on their economies, many have wondered why they did not stand firm in resisting the idea that intellectual property had a place in the WTO forum. Various explanations have been put forward to account for the ultimate surrender of developing countries. One of them is that in the years leading up to the TRIPS negotiation, most dialogues were initiated in accordance with what some scholars have termed the "Green Room" pattern.[47] The Green Room of the GATT is a building in Geneva where ministers hold meetings. The Green Room pattern required negotiators from all the countries involved in the Uruguay Round to engage in close discussion with one another. Traditionally, draft texts would be exchanged and differences reduced through consecutive versions.[48] Many countries could be involved in the negotiation process, however from February 1991 onwards; the Green Room approach was abandoned in favour of a "ten plus ten group" approach. The "ten plus ten group" approach at the Uruguay involved a situation where ten developed countries along with ten developing countries would sit down together and come up with a decision.[49] The ten plus ten group was headed by the chairman of the TRIPS Working Group where experts and negotiators on intellectual property from ten developing countries which included India and Brazil would bring unto the discussion table their views and vice visa the developed countries. What later became apparent was that members of the ten\ developed countries which comprised of the US, some members of the European Union, Japan and Canada were meeting in private and agreeing on what direction the negotiations would take before they met with the developing countries.[50] This evidently put the developing countries at a disadvantage. Another reason why the group of developing countries were at a disadvantage was because at the time, many of them lacked the technical

[47] Gorlin J (1991) *An Analysis of the Pharmaceuticals-Related Provisions of WTO TRIPS (Intellectual Property) Agreement* (London: Intellectual Property Institute) p4 and Matthew, D (2002) Globalising intellectual Property Rights *The TRIPS Agreement (London* Routledge)
[48] Matthews, D (2002) *Globalising Intellectual Property Rights: The TRIPS Agreement* (London: Routledge) pp38
[49] Ibid
[50] Ibid

capacity to participate actively in the TRIPS negotiation process. The reduction of a huge number of players in the negotiation process allowed the bloc of developed countries spearheaded by the US to gain an upper hand in deciding the direction of the negotiations. However despite the pressure developing countries continued to forge on in their quest to resist stronger protection of intellectual property rights in the TRIPS Agreement.[51]

Another theory for the submission of the developing countries is that when the US responded by sanctioning headstrong developing countries through its Special 301 powers, this further split the alliance of developing countries.[52] The main US target was the Indian pharmaceutical industry whose export into the US was in the region of $60 million per annum.[53]Export into the US from India was very important for the India economy. India fearing reprisals and trade sanctions by the US felt pressurized to succumb and eventually agreed to the terms of the TRIPs Agreement in 1994.[54] Without India there was no other country strong enough to resist pressure from the bloc of powerful industrialised countries

Braithwaite has suggested that "negotiation fatigue" was the principle factor in the inability of developing countries to withstand the United States pressure until the end. Other factors such as a lack of information and technical experts on intellectual property issues on the part of developing countries also played a role in defeating the developing countries resistance.[55]

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[51] Ibid
[52] See Michael Bailey, Ruth Mayne & Dr. Mohga Smith (2001) *Fatal Side Effects: Medicine Patents under the Microscope*, available at http://www.oxfam.org.uk/what_we_do/issues/health/fatal_side_effects.htm (Accessed 5 April 2006) and Sell, K Susan. *Private Power, Public Law. The Globalization of Intellectual Property Rights.* The George Washington University. Cambridge University Press. 2003. http://assets.cambridge.org/97805218/19145/sample/9780521819145ws.pdf
[53] Sudip Chaudhuri. (2006) *The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries.* Oxford University Press.
[54] Ibid
[55] See Braithwaite J and Drahos P (2000) *Global Business Regulation* (Cambridge: Cambridge University Press); Drahos, P (1995) *Global Property Rights in Information: The Story of*

2.5.1 World Intellectual Property Organisation

One of the arguments that developing countries put forward in their opposition against the TRIPS Agreement was that World Intellectual Property Organization (WIPO) was the appropriate forum to discuss any issues or amendments related to intellectual property rights matters and not the GATT.[56]

A background of WIPO is therefore required here. WIPO was established in 1967, and in 1974 it was converted into a specialized agency of the United Nations to deal with intellectual property rights matters.[57] WIPO has 184 members and one of its primary roles include the promotion of creativity; this it does through the protection and promotion of what academics term "works of the mind". WIPO also has the chief role of facilitating the transfer of technology to developing countries with a view to speeding up economic, social and cultural development.[58] Note that some critics have argued that WIPO has not been very successful in achieving the latter.

The need to have a body which protects intellectual property rights throughout the world was highlighted in 1873 when foreign exhibitors refused to attend the International Exhibition of Inventions in Vienna because they feared that their ideas would be stolen and exploited commercially in other countries.[59] Subsequently in 1883 the Paris Convention for the Industrial Protection was established to provide patent protection for new inventions. One of the key element in relation to patents in the Convention was a term called the "Paris Convention priority right". The Paris Convention priority right clause stipulates that an applicant from one contracting State shall be able to use its

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TRIPS at the GATT', Prometheus, 13, 1: 6.; Drahos, P (2001) *Bilateralism in Intellectual Property'*, Oxford: Oxfam Policy Paper.

[56] Blakeney, M. (1995) *Intellectual Property in World Trade*, International Trade Law and Regulation and Evans, G. E (1994) Intellectual Property as a Trade Issue, The Making of the Agreement of Trade Related Aspects of Intellectual Property Rights' World Competition:139

[57] Ibid

[58] Ibid

[59] http://www.wipo.int/treaties/en/general

first filing date (in one of the contracting State) as the effective filing date in another contracting State, provided that the applicant files another application within 12 months (in the case of patents).[60] The implication of this was that for the first time a treaty for the international harmonization of industrial property was established setting the stage for the stronger enforcement of intellectual property in the structure of the TRIPs Agreement.

In 1886, following in the footsteps of the Paris Convention, the Berne Convention was further developed and strongly influenced by the French 'right of the author", which means the copyrights of an author is immediately protected once they are created. Once the author registers his copyrights in any country that is a party to the convention, he automatically receives protection in other countries that are party to the convention. In other words foreign and domestic authors get the same rights to copyrighted materials in all countries that are party to the Convention.

In 1893 both the Paris Convention and the Berne Convention were amalgamated to form the International Bureaux for the Protection of Intellectual Property (BIRPI). As the significance of intellectual property began to grow and many developed countries began to rely heavily on intellectual property for the growth of their economies, the structure and form of the BIRPI further evolved into WIPO in 1967.

2.4.3 Problems with WIPO

Despite the high hopes that the international committee had for WIPO, by the early 1970s it was becoming increasingly clear to many developed countries that WIPO did not have the power to put in place a strong global enforceable system for intellectual property rights protection.[61] A strong enforcement

[60] http://en.wikipedia.org/wiki/Paris_Convention_for_the_Protection_of_Industrial_Property
[61] Matthews, D (2002) *Globalizing Intellectual Property Rights. The TRIPS Agreement*. Routledge.

procedure for the protection of intellectual property was considered essential by many developed countries because without it, it would be impossible to combat the problems of international piracy and counterfeit. Particularly, corporate America was worried that piracy and counterfeits was costing the US industries billions of dollars.[62] For example in 1984, the Automotive Parts and Accessories Association told the US House Sub-committee on Oversight and Investigation that the US industry had lost $12 billion from counterfeiting of spare parts.[63] A year later, in 1985 the International Intellectual Property Alliance (IIPA) representing seven trade associations of copyright-related industries conducted a study of the copyright laws of Brazil, Egypt, Indonesia, Malaysia, Nigeria, Philippines, Republic of Korea, Singapore, Taiwan and Thailand revealing that lax copyright laws in the above mentioned countries were costing the American copyright industries $1.3 billion.[64]

Subsequently in 1984 an attempt was made to amend both the Paris and Berne Convention in Geneva to improve the effectiveness of WIPO by giving it more enforcement powers. Developed countries had two major issues that they wanted resolved. Firstly, they wanted WIPO to set out clear rules on enforcement rights before national judicial organization on intellectual property matters; secondly they wanted the absence of an obligatory and effective mechanism to settle disputes between states on intellectual property matters resolved.

Unfortunately, the two parties of developing countries and developed countries could not come to a common resolution. A premonition of what was to take place in the Uruguay rounds. Whilst developed countries were concerned about competing with mass-produced unauthorised copies of their patented,

[62] Stewart, T.P. (ed) (1993) *The GATT Uruguay Round: A negotiating history (*1986-1992), Deventer, Netherlands: Kluwer Law International : 2254
[63] Unfair Foreign Trade Practices, Stealing American Intellectual Property: Imitation in Not Flattery, 98th Cong. 2nd Sess. 1-3 (1984)
[64] *I*IPA, *Piracy of US Counterfeited Works in Ten Selected Countries* (1985), 7.

trademarked and copyrighted goods in domestic and foreign markets;[65] developing countries on the other hand wanted a relaxed system of intellectual property so as to accomplish technological progression and economic growth. Both blocs were unyielding in their position and could not come to a common consensus thereby blocking any resolution that might have been.[66] Pressure from US industries was steadily increasing and by 1986 the Intellectual Property Committee (IPC) dominated by the US research-based industry was founded. One of the major accomplishments of the IPC was that whilst it was one of the driving forces in the Uruguay round, it had successfully harmonized US industry position with the US government, and by so doing became extremely influential in pushing through its agenda in the GATT.[67] Another major body that the US industries used to push some of its agenda of a stronger intellectual property regime in international circles was the Office of the United States Trade Representatives (USTR), who became the biggest driver of overcoming developing countries opposition during the Uruguay rounds.[68] As a matter of fact during the Uruguay negotiation the USTR was strongly influenced by the IPC who had a confidant in Edmund Pratt of Pfizer, who was at the time the chairman of the Advisory Committee for Trade Negotiations and an adviser to the US official Delegation.[69] Note that the influence of US industries on the USTR has sustained itself even until today. For example the Program on information Justice and Intellectual property (PIJIP) 2008 Special Report showed that US Industry still has a strong influence on government policy. Majority of the countries placed on the Special 301 list[70] were

[65] Sell. K. Susan (1998) *Power and Ideas: The North and South Politics of intellectual property and antitrust*, New York: State University of New York:132
[66] Matthews, D. *Globalizing Intellectual Property Rights. The TRIPS Agreement*. 2002 Routledge.
[67] The influential members at the time were Pfizer and IBM.
[68] Ryan M. P. (1998) *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property, Washington, DC*: The Brookings Insitution:105
[69] Sell, K. Susan. (1998) *Private Power, Public Law, the Globalization of Intellectual Property Rights*. Cambridge Studies in International Relations.
[70] The Special 301 is a mechanism that the USTR use to force countries to provide better protection for intellectual property rights by putting countries on either a Priority Watch List, Watch List or Section 306 Monitoring Status.

recommended by Pharmaceutical Research and manufacturers of America (PhRMA) or the IIPA, 86% of them were chosen by IIPA and 75% were chosen by PhRMA.[71]

The key thing to note however is that, the adoption of the TRIPs Agreement in 1995 signalled a turning point for intellectual property rights, because it established a higher level of intellectual property protection standard that was previously lacking in the Paris and Berne Convention. Although some have argued that the WTO replaced WIPO as the chief intergovernmental organization for intellectual property rights matters, this is not entirely true. Indeed, the TRIPs Agreement requires compliance with the Paris and Berne convention. [72] It still recognizes the importance of WIPO as a medium for negotiating treaties, especially those representing a "higher levels of protection of intellectual property rights."[73]

Another important role WIPO took up after the WTO was established is evident in the WIPO-WTO Cooperation Agreement where the International Bureau of WIPO took on the role of providing legal technical to developing countries.[74] Indeed the cooperation between WIPO and the WTO in sharing expertise created a doppelganger intellectual property position.[75] Helfer's quote typifies WIPO and the WTO's bond sufficiently when he states that 'Whereas the WTO emphasized implementation, enforcement, and dispute settlement, WIPO focused on generating new forms of intellectual property

[71] PIJIP Snapshot of Industry Influence on the 2008 Special Report. http://216.239.59.132/search?q=cache:OOxozIHF46UJ:www.wcl.american.edu/pijip/download.cfm%3Fdownloadfile%3D9BA6937C-0260-01BA-625C00EDD0AC29C6%26typename%3DdmFile%26fieldname%3Dfilename+influence+of+industry+on+USTR&hl=en&ct=clnk&cd=2&gl=uk

[72] With the exception of Article 6bis of the Berne Convention relating to moral rights.

[73] See TRIPs, supra note 4

[74] http://www.wipo.int/treaties/en/agreement/trtdocs_wo030.html

[75] See Abbott .M. Frederick (2000) *Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governance*, 3 J. Int'l Econ. L. 63, 70 (asserting that WIPO and WTO have "entered into a symbiotic relationship that takes advantage of the strengths of each of them").

protection, administering existing intellectual property agreements, and providing technical assistance to developing countries'.[76] The question however remains, has the prominence of WIPO in dealing with intellectual property rights issues been usurped by the WTO to the disadvantage of the developing countries. Under Article 67 of the TRIPS Agreement, developed countries were promised additional measures would be put in place to assist them in their efforts to reform their domestic IPRs regimes. Some of which included "assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse".[77]

2.6 Summary

The TRIPS Agreement changed the landscape for intellectual property by giving the WTO enforcement powers which had previously been lacking in WIPO. It also gave the patent holder powers to charge whatever price he wished, and this in turn increased the prices of medicines and affected which developing countries gained access to medicines. Whilst many countries have kicked intensely against the TRIPS Agreement, some have welcomed it. It is with this background in mind that the next chapter will conduct a historical analysis of the patent system with a view of providing background information about the usefulness of it to the access to medicine debate.

[76] Ibid
[77] Art 67 of TRIPS

3 THE JURISPRUDENCE OF INTELLECTUAL PROPERTY RIGHTS – A VALUABLE BACKDROP TO PATENTS

3.1 Introduction

A look at the past reminds us of how great is the distance, and how short, over which we have come. The past makes us ask what we have done with us. It makes us ask whether our achievements are not ironical counterpoint and contrast to our fundamental failures.
Robert Penn Warren

History ... is, indeed, little more than the trigger of the crimes, follies, and misfortunes' of mankind. But what experience and history teach is – that peoples and government have never learned anything from history, or acted on principles deduced from it.
Georg Wilhelm Fredrich Hegel, The Philosophy of History, "Introduction," 1807

History knows that it can wait for more evidence and review its older verdicts; it offers an endless series of courts of appeal, and is ever ready to reopen closed cases.
William Stubbs

This chapter inter alia explores the history of patents from the influence of royal prerogative, the Statute of Monopolies, Elizabethan grants to common law property rights. It evaluates the birth of the concept of patents in Venice and captures the acceptance of the concept in Europe in order to show why the transition to a knowledge based economy has been easier for many developed countries. The chapter also evaluates the legal history of "owing knowledge" and the foundation of why knowledge became property. The tenets of natural

law as a foundation for the modern day intellectual property rights are also considered with the aim of understanding why patents are important in our modern day society. This chapter is important to the overall structure of this thesis for several reasons: by providing a historical analysis of intellectual property, it is possible to see why intellectual property laws fit into the legal systems of many countries in the developed world. It is easy to see how patents have developed in Europe and spread to other developed countries like the US and this has made it suitable for their economies. It is also easy to see that intellectual property right laws fit into the economies of poorer developing countries; thus putting the developing countries opposition to stricter IPRs at the Uruguay rounds into perspective. .The chapter is also relevant in revealing the importance of monopoly and the role it plays in today's modern patent system. This will help to facilitate a better understanding of the jurisprudence of patent and its eventual codification into the TRIPS Agreement. Indeed this chapter is important to the overall structure of this thesis is showing that whilst the journey for patents began in Europe, it successfully spread throughout the world and even states who did not previously have a background of granting patents found themselves struggling to ensure that they adhere to minimum standards of intellectual property as set out in the TRIPS Agreement (for patents see article 27-34 of the Agreement). Of course the argument continues that historically patents have had negative effects, for example in the case of access to medicines where the increased prices of medicines (a result of patent grants) have put medicines out of the reach of people; yet it has also brought with it certain benefits in the shape of FDI and technology transfer. The abuse of patent privileges in 16th century England nevertheless highlights the fear that there is a propensity to sometimes erroneously grant such privileges/rights, and that is what the international community must guard against.

Many developing countries have a common history of owing knowledge collectively, the idea of profiting from an idea or invention to the exclusion of

others for a specified period of time may therefore have been harder for them to contend with in the multilateral trading system. The usefulness of this chapter to the overall structure of this thesis also lies in that it reveals the tension between the public's claim that they should be able to benefit from the scientific and cultural rewards of innovation and the inventor's claim of being rewarded for his efforts and intellect. In some parts of this chapter the analysis will be centred on the Lockean theory and will examine whether the theory is consistent with the general pattern of positive law and modern intellectual property rights. This will facilitate an easier understanding of the overall discussion of the TRIPS Agreement and the access to medicines debate as discussed in other chapters with a view of appreciating how history has evolved to bind countries together in agreements that determine whether people live or die.

3.2 History of the Emergence of International Industrial Property

At the advent of the twenty first century there has been immense pressure to conform to international standards of harmonization around the globe. This pressure stems from the fact that the world has increasingly become a knowledge based society where information and knowledge are replacing capital and energy as the primary wealth-generating assets. Before capital and energy were replaced, land and labour were the primary source of wealth, [78]with that one can deduce that society is constantly evolving and bringing with it new challenges. Bearing that in mind, Thomas Riley stated that the "knowledge economy is about how new technologies have transformed the way we think and act".[79] The free flow of ideas and information has therefore become one of the key factors in producing the "wealth of nations",[80] and this

[78] Riley T. B (2003) *An Overview of the Knowledge Economy. By Executive Director and Chair, Commonwealth Centre for Electronic Governance'*. http://www.egovmonitor.com/features/riley07.html. Viewed 23 April 2008
[79] Ibid
[80] Adam Smith (1904) *An Inquiry into the Nature and Causes of the Wealth of Nations* 5th edition. London: Methuen and Co., Ltd., ed. Edwin Cannan

has changed our understanding of the world as it is today.[81] It follows that most developed countries generate their wealth by pursing high R&D investments into innovation and converting it into marketable products. Wakelin and Rodrigo have pointed out that one of the pre-requisites for the technology based economic growth of any country is the movement from low or no technology export to medium or high technology export.[82] A theory which clearly applies to countries like China that have been identified as one of the fastest growing economies in the world, thus in 2001 China's high technology export grew 25.4 % to 46.46% billion US dollars.[83]

Economic research also showed that innovation plays a central role in the productive growth of any new knowledge economy.[84] Indeed Robert Solow's seminal paper 1957 demonstrates that approximately 80 percent of economic growth occurred in the United States between 1909 and 1949.[85] In his work, he suggests that the driving force behind the growth was technology and innovation.[86] Many commentators therefore agree that innovation is the key justification for maintaining and guarding the new patent system. Fisher also states that "History plays an important part as it tells us that patents should not be taken for granted. They have a hard-won place in the modern economy".[87] In order to understand the origins of why a patent holder has ownership in his

[81] Ibid'
[82] Wakelin, E (1996) *Trade and Innovation: Theory and Evidence*, Edward Elger, Massachusetts, and Rodrigo, G. C. (1996), in *National Economies for Countries in Transition: Evidence from Eastern Europe and Asia Pacific* (ed. Scholtes, P. R.), University Press, Cambridge, pp. 3–33.
[83] Rapid Growth of China's high-Tech Exports. (Beijing Times), January 12, 2002. http://english.peopledaily.com.cn/200201/12/eng20020112_88493.shtml. Last viewed 01-01-2009
[84] The New Economy Task Force. Rules of the Road: Governing Principles of the New Economy. New economy Task force Report. September 13, 1999 http://www.ppionline.org/ppi_ci.cfm?contentid=1268&knlgAreaID=128&subsecid=174
[85] Solow M Robert (1957)*Technical change and the aggregate production function"* Review of Economics and Statistics No)
[86] Ibid
[87] Fisher . M (2005) C*lassical Economics and Philosophy of the Patent System*" I.P.Q: No1

invention, it is essential to examine the historical background of the evolution of intellectual rights and the role that it plays in our modern day society.[88]

3.3 What does the Phrase Intellectual Property Rights Means?

Intellectual property rights are a twentieth century generic term which refers to a group of legal regimes[89] that regulate the usage, exploitation and utilization of creation of the mind. [90] Although the term is relatively new (the term was not in widespread use until the 1960s, when it was adopted by the WIPO) the concept is a development of the last middle ages. There are various kinds of intellectual property rights and they include patents, copyrights, design, trade and service marks, rights in performance, designs, plant breeders' rights, utility models, appellation of origins, layout designs and topography; [91] however one of the major characteristics of intellectual property is that it has the ability to establish possession over intangible things that are in the form of ideas, inventions and information.[92] Thus they are sometimes referred to as knowledge reduced to practice.[93]

Knowledge is an elusive commodity[94] and the ability to use it proficiently in a production capacity is an essential necessity for economic development which

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[88] Dreyfuss Rochelle, Zimmerman, L.D Harry First, H. (2001) *Expanding the Boundaries of Intellectual Property Innovation Policy for the Knowledge Society*. Publication date.
[89] The term "Intellectual Property" refers to both industrial property and copyrights. See A. Bogsch,. (1992) Brief History o the First 25 Years of the World Intellectual Property Organization" Geneva. 8
[90] Art 2, para. Viii, WIPO Convention (1967) 'Intellectual Property' includes the rights relating to literally, artistic and scientific works –performances and performing artists, photographs and broadcasts – inventions in all fields of human endeavour – scientific discoveries –Industrial designs, - trade marks, services marks, and commercial names and designations- protection against unfair competition and all other rights resulting from intellectual activity in the industrial, scientific literary or artistic field.
[91] See Bently, L. and Sherman, B. (2004) *Intellectual Property Law.* 2nd ed. Oxford: Oxford University Press (95 -100
[92] Ibid pg 1
[93] Fisher. M (2005) Classical Economics and Philosophy of the Patent System. I.P.Q: No1
[94] See ECONOMIC COUNCIL OF CANADA, REPORT ON INTELLECTUAL AND INDUSTRIAL PROPERTY, 1-30 (1971); P. DASGUPTA& P. STONEMAN, ECONOMIC POLICY AND TECHNOLOGICAL PERFORMANCE (1987); G. YANKEY,

is imperative for the growth of any nation.[95] Braga describes knowledge as a public good,[96] and public goods have the characteristics of being non-rivalrous and non-excludable. In other words the usage of knowledge by one person does not diminish the amount of knowledge available for usage by another person.[97] A very useful illustration of this point is, if I have only one piece of chocolate and I eat it, there would be none left for anyone else to eat. This would make it a rival, excludable private good.[98] On the other hand, the amount of air I breathe will not diminish the amount of air left for other people to breath; neither will other people be excluded from using air. So when intellectual property rights are described as public goods, this is what it means, although some commentators have argued that in the real sense, there is no such thing as an absolutely non-rival or non-excludable good.[99]

Intellectual property rights create property in inventions by facilitating and imposing control of the knowledge that defines the invention, therefore enabling limitations to be placed on its supply and use.[100] They have therefore been described in economic circles as free goods, this means the goods are not scarce and are reproducible at zero cost. Free goods can also be described as non-wasting assets as they involve no "additional economic cost, beyond the

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INTERNATIONAL PATENT AND TECHNOLOGY TRANFERS TO LESS DEVELOPED COUNTRIES (1987).

[95] See Mansfield (1988) *Intellectual Property Rights, Technological Change, and Economic Growth, in INTELLECTUAL PROPERTY RIGHTS AND CAPITAL FORMATION IN THE NEXT DECADE*
C. Walker & M Bloomfield eds.

[96] Carlos Alberto Primo Braga. (1998)The *Economics of Intellectual Property Rights and the GATT: A View from the South*. 22 Vand. J. Transnat'l L. 243

[97] For the definition of public goods see Hal R. Varian, *Microeconomic Analysis (1992)* W. W. Norton; 3rd edition *and* ; Mas-Colell, Whinston & Green (1995) *Microeconomic Theory* . Oxford University Press, USA

[98] Ibid

[99] Meir Perez Pugatch. (2006*) The intellectual property debate : perspectives from law, economics and political economy.* Cheltenham, UK; Northampton, MA : Edward Elgar

[100] Matthew Fisher.(2005) *Classical economies and philosophy of the patent system*. IPQ

costs of communication and learning".[101] What makes intellectual property rights fascinating however is that it imposes a structure of artificial scarcity; some commentators have therefore argued that the benefits of free goods increase with its usage[102]- a good example of this is recycled paper. Recycling involves making something new out of something old, in this way making sure nothing is wasted. Other commentators have however argued that the very nature of intellectual property rights is to prevent the limitless usage of an inventor's idea so that he does not lose absolute rights to the information by disclosing it.[103] The rationale behind this is that many inventions are usually capital intensive and expensive to produce, therefore the creator expects to be rewarded for the disclosure of information to society. Today, inventions will rarely be brought to the public domain free of charge. Any diversion from this norm, some have argued would discourage the information holder from sharing information to avoid it being used without recourse to the inventor of the idea.[104]

Traditionally, the concept of property as an exclusive private assert has been interpreted as being dependent on government policies. Jeremy Bentham wrote that "property and law are born together and die together. Before laws were made there was no property; take away laws and property ceases".[105] However others have argued that the consensus about the perception of property was not the product of any one particular legislator or of an organized social group.[106] The concept arose as a result of an evolution of dialogues and ideas from

[101] See Taylor and Silberston, (1973) *The Economic Impact of the Patent System* . Cambridge University Press, P. 24; quoting from Arrow, "*Welfare Economics and Inventive Activity'*, in The Rate and Direction of Inventive Activity (NBER, Princeton, 1962).
[102] M. Fisher, (2004) *Classical Economics and Philosophy of the Patent System* IPQ
[103] Dr Patricia Kameri-Mbote. (2005) An Assessment of the Status of Laws, Research and Policy Analysis on Intellectual Property Rights in South Africa. IELRC Working Paper. and Karen W. Baer, (1995) *A Theory of intellectual Property and the Biodiversity Treaty*, 21 Syracuse J. Int'L L. & Com 259
[104] Ibid
[105] J. Bentham (1864) Theory and Legislation, Principles of the Civil Code. Pt 1, at 111-13 (R.Hildreth trans., E. Dumont ed.
[106] Dr. Boudewijn Bouckarest. (1990) *What is Property*? 13 Harv. J. L. &Pub. Pol' Y 777

learned jurist in different parts of Europe.[107] Interestingly, the economic value of property is shifting from tangible property such as real estate to intellectual and intangible property.[108] The difficulty however lies in that people cannot physically hold intangible property, the boundaries of where intellectual property rights should end has been hard for many to agree on. Thomas Jefferson challenges the idea of intangible goods as a form of property when he states that "If nature has made any one thing less susceptible than all other of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of everyone, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That idea should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density at any point, and like the air in which we breath, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions cannot, in nature, be a subject of property".[109]

Before Jefferson's theory of intellectual property rights as an essential tool for encouraging invention, Long argued that prehistoric laws were suspicious of intellectual property rights and did not recognize the concept of intellectual

[107] See H. Maine (1901) Ancient Law 1-20. London
[108] See BRUCE A. ACKERMAN (1977) *PRIVATE PROPERTY AND THE CONSTITUTION 98-100 and Grey, C.T. (1980) The Disintegration of Property, in NOMOS XXII: PROPERTY* 69, 69 distinguishing thing- ownership and bundle-of-rights metaphors). Even after Ackerman's book, the "thingness" of property plays an underappreciated role in property theory.
[109] Barlow, J. B (1997) *The Economy of Ideas: Everything You Know about Intellectual Property is Wrong, in Intellectual Property: Moral, Legal, and International Property: Moral, Legal, and International Dillemas* 349 (Adam d. Moore ed)

property rights. Genius, it was believed is a gift from God, and therefore could not have commercial value because it was granted by grace from God.[110] Long argues that the concept of the intellect as property only began to be recognized after two criteria were established; the first was the establishment of the understanding that inventions or ideas could and were the end product of human intellect rather than a gift from the gods or the gift of God: and secondly the product of the intellect in its intangible from could also have commercial value.[111] Some commentators argue that the concept of intellectual property rights has existed for over 6,000 years.[112] Initially it existed in the form of a marking to establish ownership of animals. Other markings included markings to identify the property of a certain clan or group of people and markings to identify specific wares and ownership of household goods.[113] Evidence further suggests that the Greeks were the first civilized society to have rewarded genius which in the end became the accolade of intellectual property rights. During the 4th and 5th century BC, the Greek culture of Simonides and other poets were recognized as intellectual entrepreneurs and as such were expected to perform on demand for a fee.[114] Around the same time, the Sophists who were Greek lecturers, writers, and teachers travelled around the Greek speaking nations giving lessons on many subjects from household management to wrestling in exchange for a fee.[115] These Sophist philosophers were all said to possess encyclopaedic knowledge which they offered for a price,[116] thus began the rudimentary idea that the content of the mind could be sold as property. The Sophists had manuals which they carried around and

[110] P. O Long, (1991) .*Inventions, Authorship, "intellectual Property,' and the Origins of Patents: Notes towards a Conceptual History*. 32 Technology and Cultural at 858
[111] Ibid
[112] May. C and Sell. K. Susan (2006) *INTELLECTUAL PROPERTY RIGHTS:* A Critical History. Lynne Rienner Publishers, Inc
[113] Gerald Ruston. *On the Origin of Trademarks*. The Trade-Mark Reporter 45:127-144
[114] May. C and Sell. K. Susan (2006) *INTELLECTUAL PROPERTY RIGHTS: A Critical History*. Lynne Rienner Publishers, Inc
[115] Ibid pg 45
[116] Ibid

taught men how to speak and debate in public places.[117] Although some have argued that the work the Sophist carried out was in some way analogous to payment for intellectual knowledge, evidence points to the fact that the Sophists did not seem to regard the content of their teaching as a form of ownership.[118]

Simonides lifetime (556BC to 468 BC) has also been identified as a landmark period when art began to become commercialized. This is the period in which money first began to be circulated. Coincidently that was the same period in which poetry first became commercialized. As a result some have claimed that these are the events which led to the development of a rudimentary form of intellectual property. From that time onwards poets and artist alike signed their paintings and work as a "recognition of personal achievement, and a warning of ownership" thus began the recognition of individual talent and innovative capability as a proponent of intellectual property rights, although as stated above, the term intellectual property rights was never employed at the time.[119]

The recognition of the need to codify intellectual property into a law however has its origins in the guilds of the Roman era. Under the Lex Cornelia de ininriis c.81 B.C., a person was prohibited from using another person's name for profit.[120] Whilst the law recognized that there is commercial value in craft knowledge and it ought to be protected. It also recognised a purchaser right to bring an action against the vendor of goods with a fraudulent mark who had the intent to deceive and defraud. The Roman publishing industry also emerged and flourished in the first century B.C because the environment

[117] Jacqueline de Romily (Author), Janet Lloyd (Translator) (1998) THE GREAT SOPHISTS IN PERICLEAN ATHENS. OXFORD UNIVERSITY PRESS.
[118] Masterson, Salathiel C. (1940) *Copyright: History and Development.* California Law Review 28, no 5 (July): 620-632 (pg. 621)
[119] Vukmir, Mladen. 1992, "The Roots of Anglo-American Intellectual Property Law in Roman Law." IDEA- The Journal of Law and Technology 32, no. 2:123-154 (pg192)
[120] Ibid

encouraged authorship through the use of patronage and rewards.[121] It is acknowledged that Marcus Tullius Cicero (January 3, 106BC- December 7, 43 BC), the prominent Roman statesman, lawyer and philosopher who was one of the supreme writers and orators of prose had commercial interest in the sale of his books including those on humanism, philosophy and politics. The assertion therefore implies that even though they were no codified intellectual property laws then, they appeared to be the recognition that artists have justified rights over their works.[122]

The transition from a rudimentary form of intellectual property into modern day intellectual property rights as we know it today took place during the Early Middle Ages. [123] As a result of which several statutes were passed across Europe covering different guilds from woollen textiles industry to weavers and goldsmiths.[124] Guilds functioned by establishing ownership of marks so that nobody outside the guild could legitimately use them; as such guilds prevented non-guild members from selling products within the area of guild monopoly. [125] The guild system established who had the right to produce certain goods; this had the effect of producing scarcity in the use of certain knowledge or ideas. [126] Although guilds were to protect and further the guild members; professional interests, it became a very important part of the economic and social fabric of that society.[127] In the same way modern day guilds can be compared to early guilds which have rejuvenated itself as local organization for craftsmen in traditional skills. These guilds operate like small business

[121] May. C and Sell. K. Susan (2006) *INTELLECTUAL PROPERTY RIGHTS: A Critical History*. Lynne Rienner Publishers, Inc
[122] Ibid
[123] In European historiography, the term Dark Age(s) refers to the Early Middle Ages, the period encompassing (roughly) 476 to 1000 AD.
[124] Epstein. S, (1991) *Wage Labor & Guilds In Medieval Europe.* University of North Carolina Press.
[125] McClure, D. M. (1979) *Trademarks and Unfair Competition : A Critical History of Legal Though* ." 310-311
[126] Williston, S (1909). *The History of the Law of Business Corporations Before 1880.* In Select Essays in Anglo-American Legal History, vol. 3. Cambridge: Cambridge University Press.
[127] Ibid

associations and are renowned for exercising very strong influence in their field. For example the Screen Actors Guild and Writers Guild of America are prominent for exercising very strong control in Hollywood because of the very robust and rigid structure of intellectual property rights there. Other examples of guilds such as the American Bar Association and the Air Pilots and Air Navigators suggest that such associations have an extremely strong political influence on the fabric of any nation.

3.4 Patents

A patent is a form of property right in inventions which is granted for a limited time in exchange for the disclosure of technological or scientific information.[128] Patents (previously referred to as patent customs) can also be described as a form of limited monopoly which in the past involved privileges rather than property rights[129]. Although patents have existed for centuries and are perhaps the most essential legal mechanism for protecting intellectual property rights, the reality is that some commentators see it as a process in which government policy goals are implemented and enforced.[130] The monopoly concept of a patent confers on the inventor the sole right to exclude others from economically exploiting the innovation for a limited time. The most important international agreement on patents in the 20th century has been established in the form of the TRIPS Agreement which limits the patent period to a twenty year time frame. Article 33 states that "the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date"[131]

[128] E. Walterscheid (1994) *The Early Evolution of the United States Patent Law (Part 1))* 76 J. Pat & Trademark Off. Society at 697.
[129] Patents as a form of privileges will be discussed below
[130] Bently L and Sherman. B. *INTELLECTUAL PROPERTY LAW.* 2nd Edition Oxford University Press. 2004
[131] Ibid

For an invention, whether it is a product or process to pass the patent test, it must meet the three-tier test in Article 27, it must be new, involve an inventive step and be capable of industrial application. (Note that Article 27.1 of TRIPS could be considered a flexibility, e.g. section 3(d) of the India Patents Act which interprets narrowly the novelty of pharmaceutical products.) It must be new or novel in the sense that the idea or information should not be in the public domain before the date of filing and should not have been patented before that date. The inventive step also implies that the invention must not be an obvious one; in other words the idea should not be common sense to any "person skilled in the art". It must constitute nonobvious improvements over past inventions. Section 3 of the 1977 Patent Act and Article 56 of the EPC state that inventive step/obvious step is determined from the view of the average person who is skilled in the art.[132] For a patent to be useful and applicable in the industry, the device must have a stated function and be capable of being used for the proposed function. A patent holder cannot patent the theory that light travels through transparent bodies in straight lines; however he can patent a machine which measures the distance that the light travels into space.[133] Although note that in the United States, utility is a requirement that must be fulfilled before the patent test is fulfilled, however with the European patent law, utility is not a pre-requisite for an invention to pass the patent test.

3.4.1 The Venetian influence on Patents

Mandich's research points out that the earliest record of law in Venice which looks like a rudimentary form of patent was the decree adopted by the Major Council of Venice on 21, May 1297.[134] The law regulated the making and

[132] Brugger v. Medic Aid [1996] RPC 635, 653. See J. Bochnovic, (1982) *The Inventive Step*, 59; J. Pagenberg (1978) *The Evaluation of the "Inventive Step" in the European Patent System: More Objectives Standards Needed*" 9 IIC 1, 16-17; J. Tresansky, (1991) *PHOSITA: The Ubiquitous and Enigmatic Person in Patent Law* 73 JPTOS 37.

[133] What can be patented is highly controversial. Consider the recent furor over patenting genetically manipulated animals or patenting computer programs.

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selling of medicines, syrups, and confections which it confined to state run shops. The law stated that "all medicines, syrups and confections are to be made from the best materials available and to be sold only by those licensed".[135] Other commentators have singled out the Venetian movement in the fourteenth and fifteenth century as the first to repetitively and consecutively apply specific rules of patents to invention.[136] At that time glassmaking in Venice was restricted to only members of the Glassmakers Guild which was closely controlled by the Venetian commune. [137] However when the sale of its glass products spread throughout Europe, it convinced the Venetians about the great commercial importance of its glassworks. With this knowledge came the realization that the craft know-how of the state and guild must be watched closely and protected as a whole.[138] Although it must be noted that some have suggested that intellectual property rules did not emerge entirely from Venice, one thing is certain it began its systematic evolution from there. In fact, some have insisted that this formed the foundation of the ensuing development that would eventually culminate in a codified TRIPS Agreement which sets out the rules and procedures for patent application.

The rules and procedures for granting patents in Venice in the fourteenth and fifteen century were extremely exhaustive and similar to the criteria that a patentee has to establish today before he is granted a patent. For a patent to be granted the invention had to be new, i.e. the invention has to be different from any existing prior art and should not have been described in any prior public disclosures. As stated above it has to be useful, i.e. the invention must be useful in ways that represent improvements over existing products and techniques. In addition the patent also has to have a time limit in which the

[135] R. Cessi on the decrees of the Major Council of Venice 3:423 (1934)
[136] Mandich, Giulio. (1984)*Venetian Patents (1450-1550).* Journal of the Patent Office Society 30, no 3: 166- 224. 206
[137] P. O Long,(1991*) Inventions, Authorship, "intellectual Property,' and the Origins of Patents: Notes towards a Conceptual History.* 32 Technology and Cultural at 858
[138] Ibid

patent would be protected. The state also had a right to grant compulsory licensing in exceptional circumstance,[139] an exception which is also recognized in the TRIPS Agreement. These similarities are evident of the fact that the TRIPS Agreement is historically linked to this period.

One of the most striking factors that the Venetian authorities took into consideration when granting patents is that private and public interest must be balanced, and complement each other.[140] An argument that is commonly used nowadays to challenge intellectual property laws and agreements that some believe go too far in protecting multinational corporations without taking into consideration the plight of peoples public health needs. A good example of this is when the Venetian legislators prohibited the glassmakers' guild from taking a monopoly on eye glasses for reading. The rationale behind the move was the fact that the public benefit of people in society having wide and easy access to eye glasses at a time when the dissemination of knowledge through reading books was considered a key element of societal and cultural life far outweighed the absolute ownership of knowledge as a stimulus to encourage innovative activities.[141] These are some of the key factors that many commentators have argued should be taken into consideration when considering whether patents should be granted for life saving pharmaceutical products in the face of the HIV/AIDS epidemic, malaria and tuberculosis which has ravaged families, communities and nations in the developing world. In this regard, the Venetian movement has many things in common with the modern day intellectual property rights.

[139] May. C and Sell. K. Susan (2006) *INTELLECTUAL PROPERTY RIGHTS:* A Critical History. Lynne Rienner Publishers, Inc pg 58
[140] Mackenney, R (1987) *Tradesmen and Traders. The World of the Guilds in Venice and Europe* ,. C1250 –c. 1650. London: Croom Helm.
[141] May. C and Sell. K. Susan (2006) *INTELLECTUAL PROPERTY RIGHTS:* A Critical History. Lynne Rienner Publishers, Inc Pg 60

The first patent that historians found in the archives of Venice dates back to 20 February 1416. It was given to someone from the Greek island of Rhodes who introduced a new device into Venice whilst requesting for monopoly rights to go along with the invention.[142] In 1444, another patent appears to have been given to Antonio Marini of France;[143] more patents for inventions were granted in 1445, 1446 and 1450 in Venice for various things.[144] In 1469, a patent was issued to John Speyer for printing, the following year another was issued for the construction of mills. Subsequently, another patent was also granted to Branchalion in 1471 for the making of unspecified cannons or other weapons.[145] One of the most cited Venetian statute enacted in 1474 states that "We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our city, more such men come to us very day from divers parts. Now, if provisions were made for the works and devices discovered by such persons, so that other who may see them could not build them and take the inventor's honour away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth. Therefore: Be it enacted that, by the authority of this council, every person who shall build any new and ingenious device in this city, not previously made in our Commonwealth, shall give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and similar to said one, without the consent and license of the author, for the term of ten years. And if anybody builds it in violation hereof, the aforesaid author and inventor shall be entitled to have him summoned before any magistrate the said infringer shall be constrained to pay him [one] hundred ducats; and the device shall be destroyed at once. It being, however, within the power and discretion of the Government, in its activities,

[142] Giulio Mandich. (1960) *Venetian Origins of Inventor's Rights*. 42 J. Pat. Off. Soc'y 278
[143] Silberstein, JPOS 37:674 (1955)
[144] Giulio Mandich. (1960) *Venetian Origins of Inventor's Rights*. 42 J. Pat. Off. Soc'y 278
[145] Ibid

to take and use any such device and instrument, with this condition however that no one but the author shall operate it".[146]

3.4.2 Patents Spread to other Parts of Europe

3.4.2.1 France

Accordingly the patent custom spread quickly to other European countries such as France, Germany and England. During the reign of Louis XIV in the early seventeenth century to the early eighteenth century France was considered more or less one of the most advanced countries in Europe.[147] Domestic silk production and the printing/publishing industry grew to become one of the most vibrant industries in Europe at the time.[148] In that sense France inevitably became one of the chief recipient of the immigration of artisans and craftsmen from Venice and other Italian city-states.[149] Indeed the first monopoly patent known to have been granted by the French king was to an Italian, Theses Mutio in 1551 for making glassware in Venetian style.[150] However it must be noted that between 1550 and 1600, on average only one patent was granted in France every two years.[151] There were three major causes for this change in events: firstly the massacre of Protestant Christians on the night of St Bartholomew in 1572 and the religious intolerance and distaste for non-Catholics; secondly the severe interference of parliament with the granting of monopolies which were generally under-served and worked;[152] and thirdly the fact that many inventors and artist fled the country to other countries such as Germany and England deprived France of the potential to establish and maintain one of the most thriving intellectual property economies of its time.

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[146] G. Mandich, (1960) *Venetian Origins of Investors Rights* 42 J.P.O.S
[147] Louis XIV, the Great ruled under the Bourbon dynasty from 1643-1715

[149] See F. D Prager. (1944) *A History of Intellectual Property From 1545 to 1787*. 26 Pat. Off. Soc'y 711
[150] G. Mandich, (1960) *Venetian Origins of Investors Rights*" (1960) 42 J.P.O.S
[151] J. Isore, in p.114.
[152] Frank D Pager. (1944) A *History of Intellectual Property From 1545 to 1787*. 26 Pat. Off. Soc'y 711

The important thing to note from the above discussion however is that between 1551 and 1887 many similarities can be observed from the French evolution of their patent system and the modern day intellectual property formation. A body of capable and proficient experts were put in place to monitor patent applications; the two chief bodies mainly responsible for this role were the Partisan Academy of Science and the Royal Academy of Science. In 1699, a French statute was passed stating that "The Academy shall, on order of the king, examine all machines for which privileges are solicited from his majesty. It shall certify whether they are new and useful. The inventors of those which are approved shall leave a model thereof." This was apparently the first statute enacted which explicitly provided for patent examination.[153] This statute was significant because it provided a legal foundation for a patent examining convention in France in which innovation was seriously addressed.[154] In 1730 the government appointed scientists to work within the Bureau du Commerce to examine inventions. This signified a dedication by authorities to be more involved in the examination process and represented a complete revolution in the patent system in Europe.

In the sphere of French statutes that revolutionised the intellectual property landscape in France, the Design Property Statute 1711 is probably the most obvious. This statute was first enacted in Lyon and paved the way for the rest of France to expand its national policy of industrial property rights.[155] What made these statutes remarkable was the concept that an idea could be stolen in the same way that an incorporeal or unprivileged "design" can be.[156] The implication of this was that for the first time designs took on the character of property, a clear indication that intellectual property as a concept has continued

[153] See F. D Prager. (1944) *A History of Intellectual Property from 1545 to 1787*. 26 Pat. Off. Soc'y 711
[154] Ibid
[155] Ibid
[156] Ibid

to grow and evolve in ways that seemed entirely new and innovative in eighteenth century Europe. Other important Statutes worth mentioning are the 1744 act which protected both old and new designs without a time limit. Furthermore in 1762, a Statute fixed the term of patents at 15 years.[157] The distinctive characteristics of the patent were that it limited the option of being able to transfer patents. The rationale for this was so that the patent could be utilized promptly.[158] Other characteristics of the patent grants that stand out are the social obligation undertone of the patent structure which made it all the more interesting.[159] Another Act passed in 1787 added the additional administrative tool needed for establishing design inventions in a secure way and deliberately referred to designs as property.[160] This was a significant milestone because no country had ever passed a statute refereeing to designs as property.[161]

This wave of intellectual property revolution did not last very long. On the 5th of February 1776, an edict was passed by Louis XVI abolishing the guilds which subsequently became state controlled after it was reinstated that same year.[162] As a result of the high level of instability that enveloped the country, public opinion was beginning to change. The king who had once described privileges as "grace founded upon favour" found that people no longer saw their hard work as grace or favour. They were beginning to see the profits that came with the ownership of intellectual property as an entitlement and a reward for hard work.[163] Most of the textile manufacturers in France joined in demanding that designs, patents and copyrights be recognised as property.[164] After the French revolution in July 1789 the guild system came to an abrupt

[157] J. Isore, 1937 in Revue Hist. De Dr. Fr. Etr p..115
[158] Below p.57
[159] See F. D Prager. (1944) *A History of Intellectual Property from 1545 to 1787*. 26 Pat. Off. Soc'y 711
[160] Ibid
[161] Ibid
[162] Below p 754
[163] A rationale commonly used by proponents of the patent system
[164] Pouillet p.6

end and shortly after that a new statute on patent was passed in 1791 [165] The 1791 statute applied the principle of industrial property with registration to inventions and became one of the strongest intellectual property statements in France.[166] Section 1 of the French law stated that "All new discoveries are the property of the author; to assure the inventor the property and temporary enjoyment of his discovery, there shall be delivered to him a patent for five, ten or fifteen years". The significance of section 1 was it gave the inventor property in his discovery. Ironically, less than a century later in 1887, the highest court in France declared that there is no such thing as intellectual property.[167] Prager asserts that this was heavily influenced by Renouard and Olin-Picard[168] who were at that time the chief authorities on copyrights and patents. They publically denounced intellectual property because they believed that it gave the author and the inventors' limited character rights, which they did not agree with. Conclusively on the subject of the development of patent in France, the reader can appreciate that France had had connections with the idea of property rights in ideas, so the concept was not novel to them in the 20th century. Indeed some commentators have asserted that it contributed in shaping the intellectual property concept in the eighteenth century although this was destroyed in the nineteenth century.

3.4.2.2 Germany

Historically patents in Germany appear not to have been there initially; however when the concept and practice arrived and took shape, it operated for some time and then disappeared due to the dissemination of German society.[169]

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[165] Liana Vardi, The Abolition of the Guilds during the French Revolution. French Historical Studies, Vol. 15, No. 4 (Autumn, 1988), pp. 704-717

[166] Below, p756

[167] Bull. Cour de Cassation., 1887, p. 321

[168] Renouard
Traite des Brevets, p25

[169] The Thirty Years' War (1618–1648) was a religious war principally fought in Germany, it involved most of the European powers. The conflict began between Protestants and Catholics in the Holy Roman Empire, but gradually developed into a general, political war involving

Although many commentators do not acknowledge that the Germans accepted the concept of the inventor's right before the 16th century, evidence suggest that in fact the Germans had a well structured patent system that was not just based on the favours and whims of the king (as it was in England during the reign of Elizabeth I and James I which will be discussed later in this chapter), but was actually free from monopoly abuse and corruption.[170] This system it is asserted encouraged patents, a potential patentee had to establish the following specifications that the patent was capable of - application and specification, novelty and would pass the test of operability.[171] Patents in Germany also had to fulfil the requirements of being capable of technical advancement for the public benefit of society. Additionally the patent holder had to pay a fee tantamount to tax before he could operate his patent. The penalties for infringement in Germany were pretty high and the patent licences could be transferred pretty easily.[172] One of the first procedures that a patent holder had to follow in order to be granted a patent was to make an application in which the invention had to be described as accurately and clearly as possible.[173] A requirement that is very similar to most patent applications today. For a legal or natural person to make an application, it must be made at a patent office which has the jurisdiction to grant a patent of the proposed invention. The application is usually made at the national patent office but can also be made at a regional organisation, such as the European Patent Office (EPO). For a successful application to be made, it must contain the patent specification, illustrating drawings and reveal the most effective way to make the invention.[174] The latter being a specific requirement for patent application in

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most of Europe. See Geoffrey Parker and Simon Adams . THE THIRTY YEARS' WAR. 1997. 2nd Edition

[170] Hansjoerg Pohlmann. (1961) *The Inventors' Right in Early German Law, Materials of the Time from 1531 to 1700*. 43 J. Pat. Off. Soc'y 121

[171] Ibid

[172] Ibid

[173] Ibid

[174] What are the steps in getting a patent?". *Questions and Answers on Patents*. Wolf, Greenfield & Sacks, P.C..

the US.[175] 16th century German patent applications however were presided over by a board of members in the Imperial Councillor's Chamber who examined patent applications. If patents or copyrights application was too complicated, experts were called upon to assist.[176] The relevance of showing that Germany had a well sophisticated patent system must not be understated, because it reveals the foundation, background and origins of the present day patent system. It shows that most of the major super world powers today have a historically link with the patent system, and the TRIPS Agreement are former policies and rules which have perhaps evolved into a multinational codified body of law. What appears evident throughout this analysis is that you will not find any deep rooted historical link of the patent system to many developing countries for reasons that will become apparent later on in this chapter. Another interesting fact worth nothing is that the patent system has many characteristics that are similar to the pharmaceutical industry and are vital to ensuring the success of the sectors' business model. For example both have a very large market capital; R&D is the essential for the survival of both, both are high regulated and there is a huge reliance on R&D and is highly regulated.[177]

Many applications and grants in 16th century Germany made explicit and direct reference to the notion of novelty being an essential requirement for a patent application to be successful. Nevertheless, some patents were actually granted for improvements over previous patent. When one considers the requirement that a patent can only be granted for inventions that are new, one may begin to question whether the requirement that should be clearly stipulated as part of the pre-requites of a patent grant is that an inventions should be incremental as opposed to new. In the writers opinion granting patents for mere improvements

[175] Ibid
[176] Pohlmann, H. P (1961) *The Inventors Right in Early Germany Law*, (1961) 43 J.P.O.S. 121 (translated by F.D.Prager)
[177] The US Food and Drug Administration (FDA), for example, has an enormous set of rules with which pharmaceutical companies have to comply, impacting both R&D and sales.

may set a bad precedence and in the case of pharmaecticals lead to 'evergreening'. Nevertheless examples of such patents were those given to vom Creutz in 1580, 1584, 1589 and 1600 for mere improvements over old patents. Even though as many as 100 patents were issued by the Emperor between 1530 and 1630,[178] the German patent structure was such that documents have shown that many patent applications were rejected for not meeting the necessary requirements. Another major requirement that an applicant had to prove in order to be granted a patent was to pass the proof of operability test. If the new invention was a new machine or process, tests had to be carried out with a model presented to the council. When Eyring, the owner of a patent for Saxony applied for an Imperial patent in 1588, the Emperor requested that a small model of the device be produced to enable the Emperor make a decision.[179]

In order to successfully apply for a patent, the applicant had to establish that the new invention had advanced over prior arts, whether this was a legal requirement or not is not clear.[180] Many patent application documents uncovered at the time suggest that one of the ways in which patent applications were determined is by evaluating whether the invention was for the public benefit of the populace. Like the requirement of "advancement over prior art" one is not entirely sure whether this was a legal requirement or simply the norm of the day.[181] Furthermore the inventor had to pay a fee synonymous to a tax for the patent.[182]. Usually this was the only payment required and the inventor did not have to pay any extra tithe or recurring tax. This suggests that Germany operated a very efficient patent system, free from all the corruption

[178] Ibid
[179] Ibid
[180] Pohlmann H. P (1961) *The Inventors Right in Early Germany Law*, (1961) 43 J.P.O.S. 121 (translated by F.D.Prager)
[181] Ibid
[182] Ibid

and abuse that consumed the British courts and eventually led to the infamous Statute of Monopolies being passed in 1623.

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The origins of the patent system are very important for a variety of reasons. It shows the historically link between many European countries and why it seemed easier for them to conform to the TRIPS Agreement than it did for developing countries. Patents were not a complete novelty to many countries in Europe, even countries like Germany where previously it was though had no patent system in the 16th and 17th century actually had a thriving and vibrant intellectual property culture that only got eroded with the 30 years war. Of course the exact location where the patent system emerged from is still perhaps a little bit problematic, but from historically evidence it has been agreed that it indeed emerge from Venice. One thing however remains absolutely clear, it was deeply rooted within the social fabric of many European states and spread like a flame within Europe and merged with existing local practices, eventually integrating itself into the culture and beliefs of the people.

3.5 The Birth and Growth of the Early patent Doctrine in Britain.

The birth and evolution of patents as it relates to our modern day economy can hardly be successfully expended without discussing the evolution of the English patent system for two reasons. Firstly the Statute of Monopolies 1623 [183] is often cited as the legal foundation of the English patent system, and although this has been taken over by Patents Act 1977 which harmonised UK Patent law with the European Patent convention, the relevance of it cannot be overlooked. Secondly, most commonwealth countries have developed their patent system based on the English patent system, whilst some countries

[183] See Fox, H.G (1947) *Monopolies: A Study of the History and Future of the Patent Monopoly* .Toronto
Monopoly practice, was variously known as “engrossing,” “regarding,” or “forestalling,” and was generally an offence at common law.

including New Zealand and Australia still derive their definition of what an "invention" from the Statutes of Monopolies.[184]

Historically, the Statute of Monopolies 1623 is often cited as the most important milestones in the long history of patents in the United Kingdom. What sometimes does not seem obvious is the fact that a rudimentary form of patent system already existed in England before then. The Kings and Queens of England issued letters patent[185] as royal prerogatives or privileges to give their subjects monopoly powers to produce goods or provide services. These prerogatives or privileges to issue letters patent by the crown were used for a number of reasons: firstly it was used as a fundamental tool to confer privileges upon individuals in order to promote and enhance royal policies;[186] it was also used by the crown to bolster the industrial development of the early 17th century by attracting foreign tradesmen and entrepreneurs to come to England and practice their trade.[187] These earlier forms of letters patent operating in England were similar to royal charters granted by the crown authorizing the conduct of business in the state.[188] Such grants resembling today's modern day patents were divided into three types, namely royal charters, letters close and letters patent. A Royal charter is a kind of letters patent by the Sovereign on the advice of the Privy Council to legitimize an incorporated body, such as a city, company or a university. Letters close on the other hand were used for private individual, they were personal in nature and sealed so that only the recipient could read its contents.

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[184] Hulme, E Wyndham (1896) *The History of the Patent System under the Prerogative and at Common Law* (1896) Law Quarterly Review 141

[185] MacLeod, C. (1988) *Inventing the Industrial Revolution, The English Patent System*, 1660 -1880 Cambridge at 10

[186] Mossofff. A (2000-2001) *Rethinking the Development of Patents: An Intellectual History 1550-1800*. 52 Hasting L.J. 1255 and Christine MacLeod (2002) INVENTING THE INDUSTIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800. Cambridge University Press. 2002

[187] See SIR MATTHEW HALE, *THE PREROGATIVES OF KING* 260-261 (D.E.C. Yale ed., 1976).

[188] Mossofff. A (2000-2001) *Rethinking the Development of Patents: An Intellectual History 1550-1800*. 52 Hasting L.J. 1255

Letters patent which are similar to today's patents were public and directed to everyone. They were similar to legal instruments which were in the form of an open letter issued by a monarch or government. Letters patent were used to confer rights, monopoly, title, or status to a person or to some entity such as a corporation. Blackstone wrote that "The King's grants are also matters of public record. These grants, whether of lands, honors, liberties, franchises, are contained in charters, or letters patents".[189] A well noted case in point that gives an insight into the rationale for letters patent is the grant of letters patent to John Kempe of Flanders by[190] Edward III in 1331.[191] The grant issued took John Kempe and his workers into the King's protection. The letter stated that " Know you that since John Kempe of Flanders, weaver of woollen cloths, will come to stay within our realm of England to exercise his mystery here, and to instruct and teach those wishing to learn therein, and will bring with him certain men, servants and apprentices and their goods and chattels into our special protection and defence"[192] Following that in 1337, letters of protection were given to all foreign cloth workers to settle in England. Commentators have suggested that this was the "beginning of a deliberate and vigorous policy to expand English industry". [193]

The expansion of the English industry continued in Edward III reign when he instigated direct policy initiatives regarding the grant of letters patent to produce wool in England. This policy worked so well that during the 13th century England became established for providing the best luxury woollens in

[189] Vishwas Devaiah . *A History of Patent Law*" www.altlawforum.org/PUBLICATIONS/document.2004-12-18.0853561257 (Accessed 10-12-2006)
[190] See Kitzke, R.A (1959*) Historical Background of the English Patent Law*, 41 J. PAT. OFF. SOC'Y 615, 617-23 and W. Hulme (1896) *The History of the Patent System under the Prerogative and at Common Law*," Law Quarterly Review, Vol.12, p.142.
[191] Christine Macleod. (1988) *Inventing the Industrial Revolution: the English Patent System, 1660 -1800* at 51-53
[192] Immigrants and the industries of London
[193] See. Kitzke, R.A (1959) *Historical Background of the English Patent Law*, 41 J. PAT. OFF. SOC'Y 615, 617-23

Europe, in the writer's opinion a premonition of the industrial success that was to follow. Consequently in 1449 when Edward III's successor Henry VI granted John of Utynam letters patent to work all his arts and sciences without constraint it did not come as a surprise. John of Utynam's art of making coloured glass had never been practiced in England and part of the agreement between the crown and John of Utynam involved him training the King's subject. His contract also involved him fitting stained glass windows for Eton College and King's College, Cambridge which Henry VI was in the process of establishing. This he did successfully; although none of these windows still exist today it was a testament to the successful instruction of a patent system that would flourish centuries later. The issuing of letters patent in the fourteenth and fifteenth century was done sporadically, as no letters patent were issued until over a hundred years later when Edward VI granted Henry Smyth a letters patent in 1552 to make Normandy glass.

Henry Smyth was granted an exclusive 20 year letters patent to produce Normandy glass during which time "No manner of person or persons not licensed, or auctorized by the said Henry Smyth as is afore mentioned shall attempte or presume to make any kynde of the said brode glasse commonly wount to be called Normandy glasse or any other fytte for wyndowes upon peyne or forfayture of all the same glass by any of theym so to be made and as they and any of theym regarde our expresse comaundment and extende too avoyde that trouble and perell which shall earnestly and indelayedly insue in this behalfe". The grant to Henry Smyth was significant because it marked the first time that the English tradition of granting monopolies for inventions began to regularise itself.[194] What this also meant was that letters patent were not only issued on inventions but for entire industries as well, of which the Stationers also benefited from when they gained complete control of the publishing industry.

[194] Klitzke, R. A (1959) *Historical Background of the English Patent Law. 41* Journal of the Patent and Trademark Office Society *615 at 637*.

For a patent to have been issued during that time, the patentee had to meet three criteria; firstly he had to work the patent. In other words he had to establish a foreign trade within the kingdom. Secondly the trade was not to interfere with established industries, i.e., the trade was not be inconvenient to other subjects and thirdly he had to create a self sufficient industry through which English subjects could make a livelihood.[195] These requirements were very similar to the requirements that the German Emperor required the inventor to establish before he could be given a patent, i.e it had to be novel, advance technology and be for the public benefit. Henry Smyth was able to meet all three requirements. The significance of Henry Smyth's letters patent was that when Queen Elizabeth came into power she pursued these policy requirements for patent grants and implemented a system of policies that would continue to stimulate domestic production.

Queen Elizabeth's era has usually been cited as the period in which the English patent custom began to take firm roots. As a consequence of this the patent system flourished throughout her reign. When she came into power in 1558, she embarked on a strategy to encourage domestic production of goods imported from abroad by attracting advanced technology from Europe. In other to do this, like Edward III, she granted patent monopoly to entice foreigners to establish new trades in England. The new trade had to be established within a specific time, failure to do this would result in the withdrawal of the patent. Some analysts have asserted that modern day working of patents may have in fact emerged from this practice. By the time of Elizabeth's death in 1603, she had in fact issued no less than 51 patents.

Initially like some of her predecessors, Elizabeth I pursued a policy of not granting patent monopolies that acted as an inconvenience to subjects by

[195] Holdsworth, W. (1924) *A History of English Law* 349 at 345.

displacing an already existing trade.[196] One of the instances where this policy was applied was in the Matthey's Case. The patentee in that case was granted a patent for the sole making of "knives with bona hafts and paltes of lattin" because he claimed that he was the first person to import the trade from abroad, however a company of cutlers claimed that they used knifes though not with hafts and therefore his patent was considered invalid. Similarly in Birots's Case, a patent for preparing and melting lead ore was held to be invalid because it was considered as an improvement over an already existing practice. This consideration formed the key element as to whether a patent application would be accepted or not. The philosophy behind the refusal to issue patents for mere improvements was summed up by Lord Coke when he stated that 'a mans trade is accounted his life, because it maintaineth his life; and therefore the monopolist that taketh away a man's trade, taketh away his life, and therefore is so much the more odious.'[197]

Lord Coke's elucidation of the concept of the "undesirable effects" of monopoly taking a way a man's trade and livelihood conjures up images of the sometimes "undesirable effects" of Intellectual property rights. The case of bio-piracy[198] where they has been a lack of effective protection for traditional knowledge[199] is a good example of this. The Basmati case is often cited as a good example of when the protection of intellectual property rights or lack of it has the likelihood of going wrong. Basmati as a plant has been cultivated in India, Nepal and Pakistan for centuries, however in 1997, the U. S company "Rice Tec" applied for 16 patents on the generic variations of basmati of which the trademark "Texmati" is perhaps best known. Although, traditionally

[196] Wyndham. H. E (1897) *On the Consideration of the Patent Grant, Past and Present.* 13 LQR. 313 to 318
[197] Coke Edward. 1644. 1797. Institute of the Laws of England 183
[198] The term bio piracy refers to the appropriation of biological resources and traditional resources and traditional knowledge of farmers or local communities by patents without permission or payment carried out by multinational corporations with the aim to use the patent for their own investigations, production and marketing activities.
[199] See Vanada Shiva. (1997) *Bio piracy – The Plunder of Nature and Knowledge.* Between the Lines.

Basmati belongs to India, it had to acquire a license from "Rice Tec" as a consequence of the patents so as to protect itself from being sued if a WTO disagreement arose. Fortunately, this attempt failed because India was able to uphold its right to Basmati rice in court; the result of which 13 out of the 16 patents were cancelled. This example is similar to the Birot's Case because a community of people were already practicing a trade for centuries before the patent application was made.

In 16th century England many people who applied for letters patent tried to justify the reason why they should be granted the privilege. In 1559, an Italian, Jacobus Acontius explicitly invoked rights and labour as a basis for why he should be granted letters patent. Thus he wrote to the Queen Elizabeth that he had found things that were useful to the public and therefore he should have the "fruits of [his] rights and labour as he had abandoned all other modes of gain and had undertaken experiments at great expenses and sustained loss which he could only recover if there were a penalty fixed for anyone who used his invention without his consent".[200] This is similar to the arguments used by the pharmaceutical industry for their justification of why the patent system is not only imperative but indispensible. Developing and securing the endorsement for new drugs is an extremely risky and expensive business where reverse engineering is easy and the cost of manufacturing drugs is very low. Therefore it is argued that the patent system is essential to protect pharmaceutical companies against competition from the generic manufacturers otherwise they would be unable to make a profit. The absence of a patent system would lead to the lack of incentive to invest in producing vaccines and treatment for diseases from which the whole of society benefits from[201]

[200] See Fox, H. G (1947) *Monopolies: A Study of the History and Future of the Patent Monopoly*. Toronto

[201] The Patent System and Access to Medicine in Developing Countries: Possible Cures. October 2004. http://lessig.org/blog/2004/10/the_patent _system_access_t_1.html

The arguments that patent monopolies should be issued as a reward for past labour was commonplace. In the first decade of Queen Elizabeth's reign she had the good intention of granting monopolies to promote the domestic industries of England, however a rundown crown exchequer and the desire to patronise and please her favourite courtiers led to many renewed or extended period for already established trades such as starch, salt and vinegar.[202] Patentees' no longer had to meet the patent test that a practice had to meet the following requirements: be inventive, not interfere with local established industries and assist English subjects in making a livelihood in order to be issued a patent. As a matter of the fact, many patent applications were rejected even if they were real inventions; on the contrary patents were given to people as gifts and favours. For example a patent monopoly was given to Richard Matthew's widow in consideration for her husband's long and faithful services.

In the end Queen Elizabeth I's reign was perhaps best remembered for her abuse of letters patent. Many parliamentarians saw the Queen's actions as an abuse of power; however she challenged them by asserting that members of Parliament were set on taking away her prerogative.[203] In 1571 she addressed parliament saying "her Majesty hoped that her dutiful and loving Subjects would not take away the Prerogative, which is the chiefest Flower in her Garden, and the principal and head Pearl in her Crown and Diadem; but that they will rather leave that to her Disposition. And as her Majesty hath proceeded to Trail of them already, so she promiseth to continue, that they shall all be examined, to abide the Trail and true Touchstone of the Law.'[204]

[202] See generally Edward C. Walterscheid, "The Early Evolution of the United States Patent Law: Antecedents" (Pt 2) (1994) 76 *Journal of the Patent and Trademark Office Society* 849 at 851-852.
[203] Alternative Law Forum – A History of Patent Law. www.atlawforum.org/PUBLICATION/document.2004-12-18.0853561257
[204] 4 Parl. Hist. 420 (Feb. 9, 1598)

As such, Queen Elizabeth's grants of monopolies reflected significant policy changes from earlier grant of letters patent which were aimed at encouraging the introduction of new trade and industries. The highpoint of Queen Elizabeth's abuse or royal prerogative came in 1598 when Edward Darcy was granted letters patent for the sole manufacture, importation and sales of playing cards. The effect of such "odious monopoly" was disastrous for trade and the people, and provoked severe conflict and resentment. The House of Commons were infuriated and this led to a debate in 1601 between them and the crown.[205] In 1602 in the landmark case of Darcy v Allen, Edward Darcy sued Thomas Allen for infringing on his patent for playing cards and the courts were called upon to make a decision upon the validity of the patent. The facts of the case was that the monopoly on the importation of cards had initially be granted to Ralph Bowes and Thomas Bedingfield in 1576 and in 1588 it was reissued to Bowes alone. 10 years later when Ralph Bowes died in 1598 the patent was given to Edward Darcy. The court held that the patent was null and void at common law; it did not meet the criteria necessary to be granted a patent. Darcy's grant of letters patent to import cards was described as an "odious monopolies", which violated the liberty of the subjects to work in their respective trade.[206] The significance of this case lies in the fact that for the first time in English history patents was viewed as a legal right of the inventor rather than an unrestricted royal prerogative.

Critics have also argued that the case of Darcy lead to the against "odious monopolies" and the crystallization of the Statutes of Monopolies 1623. The Statute of Monopoly states that all Crown monopolies are illegal, except in the case of monopolies for inventions consistent with the Case of Monopolies.[207]

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[205] The 1601 debate in Parliament focused on a bill entitled "An Act for the Explanation of the Common Law in Certain Cases of Letters Patent" which clarified the common law limits of the Crown's power to grant monopolies.
[206] Ibid
[207] Justine Pila. (2001) *The Common law invention in its original form*. Intellectual Property Quarterly.

These exceptions are the basis of modern day patent and can be found in section 6 of the Statute of Monopoly which states that: (a) Provided also, that any declaration before mentioned shall not extend to any letters patents (b) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (c) to the true and first inventor (d) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (e), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (f):the same fourteen years to be accounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this act had never been made, and of none other (g).[208]

Interestingly, Sir Edward Coke, the Attorney General whose writings were the role models for the founders of the American constitution argued the case for the monopolist Edward Darcy. Although many saw the harm that despotic monopolies could bring, Darcy's monopoly grant was upheld. The irony of the case was that Coke despised monopolies and believed that they would lead to frustration for the poor. Indeed some have suggested Cook only acted as council to the defendant because he was duty bound to defend the queen's prerogative. After the case he reported that such grants of monopoly went against the freedom of trade and the common law.[209] Coke continued his lifelong campaign against monopolies and in 1603 when James I became King of England he was appointed Chief Justice of the Bench, a position which was at that time the highest legal title in England. James I was soon to regret this when Coke declared that "neither by the Great seal nor by the Little Seal nor by the Little Seal, justice shall be delayed, ergo the king cannot take any cause

[208] English Statute of Monopolies of 1623, 21 Jac. 1, c. 3
An Act concerning Monopolies and Dispensations with Penal Laws, and the Forfeitures thereof [A.D. 1623]
[209] http://www.altlawforum.org/PUBLICATIONS/document.2004-12-18.0853561257

out of any courts and give judgment upon it himself". Coke believed that the common law must always take precedence over acts of parliament. Coke argued that "when an Act of Parliament is against common right and reason, or repugnant, or impossible to be performed, the common law will control it and adjudge such act to be void"[210]

As a liberal thinker Coke viewed the common law thinking as equivalent to the very virtue of being human beings.[211] Commentators have expanded on this and suggested that this is what Coke meant when he said that "reason is the life of the law; nay, the common law itself is nothing else but reason...the law which is perfection of reason."[212] Coke also believed that monopolies violated the Magna Carta which was the foundation of English liberties.[213] He is also remembered for his assertion on the supremacy of the common law and the rule of law that no man is above the law; some of his beliefs also included the significance of economic liberty and his belief of the free market. Some commentators have in fact suggested that the eighteenth century principle purported by Jefferson that "all men are created equal," was probably derived from this concept, although Jefferson was supposedly only referring to "all free, property owning males" as equals.[214]

In a sense the judgment in a later case the Clothworkers of Ipswich 1615 marked the beginning of the end for odious monopolies. In this case, a group of tailors chartered by King James I to operate in Ipswich brought an action against a single tailor who was not part of the group but practising his trade in the town. The court held that the Crown could lawfully grant exclusive privileges of a new invention, a fresh discovery or a new trade within the

[210] Bonham Case
[211] Timothy Sandefur. (2007) *Sir Edward Coke and the Common Law.* http://www.deltachiwindsor.com/history/edward.html (Accessed 23 July 2008)
[212] Ibid
[213] Ibid
[214] Mason, L. I, (2000) *Against Slavery: An Abolitionist Reader*. New York: Penguin Books

realm, for a limited time. Again the significance of this case lies in the doctrinal principles it sets out for issuing such patents namely: the invention must enables the introduction of a new industry, the training of the Englishmen in the trade and the fact that no monopoly patent can be issued for a pre-existing trade. Another significance of this case was that it was clear that although the common law courts had taken over the responsibility of settling disputes over monopoly patents, they still viewed royal privileges to be for the fulfilment of royal policies and directions.[215] This was to change shortly.

The abuse of letters patent continued unabated under James I, even though he had promised in the Book of bounty to refrain from abusing royal prerogatives. In the 1620's Parliament passed the Statutes of Monopolies to the King's disappointment and displeasure.[216] In a statement to Parliament, the king said "I am grieved that you have called (my royal prerogatives to grant patents) ... and condemned them upon so short examination. I confess I might have passed some upon false suggestion and wrong information by the judges".[217] Parliament asserted its authority and this action represented the final classic step towards the shift from royal prerogative to common law and legal rights in the sphere of letters patent.[218] Along with this came the understanding that they was no need to implore an Emperor, King or Queen to have the "fruits of one's labour". In fact by the 18th century, John Locke's labour theory of property had formed the basis for the justification of the protection of the patent system. With this came the erosion of the "odious monopoly" that had threatened to plague the English subjects.

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[215] Mossofff. A (2000-2001) *Rethinking the Development of Patents: An Intellectual History 1550-1800*. 52 Hasting L.J. 1255

[216] EDWARD COKE, *INSTITUTES OF THE LAWS OF ENGLAND* 183 (1797) (1644).

[217] Walterscheild, E (1994) *The Early Evolution of the United States Patent Law: Antecedents (Part 2)* 76 J.P.T.O.S (citing COBBERT PARLIAMENTARY HISTORY OF ENGLAND 1503)

[218] Mossofff. A (2000-2001) Rethinking the Development of Patents: An Intellectual History 1550-1800. 52 Hasting L.J. 1255

The birth, growth and concretisation of patents in England and indeed many European countries reveals a lot when one considers that pharmaceutical patents is only a recent development in many European countries. For example before 1949, the UK did not offer pharmaceutical patents, Italy too did not offer pharmaceutical patents until the 1970s. In the same light before Spain joined the EU in 1986, they did not provide product patent protection for new pharmaceutical products. As part of the Treaty of Accession, Spain was required to rectify this. The argument follows that before then most of continental Europe were keen on patenting only the processes of producing a medicine, while still allowing other companies to produce the medicine using a different process. Indeed the German Association of the Chemical industry points out that the same chemical products can be obtained by different processes, methods, materials or components. [219] Hence, there is social value in patenting a new process, as it rewards the innovator without preventing further innovation.[220] Another classic example where patents were prohibited and led to the growth of the Industry is the Swiss Chemical Industry. This is in contrast to the French Patent laws which allowed chemical patents.[221] Imperative to note however is that most of Europe did not introduce patents until they had had the opportunity to develop their pharmaceutical industry

3.6 The Birth of the Modern Patent Doctrine

Before an exploration of the Locke theory and other professed theories of the justifications of patent system can be carried out, a modest elucidation of the foundation of the modern patent doctrine will be carried out here to set the scene for further erudition. It follows that after the Statutes of Monopoly 1623 was passed, they still existed some degree of uncertainty about the rationalization of the patent system. The thing that made the situation more

[219] Dutfield [2003] Intellectual Property Rights and the Life Science and Industries: A twentieth Century History. Ashgate Publishing Company, 2003

[221]

difficult was the lack of common law precedence.[222] Thus in 1795 Lord Chief Justice Eyre lamented "patents rights are nowhere that I can find, accordantly discussed in our books"[223] Mossoff comments that there is plenty of evidence in the late eighteenth century concerning the lack of precedence on the law of patent rights.[224] The law of patents was thus created, defined and applied by later courts. Many scholars have therefore investigated the theory that natural law philosophy influenced the development of the law of patent law principle particularly in the late eighteenth century.

The ensuring years reflected the evolution of the law of patents, the emergence of new conditions and tenacity of the old concept of patents as royal grants. There was a consistent state of confusion as to whether patents grants were monopolies or inventions and it was during these periods that the conditions that patents must be novel, disclosed and be granted to the true inventor were final agreed upon and established.[225] In the case of Yarranton in the late 1670s, an inventor petitioned the court to determine whether a patent had become invalid because the patentee had not worked on the grant many years earlier and if the patent was valid as similar work was being carried out by other people in the country. With regards to "modern patents" this was perhaps one of the earlier cases which re-asserted the notion that for a patent to be valid: the patentee had to work the patent and not leave it unexplored.[226]

In order to be granted a patent, the specification disclosure had to be carried out and this was reiterated in the case of Garill. Although the requirement of specification disclose was already being used in several jurisdictions in

[222] Boulton & Watt v. Bull, 1 Carp. P. C. 117, 145, 126 Eng. Rep. 651, 665 (C.P.1795)
[223]Boulton & Watt v. Bull, 1 Carp. P. C. 117, 145, 126 Eng. Rep. 651, 665 (C.P.1795)
[223] Mossoff pg 1276
[224] Hulme, E W (1917) *Privy Council Law and Practice of Letters Patent for Invention from Restoration to 1794* [Pat 1]") 33 L.Q.R. 63, 66
[225] Mossofff. A (2000-2001) *Rethinking the Development of Patents: An Intellectual History* 1550-1800. 52 Hasting L.J. 1255
[226] See Bircots case

Europe, it foretold the future development of the necessity of disclosure to either "prove or disprove" a patent application.[227] The facts of the case are that in 1663, Garill applied for a patent "casting for the sole casting of gold and silver Ingot for Lace".[228] However his petition was contested by the officers of the Mint and the Goldsmith and wiredrawers of London, who maintained that this invention was already in use by some of the traders and that a patent would hurt the trade and deprive many people of their livelihood.[229] The privy Council responded by asking Garill to disclose his new method for casting precious metal stones as wire, so as to determine if the method was new , but Garill refused to disclose the method and the matter was concluded. Garill was never granted the patent.

Most of today's prerequisites of a successful patent application continued compellingly to emerge and gain legal precedence during this time. A case in 1719 exposed the mounting magnitude of the inherent concept of novelty as an essential element that would form the basis of future patent application. In this case a corporation of Silk Throwsters failed in their appeal to revoke a patent for "spinning organzine silk" because they were unable to prove that the engines used by the patentee were ever used before in the kingdom.[230] Of course they were numerous cases that reflected the growing momentum towards the development of the patent doctrine in the modern sense of the concept,[231] the point to note however is that patent grants were evolving slowly in a way that was unprecedented.

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[227] [227] Hulme, E W (1917) Privy *Council Law and Practice of Letters Patent for Invention from Restoration to 1794 [Pat 1]* 33 L.Q.R. 63, 66

[228] Ibid

[229] Ibid

[230] In 1679, the King voided a patent grant for melting lead and other metals with coal because according to Hulme, the patentee did not make use of it for the first ten year; in 1987, the King refused to grant a patent for a repeating mechanism for clocks and watches" after the clock makers proved that the mechanism s had been used before ; in 1693, a patent for the manufacture of pitch and tar was voided because the patentee was not making use of the patent and had returned to his native homeland, France

[231] Mossofff. A (2000-2001) *Rethinking the Development of Patents: An Intellectual History 1550-1800*. 52 Hasting L.J. 1255

The Privy Council was slowing relinquishing power to the common law courts thus patents were no longer being seen as a matter of royal favours, but as the "natural right" that belonged to innovators. Another landmark case establishing the shift of jurisdiction from the Privy Council in the case of patents was resolved in 1752. It involved a Chemist, Walker Baker who challenged a patent granted to Dr James for his invention of fever powder. Baker claimed that Dr James was not the inventor of the drug and therefore the patent should be voided. The Privy Council rejected Baker's petition and in 1753, Baker brought another case against Dr James accusing him of perjury. He petitioned the Privy Council to order its clerk to testify as to the affidavit filed by Dr James in support of his patents, in the end Baker was not successful. Some have however suggested that there was a deliberate conspiracy by the Privy Council to arrive at that decision.[232] The important thing to note about this case is that although the Privy Council eventually prevailed in this case, the fact that innovators who felt that they had a natural right to be rewarded for their endeavours would stop at nothing to challenge the crown.

3.7 Monopoly

The word monopoly is derived from the Greek word monopolian, which means the right to exclusive sale, derived from monos, meaning alone, and polein meaning sell. In England the word monopoly was understood by the public as the privilege of having the sole autonomy to sell a product or service even if the product or service has been in the public domain before.[233] Rich contends that this disposed the public of some freedoms and liberties that they held very dear; and perhaps this was the reason why the public began to detest the concept of monopoly. Robinson states that "patent privilege is a true

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[232] Ibid
[233] ARISTOTLE, (1989) THE POLITICS 20-21 (William Ellis Trans., Prometheus Books

monopoly, granted in derogation of the common right.'[234] Intellectual property has been described by some economists as a form of temporary monopoly.[235] Thus Stiglitz writes "an intellectual property regime rewards innovators by creating a temporary monopoly power, allowing them to charge far higher prices than they could if there were competition. In the process, ideas are disseminated and used less than they would be otherwise".[236] It further remains that commentators have contended that the exclusive rights granted by intellectual property laws are generally negative in nature, and subsequently gives the holder of intellectual property rights the ability to exclude third parties from infringing on their monopoly. Although note that these exclusive rights can be conferred or transferred through license or mortgage to third parties.[237]

Before the reign of Elizabeth I, the grant of monopolies appeared to have a legitimate function, i.e. to allow "genius" engage in business that would benefit the public and encourage the growth of industry in the realm. By the end of Elizabeth I's reign, this doctrine had in effect lost its professed function. Patents were not only granted to people who had the intention of establishing a new trade and engaging in that trade, but were given in industries that were already flourishing. Such grant of monopolies was considered to be odious. The odiousness of monopolies derived itself from the fact that the rights, freedom, and liberty of the community to engage in activities that they were accustomed to enjoying were taken away from them collectively and given to a singular person or corporation. An act which many thinkers believe is ludicrous. Thus many people have interpreted the concept of monopoly as taking away from the community things that are invaluable and giving them to the monopolist, whilst the latter gives nothing in return. Although this stance is

[234] ROBINSON. C. WILLIAM (1890). *THE LAW OF PATENTS FOR USEFUL INVENTION*. At 18-19 (Boston, Little Brown and Co.
[235] http://www.ladas.com/Patents/USPatentHistory.html
[236] http://righttocreate.blogspot.com/2005/10/intellectual-property-monopoly-regime.html
[237] Ibid

debatable as the inventor in return for the monopoly gives the public something that they may not otherwise have had. The argument continues that if the product or service that became monopolized was in the public domain before the grant of the monopoly, the monopoly is illegal and therefore odious. If the product or service was new and not obvious, a temporary monopoly was a fair price (quid pro quo) for society to pay as a reward of inducement to the inventor who had taken the financial risk of commercializing that product or service so that society can eventually benefit from the knowledge and inventiveness of the creator.

Although economic power and exclusive rights are concepts that remain resonant in both monopolies and patents as a whole, patents are not monopolies and this distinction must be established. Thus Lord Chief Justice Coke declared that "all Grants of Monopolies are the ancient and Fundamental laws of the Kingdome".[238] Similarly Blackstone points out that the Statute of Monopolies [which is according to some the cornerstone of patents] did not declare monopolies to be contrary to law, certain exceptions must be made, some of which included patents for new inventions.[239] Interestingly even when the Court of King's Bench deliberated on the Clothworkers Case, it avoided calling a patent an exclusive privilege.[240] In this regard, some questions that were raised in United States v. Dubilier 289 US 178 (1933) may be helpful in shading more light on the issue. In this case the US Supreme Court relied on the Webster Dictionary for the definition of monopoly which states that a monopoly is "the exclusive right, power or privilege of engaging in a particular traffic or business, or the resulting absolute possession or control; especially, in political economy, such control of a special thing, as a commodity, as enables

[238] Coke Edward. (1628). *Institute of the laws of England* 181. London, M. Flesher
[239] Blackstones William, Commentaries on the law of England, ch 12. at 9 (Dawsons of Pall Mall, 1966) (1769)
[240] The ClothWorkers of Ipswich Cases (K.B. 1615) reprinted in 1 BENJAMIN V. ABBOTT, DECISION ON THE LAW OF PATENTS FOR INVENTION 6 (Washington, C.R. Brodix 1887)

the person or persons exercising it to raise the price of it above its real value, or above the price it would bring under competition'.[241] The unease with the idea that patents are regarded as "patent monopoly" was highlighted in the Court of Appeals for the Federal Circuit (CAFC) in several judgements in the late 20th century where the question whether patent rights should be referred to as "patent property" were brought into question.

Chief Judge Markey of the Court of the Customs and Patent appeals quoted a statement from the Supreme Court's ruling in Dubilier that "a patent is not, accurately speaking, a monopoly.... [t]he term monopoly connotes the giving of an exclusive privilege for buying, selling, working or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge.... He may keep his invention secret and reap its fruits indefinitely." Accordingly under the statute, Title 35 U.S.C. section 261, a patent is a form of property rights, and the right to exclude recognized in a patent is but the essence of the concept of property".[242] Rich is of the opinion that letter patents or patents should not be regarded as the original documents by which all kinds legal and illegal patents were granted, but has encouraged the reader to think of patents as they know today as grants for limited times of privileges to new inventions and discoveries.[243]

Kitch has asserted that in the field of intellectual property, there continues to exist several persistent errors,[244] of which one of the most common is that patents are monopolies. Kitch contends that the reason why patent is the

[241] Ibid 722 F. 2d at 1548.
[242] Giles R (1993) *Are Letters Patent Grants of Monopoly.* 15 Western New England Law Review 15:239
[243] Kitch, E. W (2000) *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vand. L. Rev. 1727, 1730
[244] Ibid

strongest case for this assumed claim is that patents confer monopoly market power, and even though these kinds of situations are rare, the presumption remains. Likewise he discusses the issue of patents (and other intellectual property rights) conferring economic monopoly which inevitably leads one to associate social welfare cost with monopoly. But the point remains that any system of property rights brings with it cost, be it the cost of "preventing trespass' or arming oneself with the right tools to prevent one's property from intrusion. The point to note however is that whether a particular right confers an economic monopoly is more of a practical question than a general presumption. Mark A Lemley has written "while some intellectual property right may in fact give their owner power in an economically relevant product market, most do not; they merely prevent others from competing to sell copies of a particular product not from selling different products that compete with the original".[245] Regardless of the foregoing, many people still believe intellectual property rights including patents confer monopolies.

The Court in Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990) noted that "The two bodies of law [competition laws and patent laws] are actually complementary" as both are aimed at encouraging innovation, industry and competition. Although there are many circumstances where the protection of the legitimate interests of a patent owner and antitrust law violation coincide, innovators must be allowed to protect the property rights given to him under the patent laws. In a case where a patent owner takes the property rights granted by a patent and uses it to extend his power in the marketplace improperly, i.e. beyond the limits of what Congress intended to give in the patent laws; the patent given to him will not insulate him from the antitrust laws. The court went further to say a "patent is a 'shield' to protect an invention," "not a 'sword' to eviscerate competition unfairly." Such assertions have been helpful in making a distinction between the average everyday

[245] Lemley, W. M. A (1997) *The Economics of Improving in Intellectual Property Law*, 75 Tex. L. Rev. 989

definitions of monopoly (to have exclusive or dominant possession of something) and the economic monopoly that the patent system brings which is to have the exclusive right to sell into a market for a limited period of time.

Richard Epstein subsequently notes that "the patent system, in fact, undermines the economic power of the first patentee by giving incentives to rival inventors" to be more innovative.[246] This declaration can be interpreted as encouraging competition, as opposed to preventing it. Whether this declaration applies to the case of poorer countries who lack the economic power and expertise to invest in R&D and engage in such activities is doubtful. Some of such poor countries have no resources, no skills, and no access to the technology, funds or support to undermine the economic power of the first patentee or any other patentee for that matter. Some commentators have argued that patents must be upheld regardless of its effect on access to medicines. Solveig Singleton states that "those who suffer from illness does not constitute an argument against patent system",[247] a position which may seem very inhumane in many people's opinions.

3.8 Justifications for intellectual property rights – patents

The struggle to justify the essence of the patent system has been ongoing since the birth of the concept, and this battle continues to rage in some anti-patent camps where property rights in the intangibles is still being questioned and abhorred. The reasons why intellectual property rights are difficult to justify are numerous, and one of the reasons why it is difficult to justify is that it is hard "enough to determine the appropriate kinds of ownership of corporeal objects (consider water or mineral rights): it is even more difficult to determine what types of ownership we should allow for noncorporeal, intellectual

[246] Epstein, R. A (2006) *The Structural Unity of Physical and Intellectual Property*, Progress on point 13.4, October, at 9
[247] Singleton. S (2006) *The Patent Prejudice: Intellectual Property As Monopoly.* Release 13.28 October. Progress on Point. Periodic Commentaries on the Policy Debate

objects".[248] Another reason why intellectual property rights are difficult to justify is its link with the corruption and abuse of power during Elizabeth that is associated with patents. Many people consider patents to be the cornerstone of intellectual property rights. According to one author "patents are the heart and core of property rights, and once they are destroyed, the destruction of all other property rights will follow automatically,"[249] hence the strong dislike for the patent system.

The purpose of patents is to reward inventors for their inventions, however as stated above the fact that a patent is sometimes seen as a monopoly does it no justice, and has made the case against intellectual property rights stronger. One of the strongest arguments against patents however is the effect that it has had on access to medicines since the TRIPS Agreement came into being in 1995. Patents have led to higher prices for pharmaceuticals, which have in turn put them out of reach for poorer people living in developing countries. Whether the flaws of the patent system outweighs its gains is debatable, however the value of having a patent system cannot and should not be denied. Below are some of the justifications that writers, scholars and thinkers have come up with in their bid to support or in some cases denounce intellectual property rights.

3.8.1 Natural Rights Theory

The natural law hypothesis is based on the moral justification that individuals have a natural right in their ideas.[250] The most well-known proponent of this doctrine is John Locke, who based his theory on the core principles that a person owns his body and therefore whatever he decided to do with it, including its labour belongs to him. If another person unauthorised by the owner of the labourer uses the labour of the said person, he is in effect a thief. These are very profound and serious allegations that must not be taken for

[248] Hettinger. E. C (1989) *Justifying Intellectual Property. Philosophy and Public Affairs*, Vol. 18, No 1, pp. 31-52nd
[249] Rand, Any (1966) *Capitalism: The y Ideal* (New York: New American Library, p.128.
[250] Fisher.M (2005) *Classical economics and Philosophy of the Patent Syste*m. IPQ.

granted if that is the case. Locke's hypothesis is centred on the belief that humans are by their very own nature rational and good, and they should be able to carry such rights, including the right to property into the political society. This assumption that people are by nature good and rational is very optimistic indeed. Locke's core proposition are based on six main summaries, namely: God has given the world to people in common; Everybody has a property right in his own person; A person's labour belongs to him; whenever a person mixes his labour with something in the commons he makes it his own property; The right of property is conditional upon a person leaving in the commons enough and as good for the other commoners; A person cannot take more out of the commons than they can use to advantage.[251] That being said, some commentators including Robert Nozick has questioned some of these core propositions, particularly the stance that when a person mixes his labour with something in the commons he makes it his own property. Nozick asks why a person by mixing his labour in the commons should not lose his labour instead of making it his own. The example which he uses drives home the point succulently, when he gives the example of a person pouring a can of tomato juice into the ocean. Should the person gain the ocean or lose his can of juice?[252]

Locke's "labour theory" is rooted in the idea that objects have little value until laboured upon, at some point Locke suggested that labour creates 99 percent of value, however Hettinger questions this stance by asking the reader to contemplate how an individual can add 99 percent of the total value of an object by merely labouring upon it, if he has to mix that labour with other things in the commons such as land and other natural resources.[253] Hettinger also questions the labour theory by asserting that intellectual products are in fact social products. In other words, inventions (no matter how novel) do not

[251] Ibid
[252] Robert Nozick, (1947) *Anarchy, State and Utopia*. New York: Basic Books. p. 175.
[253] Hettinger, E. C (1989) *Justifying Intellectual Property. Philosophy and Public Affairs*, Vol. 18, No. 1, pp. 31-52

operate in a vacuum; a person's thoughts depend on the ideas of the people before him. Thus he quotes "A person who relies on human intellectual history and makes a small modification to produce something of great value should no more receive what the market will bear than should the last person needed to lift a car receive full credit for lifting it"[254] Opponents of the natural law theory have shared very strong opposition to this hypothesis as the justification for intellectual property rights, thus the Westminster Review castigated the idea by stating that to "talk of the natural rights of an inventor is to talk nonsense".[255] It must be noted however that during the time of Locke's writing it is doubtful if envisaged the idea that property in the intangible was part of a labourer's natural rights. Locke's philosophical ideas were more directed towards the enlightenment of corporeal, however this did not prevent proponents of the patent system in the 19th century from applying this theory to intellectual property and concluding that inalienable property rights indeed exist in ideas.[256]Regardless of the foregoing, Locke's two treaties has been used by some as a defence for the patent system.[257]

Jean Jacques Rousseau attempted to merge the natural rights of the individual with the need for social unity and cooperation through the concept of the social contract.[258] However the main elaboration of the natural rights came in the North American colonies. The writings of Thomas Jefferson, Samuel Adams, and Thomas Paine concentrated on the natural rights theory made it a commanding and authoritative justification for the American Revolution

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[254] Ibid
[255] The Patent laws, (1829) XXVI Westminster Review 329. John Farey was quoted as saying this before the 1829 Select Committee, at p21 of the report.
[256] See the case of International news Ser. V. Associated Press 248 U.S 215, 239 (1928)
[257]See John Locke, TWO TREATIES OF GOVERNMENT OF GOVERNMENT 287-288 (Peter Laslett ed., 2edition. 1967) 3rd edition, corrected by Locke) (bk.II&27) The Proviso is discussed in Part II(D0
[258] See Wright, B. F (1931) *American Interpretation of Natural Law* (repr. 1962); L. Strauss, (1957) *Natural Right and History* ; O. J. Stone, (1965) *Human Law and Human Justic*e ; Tuck, R (1982) *Natural Rights Theories* (1982); L. L. Weinreb, *Natural Law and Justice* (1987); R. Hittinger, (1988) *A Critique of the New Natural Law Theory*

fought between 1775 and 1783.[259] Interestingly some of the most powerful classic expressions of natural rights are the English Bill of Rights (1689), the American Declaration of Independence (1776), the French Declaration of the Rights of Man and the Citizen (1789), the first 10 amendments to the Constitution of the United States (known as the Bill of Rights, 1791), and the Universal Declaration of Human Rights of the United Nations (1948). The French patent law of 1791 amended in 1800 and 1844 states that "every novel idea whose realization or development can become useful to society belongs primarily to him who conceived it, and that it would be a violation of the rights of man in their very essence if an industrial invention were not regarded as the property of its creator".[260] Machlup contended that French lawyers passed this legislation because they preferred to speak of natural property rights as a substitute theory for monopoly rights, because such privileges were so unpopular.[261] Machlup's theory may be acceptable to some, however it must be noted that most American and English writers have dismissed the natural law theory as having played any part in the development of the modern patent laws. Webster summed up 18th and 19th century opinion when he stared that "those who believe the inventor to have a natural right ... must have an entire misconception as to what it is the inventor really achieves".[262]

In 1996 Odili suggested in his article that natural rights theory has been a major driving force in making the international community adhere to an international standard of intellectual property in order to protect people against piracy and international theft.[263] Some of the basis of his argument was that the

[259] Bernard Bailyn (1967) *The Ideological Origins of the American Revolution*. Harvard University Press.
[260] Ibid
[261] Malcup and Penrose, (1950) *The Patent Controversy in the Nineteenth Century.* 10 Journal of economic History 1 at 10-26
[262] Webster, Law and Practice of Letters Patents for Inventions (London, 1841), p3 quoted from Dutton , (1982) The Patent System and Invention Activity during the Industrial Revolution 1790-1852(Manchester University Press pp.17-92
[263] Samuel Oddi, (1996) *Nature and Scope of the Agreement TRIPS - Natural Rights and a "Polite Form of Economic Imperialism*," 29 Vanderbilt Journal of Transnational Law 415

"natural rights" theory holds that an individual goes into society with certain basic rights and that no government can refute these rights.[264] In other words people, as creatures of nature and God, should live their lives and organize their society on the basis of rules and precepts laid down by nature or God.[265] Individuals have a natural property right in their ideas and therefore countries must recognize the natural property entitlement of the inventor.[266] Any unauthorized use by others without consent from the inventor would therefore be considered illegal. Odili however acknowledges that developing countries may not be so enthusiast to accept the intellectual property based on a natural rights theory, considering that if one was to go by the natural law theory the United States and many developed countries were at one time or the other "thieves" during the era of their industrialization. There are indeed many flaws that make the natural rights theory unworkable in the 21st century, however there is also strong evidence to suggest that it played a huge part in the development of how patents are perceived today and what justifications are appropriate when attempting to rationalize it. Other questions that may be raised to disqualify the natural rights theory is if for example an inventor has the "natural right" to his labour, and therefore his invention, why are patents given for only a limited time? Does it not make commonsense for the right to his labour to be perpetual?

3.8.2 The "Incentive to Invent" Theory

Some authorities have linked patents and economic development as a lever of industrial progress.[267] Proponents of the patent regime have been instrumental in advancing one of the key arguments for the protection of the patent system in the 21st century. The industrial revolution in Britain in the late 18th and early 19th centuries, where major changes in agriculture, manufacturing and transportation had a tremendous effect on the socioeconomic conditions has

[264] Ibid
[265] John Locke's theory
[266] Ibid
[267] Ibid

frequently been cited as the perfect example of the patent system's success in encouraging technological advancement.[268] At that time England had a functioning patent system, thus Price wrote that the monopoly policy which began under Elizabeth had produced a system of patents for the encouragement of new inventions.[269] Innovations were made in the textile industry with Richard Arkwright's water frame (1762); James Hargreaves's Spinning Jenny (1764) which facilitated the handling of large quantities of harvested cotton.[270] Other areas of innovation were the steam power and the iron founding industry. James watt's steam engine was used for pumping mines and later powering machines; and the iron founding which saw iron being potted and stamped was patented in 1783 by Henry Colt. These represent three major sectors, in which patents encouraged key innovations, thereby resulting in the economic take off by which the Industrial Revolution is usually defined. The coincidence however lay in the boom that came with the industrial revolution and the need to have patents protect inventor's rights and act as incentives and enticements.[271] Although some commentators have been suspicious of the coincidence and suggest that the development of the English industry would still have occurred regardless of the patent system, others have acknowledged that the patent system assisted in catapulting the industrial revolution nevertheless.[272] Thus Abraham Lincoln notably wrote that "the patent system added the fuel of interest to the fires of genius".[273]

The "incentive to invent" theory is one of the most recognised justification of the patent system in the 21st century. Many multinational companies assert that

[268]Wikipedia The Free Encyclopaedia. http://en.wikipedia.org/wiki/Industrial_Revolution
[269] Price, The English Patents of Monopoly (Harvard University Press, Cambridge, mass, 1913), p.3
[270]Spinning Jenny- James Hargreaves.
http://inventors.about.com/library/inventors/blspinningjenny.htm
[271] Fisher. M (2005) Classical economics and Philosophy of the Patent System. IPQ.
[272] Coulter, (1991) *Property in Ideas: The Patent Question in Mid-Victorian Britain* (Thomas Jefferson University press, Kirksville.
[273] Lincoln,(1859) *Discoveries, Inventions and Improvements*, in The Complete Works of Abraham Lincoln (3rd ed., Francis D Tandy Co New York, 1905) Vol.5, p 113

without patents, they would have a problem securing sufficient capital to exploit their inventions. The invention process, they assert can be considerably expensive because it involves trial and error and numerous testing.[274] These procedures require facilities, labour, and supplies. This explanation is not a novel one and has been purported by inventors even in the 19th century, thus Siemens who was a Fellow of the Royal Society, and President of the Institute of Mechanical Engineers stated at the 1872 Select Committee that "the fact of there being no properly understood and regulated Patent Law in Germany [that] induced me to come to this country and make this my real home".[275] In Ziv M. Preis thesis, he argues that there is no empirical evidence to suggest that if patentees did not have the right to patents as most of them claim, it would discourage their incentive to invent and disclose their inventions. His assertion is based on an examination carried out on 54 Federal Trade Commission antitrust decrees from 1980 to 1999 which revealed that antitrust decrees with substantial compulsory licensing provisions weaken the motivation to invent.[276] This research in a sense confirms some of Turners position that no incentive is required to induce invention.[277] Although one must note that Turner was in fact a supporter of the natural rights theory. Thus Sir William Armstrong, president of the British Association for the Advancement of Science in 1863 said "seeds of invention exist, as it were, in the air, ready to germinate whenever suitable conditions arise, and no legislative interference is needed to ensure their growth in proper season".[278]

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[274] The Patent Prospector. Jackass Kicked in Texas. http://www.patenthawk.com/blog/2005/04/patent_economics_part_4_incent.html (accessed 5 April 20070

[275] Report of the 1872 Select Committee on Letters Patent, house of Commons Paper 1872 (Command Paper No. 193), p.433

[276] Ziv M. Preis. *The Incentive Theory of Patents in Action: The Effects of Patent Relief on the Incentive to Invent and the Incentive to Disclose" Dissertation.* http://www.law.harvard.edu/academics/graduate/sjd_candidates/zivpreis/ Accessed 6 May 2007

[277] Turner,(1850) *Counsel to Investors of Improvements in the Useful Arts* .F. Elsworth, London. p.50

[278] The Opening address of the president, Report of the 33rd Meeting of the British Association for the Advancement of Science (London, 1864), Quoted from Machlup and Penrose, n 21

It is important to note that many academics, committees and courts find it difficult to deny that patents to some extent instigate technological advance and growth in today's modern day economy[279], however Macfie proposes that inventors should be rewarded by monetary awards and cash subsidies and believes that they are less harmful than patents.[280] The problem however with Macfie's proposition is that if cash subsidies were awarded as the reward for new inventions, how would the cash subsidies be calculate? Would a national or international body be set up to determine how much an inventor should be paid? Would this open up the floodgates of litigation with disgruntled innovators asking the court to review settlements that had been made to them? Would this be an impossible task to embark on? Different scholars and commentators have tried to come up with different solutions to the patent problem, however Grove's (a devoted abolitionist) statement sums it all up , he says :"the sole ground on which letters Patents can be held to be justifiable or permissible, is that they are beneficial to the public. If they are, and, so far as they are, keep them; if they are not, abolish them."[281]

3.8.3 To promote Investments

Other scholars have come up with other justification for the patent system, and one of them is the idea that patents lead to increased investment and as Sherwood puts it succinctly "technology drives investment [and] is reluctant to

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[279] See Turner, (1969) *The Patent System and Competitive Policy* 44 New York University Law Review 451; Taylor and Silberston,(1973) *The Economic Impact of the Patent System*. Cambridge University Press. comments of Lord Oliver in *Asahi Kasei Kogyo* [1991] R.P.C. 485 at 523 where he states that: " The underlying purpose of the Patent System is the encouragement of improvements and innovation" . See also comments of Jacob J. (as he was then) in Teva Pharmaceutical Industries Ltd v Instituto Gentili SpA [2003] F.S.R. 498 that " … Patents are provided to encourage research" . American judicial opinion is apt to voice this justification slightly more vociferously: " Strong Patents protection is key to encouraging innovation, economic growth, and American competitiveness" *per* Circuit Judge Linn in *Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co*, 234 F.3d 558 (2000, CAFC, *en banc*) at 621

[280] See Macfie, (1863) *The* Patent *Question under Free Trade: A Solution of the Difficulties by Abolishing or Shortening the Inventor's Monopoly and Instituting National Recompenses* . 2nd ed., W. Johnson, London; also Macfie, (1869) *Recent Discussions on the Abolition of Patent for Inventions* (Longmans, Green, Reader & Dyer, London.

[281] *Report of the 1871 Select Committee,*

flow where it is not protected".[282] Kitch also contends that strong intellectual property rights offers a framework within which firms in the developed countries can easily engage in FDI and technology transfer to developing countries.[283] Makus maintains that nations with stronger intellectual property rights (patents) have benefited from a greater willingness on the part of the developed countries to engage in FDI and technology transfer.[284] Evidence suggest that indeed this is the status quo, for example stronger IPRs in industrializing economies such as China, Brazil, and India have produced significant growth bonus, indeed as much as 0.5 percent per year through enhanced inflows of trade, foreign direct investment FDI, and licensing.[285] Likewise Primo Braga and Fink have argued that firms in developed countries are more prone to invest in countries with higher levels of intellectual property protection. [286] The argument centres on the fact that multinational companies in developed countries are unwilling to assist developing countries in projects that require significant transfer of proprietary knowledge, including technology intensive manufacturing processes. The fear that firms in developing and LDC will steal the technology to produce and sell their own products to third parties at a lower price which may result in a loss of profit has been one of the key arguments for mainlining a strict and vibrant intellectual property regime.

Mansfield conducted a survey showing that increased protection for intellectual property rights leads to an increase in FDI. [287] His survey was based on the performance of executives of major US corporations and patent

[282] See Robert M. Sherwood, (1988*) the Benefits Developing Countries Gain from Safeguarding Intellectual Property, Paper for Intellectual Property Committee*, Washington, D.C

[283] Edmund W Kitch (1994) *The Patent Policy of Developing Countries.* 13 UCLA Pac. Basin L.J. 166, 167 -78

[284] Maskus, K.E (2000) *Intellectual Property Rights in the Global Economy*. Institute for International Economics,U.S.

[285] Maskus. K.E (1998) *Intellectual Property Rights Can Spur Developing Countries and World Growth*. August 16,

[286] Primo Braga C.A & Fink, C (1998) The *Relationship Between Intellectual Property Rights and Foreign Direct Investment.* 9 Duke J. Comp. & Int'l L. 163, 166

[287] Sherwood, R,M. (1996) *Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries.* 37 IDEA 261, 351-52

attorneys, where he found that there was a strong positive correlation between higher levels of intellectual property protection and FDI. [288] However Mansfield's analysis did not show a positive correlation in higher levels of intellectual property protection and increased FDI in all industrial sectors.[289] Although Mansfield found that when a country enacts strong intellectual property rights, firms in the chemical, pharmaceutical, machinery, and electrical equipment industries increased their levels of foreign joint venture and FDI.

Justifying the patent system with the need to promote investment is according to some school of thought the key to economic growth.[290] Economic growth and the eradication of poverty which are core goals of the Millennium development Goals to be achieved in 2015 depend very much on investment in the form of capital accumulation; this requires investment in plant and machinery along with its drive to gain access to new ideas and technologies.[291] For developing countries and other economies in transition, the promotion of investment is imperative in order to enhance their core competencies and competitiveness. Although the flows of investment and technology to developing countries have not materialized to the extent that would eradicate extreme poverty and hunger, promote gender equality, empower women, combat HIV/AIDS, malaria and other diseases, ensure sustainable development and develop a partnership for development;[292] hope is still centred that with the promotion of investment these goals can be achieved if not now than sometime in the future. Whether this will happen or not remains to be seen.

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[288] Mansfield, E. (1995) *Intellectual Property Protection, Direct Investment, and Technology Transfer* 2 (International Finance Corporation Discussion Paper No. 27
[289] See Ibid at 2-4.
[290] http://www.unido.org/index.php?id=o18264 (Assessed 5 June 2006)
[291] Ibid
[292] About the MDGs: Basics. What are the Millennium Development Goals? http://www.undp.org/mdg/basics.shtml (Assessed 6 June 2007)

3.9 Summary

The patent concept has its admirers and its opponents; however one thing remains certain the concept has evolved rapidly and has a high place in today's modern day economy. Whilst it remains clear that the history of patents have its foundation in Europe, it has spread its tentacles to many developing countries and is enshrined in many multilateral agreements, its application and relevance is still questioned by many especially in the developing world. It follows that in matters of life and death or in a situation where if a patent were granted it would take away the only source of livelihood of a person or community; the matter becomes a human right issue. It is with the foregoing in mind that the next section puts the TRIPS Agreement into a human rights perspective with the ultimate aim of discussing the situation in Nigeria.

PART II

4 HUMAN RIGHTS

4.1 Introduction

Therefore, let us not despair, but instead, survey the position, consider carefully the action we must take, and then address ourselves to our common task in a mood of sober resolution and quite confidence, without haste and without pause'

Arthur Henderson

Men occasionally stumble over the truth, but most of them pick themselves up and hurry off as if nothing ever happened

Sir Winston Churchill

More than any other time in history, mankind faces a crossroads. One path leads to despair and utter hopelessness. The other, to total extinction. Let us pray we have the wisdom to choose correctly'.

Woody Allen[293]

The compatibility of the intellectual property rights and human rights can sometimes be seen as strange bed fellows.[294] Activists and scholars alike have asserted that the TRIPS Agreement undermines the capacity of member states to achieve and implement important policy goals with regards to their human rights obligations.[295] These policy goals include the obligation of states to respect, protect, advance and defend the fundamental human rights of the general population. The interaction between trade and human rights is not a novel concept. The economist Peter Temin noted that in ancient times, traders were constantly in fear of being captured and sold as slaves, or incarcerated by

[293] Woody Allen quotes
[294] Two premises are strange bedfellows if they are diagrammed as co-premises in one reason when in fact they belong to completely different reasons.
[295] Consultative Board 2005

pirates at sea whilst carrying out trade.[296] Thus as early as 432 BC, the Greeks used the Megarian Decree (the Megarian Decree can be compared to a modern trade embargo) to exclude Megara merchants from the markets and ports of Athens for the kidnapping of Aspasian women.[297] Note that kidnapping is a pure violation of Article 3[298], 4[299] 5[300] and 12[301] of the Universal Declaration of Human Rights (UDHR). The interesting point about the Decree was that trade embargos were relatively unheard of in peace times in that part of the world.[302] The tension between trade and human rights issues has presented many problems for centuries, however some commentators have asserted that trade should not be mixed with human rights issues. The tension nevertheless persists even in the 21st century. For example when China joined the WTO, it agreed to improve its human rights record; the Chinese government claimed that trade would encourage more transparency, cross cultural communication which would give the Chinese people more access to education and freedom of speech. However the fact remains that China continues to suppress political and religious rights.

Other examples of trade and human rights being interconnected is the approach that the EU takes in setting its criteria for EU membership. The Copenhagen

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[296] Peter Temin Also see 4 and 5 of UNDR

[297] For a similar case of Kidnapping - see L.M. HANDRAHAN. (2000) *Implications of International Human Rights Law and Bride Kidnapping in Kyrgyzstan*. RAXIS *The Fletcher Journal of Development Studies* VOLUME XVI

[298] . Universal Declaration of Human Rights (UDHR), *adopted* 10 Dec. 1948, G.A. Res. 217A (III), U.N.
GAOR, 3d Sess., (Resolution, part 1), at 71, U.N. Doc. A/810 (1948), *reprinted in* 43 AM. J. INT.L. L
SUPP. 127 (1949), art. 3, art. 4, art. 5, art.9, art. 12, art. 16 (1, 2, 3), art 29 (1, 2, and 3),.art. 3. .Everyone has the right to life, liberty and security of person..

[299] Art. 4..No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms..

[300] Art. 5. .No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment..

[301] Art. 12 .No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks

[302] Hufbauer, Gary Clyde *et al.* (1990), *Economic Sanctions Reconsidered: History and Current Policy*, second edition, Washington: Peterson Institute for International Economics; see Megarian Decree. http://www.livius.org/mea-mem/megara/decree.html

criteria requires that a state puts in place institutions to preserve democratic governance, human rights and a functioning market economy before acceding into the EU. Thus whilst the EU supports a strong multilateral trading system and is committed to ensuring that the European economy is open to the world, Article 6(1) of the EU Treaty states that the "Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law". Thus there are indeed numerous examples of legislations around the world that have linked trade and human rights issue. Another example is under section 51 of the US Tariff Act 1890, goods produced by convict labour were banned in the US and this caused a chain reaction with Great Britain, Australia and Canada following suit. [303] The testament not only goes to the fact that trade and human right issues go hand in hand, but the fact that national laws sometimes instigate international collaboration. Francisco de Vitoria (one of the founders of international laws) states that the right to trade is "derived from the law of nations...Foreigners may carry on trade, provided they do no hurt to citizens."[304] Bearing the above in mind, it is important to note that trade has been used to lift people out of poverty, create strong economies; however it has also been used to enslave and destroy many communities. It has dispossessed people of their fundamental human rights and left many destitute. It is with background in mind that this chapter will seek to evaluate the human rights obligations of developing countries and Multinational Corporations (MNC) in view of the public health crisis facing poorer nations today.

The concept of human rights in modern context is enshrined in John Locke's natural rights notion which states that people possess certain rights by virtue of them being human beings.[305] The Lockean natural rights ideology is not based

[303] Susan Aaronson and Devin T. Stewart. http://www.policyinnovations.org/ideas/commentary/data/000025 (Assessed 1 April 2008)
[304] Irwin, Douglas A. (1996), *Against the Tide: An Intellectual History of Free Trade*, Princeton, NJ: Princeton University Press.
[305] Ibid

on citizenship, law of the state ethnicity, cultural background or religious affiliation; it is indeed a right that should be available to all.[306] As Justice B.N Bhagwati succinctly put it human rights are "not ephemeral, not alterable with time and space and circumstances. They are not the product of philosophical whim or political fashion. They have their origin in the fact of the human condition and because of this origin, they are fundamental and inalienable. More specifically constitutions, conventions or governments do not confer them. These are the instruments, the testaments of their recognition; they are important, sometimes essential elements of the machinery for the protection and enforcement of human rights but they do not give rise to human rights. Human rights were born not of humans but with humans".[307] Human rights are therefore the "basic rights and freedoms, to which all humans are entitled",[308] these rights include civil and political rights such as right to life, liberty, freedom of expression, equality before the law, right to food, culture, work, association, participation and education. It follows that most human rights are interrelated so that the right to health is interconnected to the exercise of other relevant human rights. Imperatively, human rights involve the relationship between the state and individuals and by and large the state has an obligation to ensure that the most vulnerable people in society are not neglected.[309]

Bearing the above in mind, commentators have asserted that HIV/AIDS is one of the greatest human rights issue confronting the world today. The reason for this affirmation is that it raises questions about the patients' other human rights such as the right to housing, medical care, health care and mental health

[306] Ibid
[307] Center for the Rights to Health (2001). HIV/AIDS & Human Rights: The Role of the Judiciary.
[308] Houghton Miffin Company (2006)
[309].Hans Hogerzeil. *Access to Essential medicines ad a Human Right.* ESSENTIAL DRUGS MONITOR

care.[310] In June 2001, the UN general Assembly –Special Session on HIV/AIDS advocated an extraordinary response based on a nation-wide, multi-sector and gender sensitive approach to halting the spread of the HIV/AIDs epidemic[311], this was verification that the epidemic has fundamentally affected all sectors of society globally. The economic effect of the disease was so much so that Brainerd and Siegler compares the long term economic effects of the HIV/AIDS epidemic to the 1918 Influenza epidemic which killed between 20 and 100 million people worldwide, an approximate equivalent of one third of the population of Europe.[312] Another evidence that the HIV/AIDS epidemic is a global health problem that has affected all segment of society can be found in the Presidential Address to the Economic History Association in 2000, where Neal stated that his fellow economic historians would do the "economics profession, and the society at large, a big favor if [they] focused an increasing the share of research efforts on shocks, rather than on longer periods of 'normal' economic change."[313] The economic facts of the effects of HIV/AIDS on the world are not conclusive, however research suggest that the likely effects of it on growth in African countries will decrease GDP by 15-25 percent and per capita income by 0-10 percent in 2010.[314]

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[310] Nigeria, Access to Health Care for People Living with HIV and AIDS. A Report by Physicians for Human Rights in Co-ordination with Future Groups with International/POLICY Project and Centre for the Right to Health.

[311] Report on the United Nations General assembly Special Session (UNGASS) on HIV/AIDS, June 2001. http://www.hc-sc.gc.ca/ahc-asc/pubs/int-aids-sida/ungass-eng.phpfc

[312] Brainerd Elizabeth and Siegler Mark V (2002) *The Economic Effects of the 1918 Influenza Epidemic.* June http://birdflubook.com/resources/brainerd1.pdf and Keyfitz, N., and W. Flieger. (1968) *World Population: An Analysis of Vital Data*. Chicago: University of Chicago Press, 1968

[313] Larry. Neal, (2000) *A Shocking View of Economic History.* Journal of Economic History 60 (2): 317-331.

[314] Cuddington, John T. (1993) *Modeling the Macroeconomic Effects of AIDS, With an Application to Tanzania."* The World Bank Economic Review 7 (2)
173-189. and "Further Results on the Macroeconomic Effects of AIDS: The Dualistic, Labor-Surplus Economy." *The World Bank Economic Review* 7
(3), 1993b: 403-417.

The Brazilian Health Minister once stated that "access to medicines is a basic human right",[315] however the birth of the TRIPS Agreement in 1995 has been criticized for dangerously curbing the availability of cheap patented medicines by increasing the prices of patented medicines in developing countries and by so doing denying people access to medicines. Many commentators have contested the injustice of the access to medicines between the rich and poor countries by highlighting HIV/AIDS, Malaria and Tuberculosis which has ravaged the developing world as one of the injustices of the international trading system. Whilst it is easy to make the case for access to medicines a fundamental human right that must be protected from the multinational trading system; protecting the fundamental human right of inventors from free-riders and piracy is equally at the forefront of international human rights obligations. The question then lies, which human right should take precedence in the face of such conflict?

Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) states that intellectual property right holders must have the right to enjoy the absolute "protection of the moral and material interests resulting from scientific, literary or artistic production".[316] In other words patent holders must be given the unequivocal right to have their works protected from unauthorised use by the public whilst at the same time making sure that the public benefits from the scientific and cultural progress that comes from the patent holder's work.[317] The complexity nonetheless lies in; where to strike a balance between the two human rights; how can society, governments and the international community reach an arrangement where the two rights can complement each other, as opposed to clashing with each other.

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[315] Paying the Price (Television Trust for the Environment, U.S. Release 2002). The transcript for the film is available at http:// www.tve.org/lifeonline/index.cfm?aid=1174.
[316] See Lipinski T. A. and Britz, J.J (2000) *"Rethinking the ownership of information in the twenty first century: Ethical implications"*, Ethics and Information Technology, Issue 2, pp. 49-71.
[317] http://www.eumap.org/journal/features/2004/infohr/infohr1/ipandhr

4.2 The Development of the Right to Health in International Law

The right to health in international law has come leaps and bounds and is now used as an instrument to protect individuals' rights and prevent the abuse of power by states. Oppenheim stated in his treaties on International Law in 1912 that "Subjects of the rights and duties arising from the law of Nations are States solely and exclusively".[318] The argument continues that the status quo has changed. As such the United Nations Charter ushered in a remarkable era by establishing an international organization called the United Nations. By 26 June 1945 the Charter was signed at the United Nations Conference on International Organization in San Francisco, California by 50 members.[319] The Agreement entered into force on 24 October 1945. It was ratified by the five permanent members of the Security Council namely China, France, Russia, the United Kingdom, the United States and other signatories as a deliberate effort to promote human rights internationally. Thus Article 1(3) of the UN Charter states that its core objective is to ensure 'international co-operation in solving international problems of an economic, social, cultural, or humanitarian, character and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion', values which have stood the test of time.

The development of human rights has evolved into many other treaties. Some of the few which are relevant to our discussion on the right to health can be found in Article 25 and 27 of the Universal Declaration of Human Rights (UDHR), Article 7, 11 and 12 ICESCR, Article 10,12, and 14 of the Convention on the Elimination of All Forms of Discrimination Against Women, Article 5 of the Convention on the Elimination of All Forms of Racial Discrimination, and Article 24 Convention on the Rights of the

[318] Oppenheim, L (1912) *International Law. A Treaties*. Vol. 1. Peace. 2nd edn, 19.
[319] (Poland, the other original member, which was not represented at the conference, signed it later)

Child.[320] However the major international treaties we shall be concentrating on in this chapter are the UDHR, ICESCR and the International Covenant on Civil and Political rights (ICCPR).

4.2.1 UDHR

Article 25:1 of UDHR lends support to the right of individuals to have access to essential medicines, by stating that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".

The UDHR is significant because it is one of the most authoritative proclamations on human rights. [321] Its language stems from the United Nations Charter of 1945 and the World Health Constitution of 1946 which states that "The enjoyment of the highest standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".[322] The significance of UDHR is so contemporary that it was unanimously adopted by the General Assembly in 1948 against the backdrop of the violence and atrocities of World War II.[323] The Charter exemplifies the need to always have a general agreement that

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[320] Alexander, B. C (2001) *Lack of Access to HIV/AIDS Drugs in Developing countries: Is There a violation of the International Human Rights?* 8 Hum. Rts. Brief 12, 14

[321] Chapman. Audrey (2002) *Human Rights Implications of Intellectual Property protection.* J.Int'l Econ. L. 861

[322] Constitution of the World Health Organization, opened for signature July 22, 1946, reprinted in World Health Organization, Basic Documents (40th ed. 1994), at 1; for a full discussion of the Preamble of the WHO Constitution

[323] See. Craven, M.C.R (1995)*The International Covenant on Economic, Social, and Cultural Rights: A Perspective on Its Development* 3 (pg. 6 For a history of UDHR where Craven states that ("As a reaction to events prior to and during the Second World War, the allies, and later the international community as a whole, came to the belief that the establishment of the new world order should be based upon a commitment to the protection of human rights and fundamental freedoms."

codifies basic human rights norms as a common standard to which all nations must aspire to reach.[324]

Interestingly however is the fact that the UDHR is not a treaty but a General Assembly resolution that represents a statement of policy. It does not have any international binding force and is unlike international treaties which are signed and ratified by states.[325] This has raised questions about the authority that the UDHR has on the international front and some have even called it the "most fragile basis on which to construct a doctrine of individual duties to respect human rights."[326] Sohn however does not agree with this position, he asserts that the UNDR are the interpretations of the human rights provisions of the UN Charter.[327] Sohn's arguments are based on two reasons, firstly the International Conference on Human Rights at Teheran states that the UDHR is "an obligation for the members of the international community" and secondly state practice invoked UDHR as soon as it was passed.[328] In order words the UDHR has all the backing of states and is fully acknowledges and accepted by the international community.

The preamble of the UDHR is instrumental in declaring that the "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world… [the] disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind" and a proclamation of "freedom of speech and belief and freedom from fear and want

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[324]. Kuszler, P. C (2007) *Global Health and the Human Rights Imperative*, 2 Asian J. WTO & Int'l Health L. & Pol'y 99

[325] George P. Smith (2005), Human *Rights and Bioethics, Formulating a Universal Right to Health, Health Care or Health Protection?* 38 VAND. J. TRANSNAT'L L. 1295, 1300 .

[326] Nigel S. Rodley, Can Armed Opposition Groups Violate Human Rights?, in Human Rights in the Twenty-First Century: Global Challenge 297, 306 (Kathleen E. Mahoney & Paul Mahoney eds., 1993) at 307

[327] See Article 55-56 of the UN Charter

[328] Sohn, L.B (1977) *The Human rights Law of the Charter.* 12 Tex Int'l L J 129 and Sohn, L.B (1982-1983) *The New International Law: Protection of the Rights of Individual Rather than States.* 32 Am U L Rev 1, 16.

. . . as the highest aspiration of the common people."[329] For dignity and equality to qualify as a human right, Article 22 must be adhered to, thus it states that "Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality." The interpretation of Article 22 is instrumental in pointing out that state governments have an obligation to ensure that its resources are used effectively to ensure that all its citizens have the highest quality of life to participate in the free development of their personality which includes medicines to treat illness when he needs it.

Tragically however, despite the broad vision of incorporating a legal right to health in the UDHR, it has had a less dynamic effect on the conjuring up of human rights as a binding tool. Some countries have nevertheless incorporated the human right to health in their constitution. A good example are the twenty Latin America states who as far back as the 1940s took the initiative to prioritize the right to health of its citizens.[330] As a matter of fact during the drafting of the UDHR, delegates from Chile, Uruguay, and Panama had the foresight and presented a document which laid greater emphasis on the need to include a direct reference to provide health care for the sick, however the draft was never incorporated. The draft stated that "The State has a duty to maintain or to ensure that there are maintained, comprehensive arrangements for the prevention of sickness…and the provision of medical care and of compensation for the loss of livelihood",[331] a proposition which may have appeared too burdensome for the signatories to the UDHR to adhere to.

[329] Universal Declaration of Human Rights, G.A. Res. 217A, art. 27(2), U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 10, 1948) [hereinafter UDHR].Recital 1 &2
[330] See Glendon, M. A (2003) The Forgotten Crucible: The Latin American Influence on the Universal Human Rights Idea, 16 HARV. HUM. RTS. J 27, 31-32.
[331] American Law Institute, (1998) *Statement of Essential Human Rights, in American Law* Institute Seventy-fifth Anniversary, 1923-1998, at 285-86,

Ultimately the language of the UDHR has been embraced by many nations, incorporated into national constitutions, and received universal acclamation even though it has no legal obligation on the parties.[332]

In 1966, the UN initiated additional efforts to promote the international advancement of human rights and drafted other human rights instruments to refine and reformulate the rights enumerated in the UDHR, the two instruments it used were the ICESCR [333] and the ICCPR.[334] The main difference between the ICESCR and the ICCPR is whilst the former is a positive right that requires action by the states in the form of a pledge to use its resources to achieve "economic, social and cultural" rights, the former involves civil and political obligations that do not require the state to pledge its financial resources in fulfilling its duty.[335] Although commentators have argued that the distinction between civil and political and economic, social and cultural rights are not valid because civil and political rights sometimes contain positive obligations, whilst economic, social and cultural rights have a negative obligations in the form of the duty of a state to refrain from certain actions[336] The point however remains that both conventions deal directly with access to medicines and have a legally binding effect on member states that sign and ratify them.[337] As of 2006 the ICESCR had 154 State Parties, of which 145 were also members of the WTO, of the 145 members 123 had ratified the

[332] Kuszler, P.C (2007) *Global Health and the Human Rights Imperative,* 2 Asian J. WTO & Int'l Health L. & Pol'y 99 and Dennis M.J & Stewart, D.P (2004) *Justifiability of Economic Social and Cultural Rights: Should There be an International Complaint Mechanism to Adjudicate the Rights to Food, Water, Housing and Health?*, 98 A.M.J.I.L. 462, 478
[333] International Covenant on Economic, Social and Cultural Rights, G.A. Res. 22001 (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316, 993 U.N.T.S. 3 (1966).
[334] International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc. A/6316 (1966).
[335] Cranston, M (1973) *What are Human Rights?* and Holger Hestermeyer (2007) *Human Rights and the WTO; The Case of Patents and Access to Medicines.* Oxford University Press.
[336] Koch, I.E (2002)'*Social Rights as Components in the Civil Right to Personal Liberty: Another Step Forward in the Integrated Human Rights Approach?* 20 Netherlands Q of Hum Rts 29.
[337] See Sofia Gruskin, (2004) SARS, *Is There a Government in the Cockpit: A Passenger's Perspective or Global Public Health: The Role of Human Rights,* 77 TEMP. L. REV. 313, 319-20

convention (note however that both the US and South Africa have not ratified the ICESCR). On the other hand as of 2006 the ICCPR had been ratified by 157 countries, making the ICCPR one of the most powerful human rights conventions of the 21st century (note that the US only ratified the ICCPR in 1992)

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4.2.2 ICESCR

Access to medicine is protected by the ICESCR as an integral part of the human right to health. One of the strongest sources of this right is Article 12 of the ICESCR which states that:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness. Furthermore article 2(1) of the convention requires that state parties of the convention "undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."

In an ideal world, making sure that everyone enjoys the "highest attainable standard of physical and mental health" (which involves having access to

medicines) should be a task that all countries engage in freely, but the fact that we do not live in an ideal world makes the task more difficult to achieve. When one talks about access to medicines for people in the developing world, there is a general presumption that they do not mean access to "feel good medicines" such as sliming pills, sleeping pills, breast enlargement pills and sex enhancement medicines, the medicines they refer to are life saving medicines for diseases that kill if not treated. Such diseases include tuberculosis, malaria, cholera, HIV/AIDS. However the problem with the state obligation to provide such medicines in the developing world is that governments carry on the impossibilium nulla obligation (this means that there is no duty to perform the impossible). Many developing countries are poor and cannot afford to provide the level of health care that its citizens require. The ability of the state to perform its duty to provide medicines will therefore be limited to its financial resources and budgetary capacity. The ICESCR therefore limits the state obligation to providing the minimum amount of medicines that are considered essential for good health. Thus the ICESCR draft General Comment 14 Para 12(a) states that access to medicines should be limited to the definition of "essential drugs, as defined by the WHO Action Programme on Essential Drugs."[338] Thus access to medicines has been promoted and endorsed by WHO since it was established in 1948. WHO defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[339] Note that this does not require that a person attain the highest state of health, however another interpretation of it requires that states provide other interdependent socio-economic rights such as housing and healthcare as essential components. WHO defines essential medicines as "those that satisfy the priority health care needs of the population [and] are selected with due regard to public health relevance, efficacy and safety and comparative cost effectiveness".[340] The state duty to

[338] Committee on Economic, Social and Cultural Rights, general Comment No 14 (2000)
[339] WORLD HEALTH ORGANISATION. http://www.who.int/about/definition/en/print.html
[340] Essential drugs and medicines policy. http://www.who.int/countries/eth/areas/medicines/en/

provide essential medicines is generally upheld by national courts. Thus in Minister of Health v Treatment Action Campaign,[341] the South African Constitutional Court ruled that the government had to make nevirapine, a drug used to prevent mother to child transmission of HIV medicines widely available.[342] Similarly the Tribunal Supremo de Jusicia de Venezuelan held that the government has an obligation to provide antiretroviral medicines to HIV infected patients in Venezuela.[343]

The ICESCR imposes significant duties that a state has to meet before the right to health is achieved; this obligation requires the states to establish a reasonable action programme towards the full realization of the right to health for its citizens within a limited period.[344] What this implies is that states must therefore take all necessary measures to realize the right to health at all levels of state action, such actions may include health policies, trade agreements, social security laws, and adjudication processes.[345] State actions are not only limited to legislations but may include omissions such as the failure to put in place a national health policy, such actions can be interpreted to signify a violation of its obligation. On 29 October 1993 Nigeria signed and ratified the ICESCR and is therefore obligated to play an active role toward the realization of the right to health for its citizens. As such under international law, the Nigeria government must endeavour not to violate its duty to provide the right to health for its citizens either through its omission or its actions. Questions have therefore arisen about some of Nigeria's national policies which do not promote access to medicines.

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[341] Minister of Health al v. Treatment Action Campaign et al 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) (5 July 2002)
[342] Ibid
[343] Tribunal Supremo de Justicia de Venezuela. Cruz Bermudez v Minsterio de Sanidad y Asistencia Social Case No 15.789, Decision 8No 916 (1999)
[344] Commission on Economic. Social and Cultural Rights, General Comment No 14 (2000)
[345] Holger Hestermeyer. (2007) *HUMAN RIGHTS AND THE WTO. The Case of Patents and Access to Medicines.* Oxford University Press.

Eide's three tier classification of state obligation consist of the duty to respect, protect and fulfil its human rights obligation. [346] The first duty for states to respect human rights requires that a state refrain from discriminatory practices that may limit or deny access to medicines. It is important to note that the states' duty to protect health does not override the duty to protect property.[347] In the same way that the government is responsible for ensuring that everyone has access to property, meaning that government must protect us from theft is the same way that they have a duty to ensure that everyone has a right to health. Bearing that in mind some have argued that when a state adopts patent laws it limits the economic accessibility of medicines available to its citizens, and because developing countries can only achieve a positive duty by guaranteeing a realistic price level on medicines, price in this sense becomes imperative to ensuring the respect of human rights obligations.

In Nigeria an average worker earns approximately ₦6,500 ($52) per month (section 2(1) of the National Minimum Wage (Amendment) Act 2000 states that it is the duty of every employer to pay a wage not less than National Minimum Wage of ₦5,500 ($44) per month to every worker).[348] However in 2006 the average cost of a first-line treatment in most low income countries was between $ 123 per person per year for a fixed dose combination of combination of stavudine + lamivudine + nevirapine to $493 for the fixed-dose combination zidovudine + lamivudine plus a single dose of efavirenz;[349] whilst the Second-line treatment in 2006 was in the region of between $1698

[346] A. Eide, (1987) *The New International Economic Order and the Promotion of Human Rights. Report on the Right to Adequate Food as a Human Right*, UN Doc E/CN.4/Sub.2/1987/23 (1987)
[347] See Horacio M Spector. 1989. *An Outline of a theory justifying intellectual and industrial property.* European Intellectual Property Review; Harold Demsetz, (1967)' *Toward a Theory of Property Rights'* , American Economic Review, LVII (Papers and Proceedings of the Seventy-Ninth Annual Meeting of the American Economic Association).
[348] National Minimum Wage (Amendment) Act 2000. 2000 Act No . Laws of the Federation of Nigeria
[349] Summary of Global progress in priority Intervention areas see http://www.searo.who.int/LinkFiles/News_and_Events_UAPR_Summary.pdf

and $ 4735 for a dosage of didanosine + abacavir + lopinavir/ritonavir, [350] This places the antiretroviral medicines which is an essential medicines under the WHO Model List out of the reach of many HIV patient in Nigeria who earn minimum wage. The question therefore arises is the state therefore under an obligation to prevent MNC from introducing prices for medicines that are outside the reach of its population? Or they under an obligation to subsidize the prices of these patented medicines to ensure that they become affordable to the people? To answer the question, Hestermeyer argues that when corporations are given the right to patent, the price of medicines go up. State obligation to protect the human rights of its citizens requires it to enact legislations that ensure "equal access to health and health related services provided by third parties [and] ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities".[351]

Eide's second tier state duty to protect the right to health requires the State to take active measures to prevent third parties from interfering with Article 12 of the ICSECR.[352] Commentators have therefore pointed out that the State is under an obligation to take measures that will ensure access to health care provided by third parties. This obligation is relevant to evaluate the status quo in Nigeria for a variety of reasons. Firstly in many countries health care is provided by the private sector alongside the state run institutions, For example in Lagos, the most populated city in Nigeria, seven percent of healthcare is provided by private hospital. In the first half of 2008, the state government had to shut down 184 private hospitals, clinics and laboratories for failure to meet the basic standards of hygiene and staff training; in the writer's opinion, a clear

[350] Ibid
[351] General Comment 14
[352] Professor Andrew Clapham and Mariano Garcia Rubio. (2002) *Human and Health Rights Working Paper Series No 3. The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health*. http://www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf

fulfilment of Article 12 obligation to protect its people against ill health that might result from poor hygiene and treatment from unqualified staff.[353] Secondly, pharmaceuticals are almost entirely manufactured and marketed by the private sector, and because economic accessibility is a major part of the right to health, the state is responsible for ensuring that firms do not limit access to medicines through high prices. Thirdly, signatories to the ICESCR are under the obligation to abstain from "denying or limiting equal access for all persons...to preventive, curative and palliative health services".[354] Thus if a state "repeals or suspends legislation necessary for the continued enjoyment of the right or adopts legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations relating to the right to health" it is in violation of its obligation to protect the human rights of its citizens.[355] In other words when a country enters into bilateral or multilateral agreement with other states, it should not restrict access to medicines by increasing prices covertly or explicitly.[356] The TRIPS Agreement authorizes WTO Members to "adopt measures necessary to protect the public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development".[357] Supportive of this stance the Ministerial Conference of the WTO held in Doha 2001 (Doha Declaration) instructs states to interpret the Multilateral TRIPS Agreement in a way which is "supportive of the WTO members' right to protect the public health and, in particular, to promote access to medicines for all".[358] This includes the right of each member state to determine what constitutes a

[353] Nigeria shuts down private hospitals. Science and Environment Online. October 9 2008. http://www.downtoearth.org.in/full6.asp?foldername=20080531&filename=fort&sec_id=5&sid=5

[354] General Comment 14: The Right to the Highest Attainable Standard of Health, U.N. Comm. on Econ., Soc. & Cultural Rts., 20th Sess., P 12, U.N. Doc. E/C.12/2000/4 (2000).

[355] Ibid

[356] Ibid 50"

[357] The Limburg Principles on the Implementation of the International Covenant on Econ., Soc. and Cultural Rights, U.N. ESCOR, Comm'n. on H.R., 43d Sess., Annex, PP 46-57, U.N. Doc. E/CN.4/1987/17 (1987), reprinted in 9 Hum. Rts. Q. 122, 128-29 (1987).

[358] Declaration on the TRIPS Agreement and Public Health, adopted on Nov. 14, 2001, P 4, WT/MIN(01)/DEC/2 (Nov. 20, 2001)

"national emergency or other circumstances of extreme urgency"[359] including public health crises such as "HIV/AIDS, tuberculosis, malaria and other epidemics".[360] Furthermore the ICESCR committee takes the position that a country violates its obligation to promote human rights when it fails to "regulate the activities of individuals, groups or corporations so as to prevent them from violating the rights to health of others".[361]

Eide's third and final concept of state responsibility in fulfilling its human rights obligation compels her to put into place adequate legislative, budgetary and administrative procedures so that it can realize its human rights obligation .[362] In doing so states have to adopt satisfactory national health policies, health insurance schemes and provide alternative medicines such as generic equivalents to patented medicines. By accessing generic equivalents of brand name drugs, states can access cheaper medicines. For example in 2006, the Indian government announced a fall in prices for 886 generic drugs leading to a price reduction ranging from 0.2 to 74 per cent for formulations such as anti-diabetes drugs, painkillers, cough medications and hypertension drugs and other formulations such as paracetamol, cefadroxil and amoxicillin;[363] thus setting a very good example for other developing countries like Nigeria to follow. Some commentators have therefore argued that states can better fulfil its human rights obligation by providing anti-competitive measures against multinational companies to prevent them from setting prices that are extensively higher than their generic equivalent.[364] Such anti-competitive

[359] Ibid. p. 5 (c).
[360] Ibid . P 5 (5).
[361] U.N. Comm. on Econ., Soc. & Cultural Rts., General Comment 14, P 51.
[362] Koch, I.E (2002) *Social Rights as Components in the Civil Right to Personal Liberty: Another Step Forward in the Integrated Human Rights Approach?* 20 Netherlands Q of Hum Rts 29.
[363] http://www.hindu.com/2006/11/01/stories/2006110104121200.htm (Assessed 7 February 2007)
[364] Yamin. A. E (2003) *NOT JUST A TRAGEDY: ACCESS TO MEDICATIONS AS A RIGHT UNDER International law.* 21 B.U. INT'L.J. 325

measures may come in the form of regulations, protectionist measures, tariffs and quotas.[365]

The Policy briefing for Stop AIDS campaign in May 2006 stated that in order for the Universal access to treatment to be achieved by 2010 new generic versions of key drugs must become quickly accessible.[366] This is because half of the people in the developing world who are on antiretroviral therapy rely on generic versions of the more expensive patented drugs. Furthermore it seems that generic medicines essentially offer HIV patients a better chance to prolong their lives by introducing "second line" treatments, needed for patients when they develop resistance to their first combination of medicines. Treatment for HIV generally involves three drugs taken together WHO advocates that in most conditions a first line regimen ought to consist of two drugs from the nucleoside/nucleotide (NRTI) group and one drug from the non-nucleoside (NNRTI) group.[367] Second-line treatments are currently under patent and priced overtly high, so are most new upcoming successful drugs that HIV patients need that come onto the market.[368]

Generic medicines enable states to overcome the inconvenience of fixed-dose combination in cases where the various components are patented by different companies who are reluctant to work together. To clarify what fixed combinations mean to HIV patients, these medication consist of pills that contain two or three AIDS drugs in one tablet and they have been widely recognized as being a key element in efforts to scale up AIDS treatment in

[365] Article 31 (K) 3states that 'Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;)
[366] STOP AIDS CAMPAIGN. Policy briefing: Access to Essential Medicines. May 2006. http://www.vso.org.uk/Images/stop_aids_campaign_drugpricingpolicy_tcm8-8152.pdf
[367] AVERT http://www.avert.org/aidstreatment.htm . See diagram below.
[368] STOP AIDS CAMPAIGN. Policy briefing: Access to Essential Medicines. May 2006. http://www.vso.org.uk/Images/stop_aids_campaign_drugpricingpolicy_tcm8-8152.pdf

developing countries.[369] The benefits of these medicines is the fact that they are generally more affordable than purchasing separate products, they are easy to use and reduce the risk of the drug becoming which is one of the major problems that HIV patients encounter when using ARV drugs.[370] Despite the advantages of generic medicines, proponents of the patent system argue that generic drugs are not needed because pharmaceutical companies already make cheaper versions of ARV in developing countries, an example which is often cited is the Meltrex tablet formulation of Kaletra (lopinavir/ritonavir) produced in Germany which has received full marketing approval from the European Medicines Agency and is a second line treatment for the HIV virus. The main benefit of the new Kaletra tablet is that it does not need to be refrigerated.

Previous studies have found that the old Kaletra capsules deteriorated fast in countries with hot climates and needed to be stockpiled and distributed with care. Other benefits of the new tablet include dosing with or without food (this can be a real problem in poorer countries with a low standard of living where feeding is a real problem) and a reduced pill count for those on standard dosing (400mg lopinavir/100mg ritonavir) twice daily. Nonetheless big patent holding manufacturers such as Abbot have been criticized in the past for not speeding up the registration of the new tablet in developing countries that are in urgent need to provide medicines needed to the fight HIV/AIDS. Although Abbot disputed these claims, stating that it has guaranteed that the new formulation will be sold at a reduced price of $500 a year to poorer countries.[371] MSF disagrees with this claim, stating that Abbott could choose to export the drug from the United States, allowing quicker registration and therefore would not

[369] TWO PILLS A DAY SAVING LIVES: FIXED DOSE COMBINATION OF FIXED-DOSE COMBINATIONS.
http://64.233.169.104/search?q=cache:l9_1Sysh29YJ:www.accessmed-msf.org/documents/factsheetfdc.pdf+what+are+fixed-dose+combinations&hl=en&ct=clnk&cd=12&gl=uk
[370] Ibid
[371] AIDSMAP NEWS. http://www.aidsmap.com/en/news/BD54D18C-962B-46D4-8882-3327471FBBA5.asp

need to wait for European approval, since many African regulatory authorities need a certificate of pharmaceutical production from the European Union. Such discontent are evidence that even if the pharmaceutical industry feels that it is doing much to provide access to medicines and not using the TRIPS to prevent such access, some activist feel that such measures are not sufficient, states have to do more to fulfil their human rights obligation.

4.3 Human right Obligation of Multinational Corporations

Conventionally, human rights have been regarded as being solely in the domain of states and not in the realm of individuals.[372] However recent developments have changed the status quo. Many states have now privatised many of their public institutions that were previously controlled by the government and this has made the case for MNC being held accountable for human rights obligations more fervent,[373] secondly MNC have become so powerful and rich that some of them are richer than many developing countries put together.[374] In 2002 sales from Wal-Mart outdid the GDP of the many developing countries put together. Many commentators have argued that MNC should have as much human rights obligations to fulfil as states.[375] Countries such as Portugal have enacted legislation to hold both private and public institutions responsible for human rights obligations.[376] Wiesbrock suggest that the interpretation of human rights instruments suggest that rights protected by the Covenant such as the right to life and health care can be violated by individuals and corporations.[377] To support this the preambles of the ICCPR and ICESCR states that "the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for

[372] See Nowak J.E and Rotunda, R.D (1995) *Constitutional Law* 5th ed
[373] Singer, P.W (2004) *Corporate Warriors. The Rise of the Privatized Military Industry*
[374] See McCorquodale R & Richard Fairbrother, (1999) *Globalization and Human Rights*, 21 Hum. Rts. Q. 735, 742-58
[375] Wal-Mart (ed) Annual Report 2002.
[376] The Portuguese Constitution 2 April 1976. See also DM Chirwa,(2003) *The Right to Health in International Law: Its Implication for the Obligation of States Actors in Ensuring Access to Essential Medicine* 19 SAJHR 541, 564
[377]

the promotion and observance of the rights recognised in the present Covenant', thus Article 5(1) of the ICCPR states that "Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein or at their limitation to a greater extent than is provided for in the present Covenant". It is widely accepted by academics that international human rights indirectly holds member states responsible for the acts of corporations (including pharmaceutical companies),[378] Kinley and Tadaki assert that the fundamental treaty obligation imposed on members states requires that all non-state parties within its jurisdiction adhere to duties imposed in the instrument, and furthermore international human rights depends on domestic law to implement its provisions. [379]

In elucidation, the fact that MNC have become so powerful has led to a public outcry that they too must be held accountable for the violation of human rights. They are many examples of abuses by MNC, especially in the developing countries, where accountability is not as structured as those in the developed world.[380] For example in Nigeria, oil trade in the Niger Delta region of the country produces about 90 per cent of the country's budget.[381] The activities of

[378] See Clapham A& Jerbi. S, (2001) *Categories of Corporate Complicity in Human Rights Abuses,* 24 Hastings Int'l & Comp. L. Rev. 339, 341- 42, 346-47 . There is evidence to suggest that the Inter-American Court of Human Rights and the European Court of Human Rights has established a way to states responsible for the actions of non-state actors. See, in respect of the Inter-American Court, Velasquez Rodriguez v. Honduras, Case No. 4, Inter-Am. C.H.R., OEA/ser. C, PP 159-88 (1988), and in respect of the European Court of Human Rights, see Costello-Roberts v. United Kingdom, 247 Eur. Ct. H.R. (ser. A) (1993); Gustafsson v. Sweden, 22 Eur. Ct. H.R. 490, and A v. United Kingdom, 1998-VI Eur. Ct. H.R. 2692 (1998).
[379] Kinley D and Tadaki, J (2004*) From Talk to Walk: The Emergence of Human Rights Responsibilities for Corporations at International Law* 44 Va. J. Int'I L. 931.
[380] *Multinational Corporations and the Ethics of Global Responsibility: Problems and Posssibilities* (2003) 25 Hum Rts Q 965, 971ff, Multinational corporate social responsibility, ethics, interactions and Third World governments: An agenda for the 1990s. Journal of Business Ethics. Volume 12, Number 7 / July, 1993
[381] http://news.bbc.co.uk/1/hi/world/africa/6698433.stm, see Shell's involvement in violations of the rights of the Ogoni people, Social and economic Rights Action Centre and the Centre for

oil companies such as Shell and Chevron has led to a severe case of oil spillages in the region which has resulted in environmental degradation, lack of livelihood for the fisher men and poor health which has extended to other areas such as poverty due to lack of social services such as hospitals, good drinking water and schools.[382] Cases of oil pollution in the Niger Delta have raised many human rights issues because the oil industries have not always been prepared to face up to the negative effects that their activities has on the communities of the region. The tragedy of the actions of MNC is captured in the statement by Mr. Louis Nwanchukw "Shell has promised us several things, but have not done any. Apart from that, the issue of environmental devastation that is still threatening us. Two major spills have occurred between 1991 and 1999 and Shell refuses to clean spills from our lands and rivers and pay compensation to us".[383] Similar cases of MNC violation of human rights obligations is prevalent throughout the developing world, for example in 2006 a Netherland based commodities company Trafigura Beheer dumped toxic waste in Abidjan, Cote d'Ivoire killing eight people and resulting in more than 77,000 people needing medical attention.[384][385]

The history of MNC violating the human rights of individuals in developing countries is common. Cases of MNC and countries dumping hazardous waste are examples of how MNC have violated the human rights of people in some developing countries. In 1979 the American company, Nedlog Technology Group, Inc., offered Sierra Leone $25 million to use its territory for waste disposal. In the case of Nigeria, in 1987, an Italian waste broking firm Ecomar

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Economic and Social Rights v Nigeria, Communication No 155/1996, ACHPR/COMM/A044/1 (27 May 2002)

[382] http://www.american.edu/TED/iko.htm

[383]"Shell fails to clean spill, refuses to pay compensation" FOR OIL SPILLS IN AMUSIA, RIVERS STATE OF NIGERIA'S NIGER DELTA. Mr. Louis Nwanchukwu, chairman, Umusia Community development Committee (CDC). http://www.waado.org/Environment/OilSpills/NigerDelta/Amusia_Rivers.html

[384] Ivory Coast parliament open hearing into toxic waste scandal http://www.reliefweb.int/rw/RWB.NSF/db900SID/HMYT-6TYM8P?OpenDocument Last visited 12-03-07

and Jelly Wax signed a contract with a construction company where it would store its hazardous waste of 18,000 drums for approximately $100 a month. They have been numerous cases of gross human rights abuses, however some have argued that Covenants define the obligations on State Parties, but not individual.[386] One of the strongest cases against individuals and corporations being held responsible for adhering to the human rights obligations is Article 2 of the ICCPR and Article 2 of the ICESCR which make no mention of individuals being bound by the rights in the Covenants, and secondly state practices do not support individuals and corporations being bound by human rights obligations. The German Federal Constitutional Court stated that "outside the area of minimum human rights standards current general international law contains only few norms that create right or duties of private individuals".[387] Bearing this in mind international human law may have to undergo a constructional evolution to determine MNC'S accountability in relation to international law.[388] The US suggested that the future Article 7 of the future ICCPR should be rephrased to "no one shall be subjected to torture" as opposed to "no state shall be subjected to torture".[389] This may broaden the umbrella in which human rights obligation applies to include both states and individuals because at the moment, there is no bold and clear evidence that MNCs can be held in violations for human rights obligations under the Covenant as state parties can.

4.4 Summary

The relationship between trade and human rights has caused a lot of tension in the access to medicines debate. Whilst some commentators have argued for the

[386] Klein, E (2000)*The Duty to Protect and to Ensure Human Rights Under the International Covenant on Civil and Political Rights* in E Klein (ed), The Duty to Protect and to Ensure Human Rights. Colloguium. Potsdam, 1-3 July 1999
[387] Memorandum for the United States as Amicus Curiae in Filartiga v Pena-Irala, at 21, 630 F2d 876 (2nd Cir, 1980)
[388] See Kinley D & McBeth, A (2003) Hum*an Rights Trade and Multinational Corporations, in Business and Human Rights* 52-68 (Rory Sullivan ed.,
[389] Holger Hestermeyer. (2007) *HUMAN RIGHTS AND THE WTO. The Case of Patents and Access to Medicines.* Oxford University Press

international recognition of the human right to health and access to medicines as fundamental human rights that must be protected by the state, the authority to back the assertion up has been debatable. Whilst the UDHR and other international human rights instruments such as the ICESCR and ICCPR can be used as authorities to back the assertion up, the matter has been left for the state governments to implement. It follows that most state are shielded by impossibilium nulla (meaning that the state is under no duty to perform the impossible). Many developing countries have a weak healthcare delivery system and the budget for their health care expenditure is not high enough to meet the medical expenses of ensuring that majority of it population receive the treatment or necessary medicines that they require. In my opinion, MNC have also played a part in preventing state governments from affording to meet their human rights obligations of ensuring that there is access to medicines. State governments have to enunciate laws and national policies that will ensure that access to medicines and good health are a priority for their nations. It is with the foregoing in view that an in-depth analysis is conducted in the next chapter to ascertain the healthcare crisis in Nigeria with particular emphasis on the HIV/AIDS epidemic.

5 HIV/AIDS EPIDEMIC IN NIGERIA

5.1 Introduction

It is my aspiration that health finally will be seen not as a blessing to be wished for, but as a human right to be fought for.

—United Nations Secretary-General Kofi Annan

I cannot take that rubbish any longer. Can you believe it? I have never in my life heard such rubbish. Here we have a situation where the minister of health sends out a document, amongst others, that is Looney tunes, that suggests that the Illuminati have conspired with the aliens to bring about Aids to reduce the African population.

> A reporters' response to Manto Tshabalala Msimang assertion that raw garlic, onion, lemon and beetroot are the best remedies for HIV.

Even if he can vote to choose his rulers, a young man with AIDS who cannot read or write and lives on the brink of starvation is not truly free… Larger freedom implies that men and women everywhere have the right to be governed by their own consent… without discrimination or retribution… They must also be free from want — so that the death sentences of extreme poverty and infectious disease are lifted from their lives — and free from fear…Indeed, all people have the right to security and to development."

—United Nations Secretary-General Kofi Annan

The HIV/AIDS epidemic is one of the leading challenges facing our modern day society. The severity of the epidemic comes from the fact that it threatens to undermine the millennium development goals to reverse the spread of HIV/AIDS by 2015. In the twenty- eight years since HIV was first identified

there have been considerable advances in the understanding on how to prevent and treat HIV infection and by so doing alleviate the social, economic and financial impacts that the diseases has on individuals, families, and communities. Successful programs have been implemented to halt and slow down the rate of new infections among specific groups in many parts of the world. But despite such considerable progress the AIDS epidemic continues to gain momentum in a number of new countries where early intervention could have prevented its spread if more medicines were available. HIV/AIDS is clearly a major human rights issue, and the inability to pay for treatment because of the high cost set by MNC has further compounded the problem. In the case of Nigeria, the prevalence rate of the diseases continues to rise, while the people suffering from HIV/AIDS continue to face the pangs of discrimination and other human rights abuse. Whilst the government has set out programs to respond to the epidemic and ensure that people gain more access to medicines, some have argued that the governments are not doing enough. This chapter focuses on the HIV/AIDS epidemic in Nigeria with a view to showing that the inability to gain access to medicines is not so much an international problem caused by the TRIPS Agreement, but an internal one caused by domestic factors that make up the fabric of the Nigerian society.

5.2 Background of AIDS in Nigeria

The first case of HIV/AIDS in Nigeria was reported in 1985 by the Federal Ministry of Health (FMOH).[390] Subsequently in the two decades since AIDS was first discovered in Nigeria, many individuals and communities are still adversely affected by the destructive forces of the disease.[391] When the finding of FMOH was reported to the Nigerian government as far back as 1986, the government was thrown into a state of panic about the effect that the disease would have on the Nigerian economy. In 1987 the National Expert Advisory

[390] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development
[391] HIV/AIDS National Strategic Framework for Action 2005 -2009 NACA Published by the Society for Family Health. September 2005

Committee on AIDS (NEACA) was established to control and fight the disease. A year after that, the National AIDS and STDs Control Program (NASCP) was established to replace NEACA with the hope that it would be more effective in halting the AIDS epidemic in the country. In 1991, the NASCP program was expanded to include sexual transmitted infections (STIs), and today NASCP focus principally on the health sector responses to HIV and other STIs. Its work is centred mainly on the monitoring and surveillance of the epidemic, syndromic management of STIs, voluntary counselling and testing (VCT), prevention of mother-to-children of HIV transmission (PMTCT) and management of HIV/AIDS, including treatment of opportunistic infections, administration of antiretroviral (ARVs), and home based care.[392]

In the 1980's Nigeria was considered to be at a moderately early stage of the HIV/AIDS epidemic when compared to many countries in the East and South of Africa; however the prevalence of the disease continued to grow.[393] Indeed the effects of HIV/AIDs have become so severe that many Nigerians are afraid that if not checked, the epidemic could spill into all other fabrics of society.[394] The most direct impact of AIDS in Nigeria however has been an increase in the number of infant mortality, reduced life expectancy and adult deaths.[395] Statistics show that the increase in the level of HIV prevalence in Nigeria indicates a rise from 1.8 % in 1991 to 3.8% in 1995, to 5.4% in 1999 to 5. 8% in 2001, and 4.6 % in 2008.[396] These figures shows that because of the high level of HIV prevalence in Nigeria, 9.8 out of every 1000 people in the population is dying as a direct or indirect result of AIDS.[397]

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[392] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development pg. 18
[393] Ibid
[394] Pew Research Center, 2002 Pew Research Center for The People and the Press, "What the World Thinks in 2002", December
[395] HIV/AIDS: The Disease Burden and the level of Funding in Nigeria. A Publication of aids alliance in Nigeria
[396] 2007 National HIV/AIDS and Reproductive Health Survey (NARHS Plus 2007)
[397] Epstein, B. G. (2005) *The Demographic Impact of HIV/AIDS*, Chapter1: 1-40

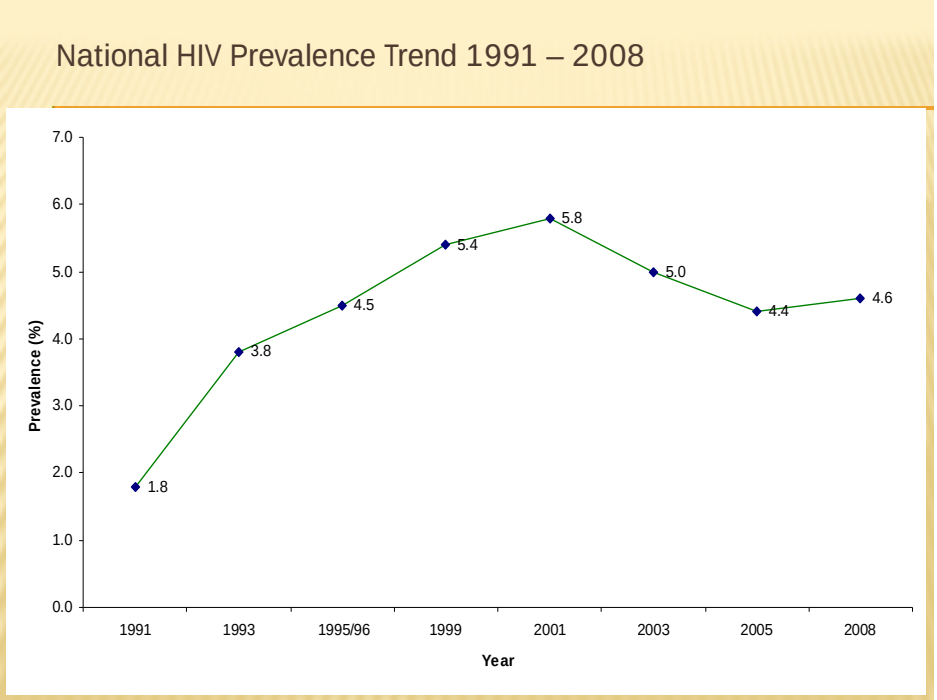

Diagram 1: National HIV Prevalence 1991 -2008

Source: NACA

Disturbingly too is the fact that more than half of the people living with AIDS in Nigeria are women (58%), consequently statistics show that HIV prevalence among women is very high especially among young women between the age of 20 and 39 years.[398] (See Diagram 2) The implication being that many women are getting ill and dying in their reproductive years, and there is also an increase in the number of children born with HIV. It is no wonder that Nigeria has the highest number of AIDS orphans in sub-Sahara Africa aged between 0-17 at an estimate of 1.3 million.[399]

[398] UNAIDS, 2004b
[399] UNAIDS, 2004a

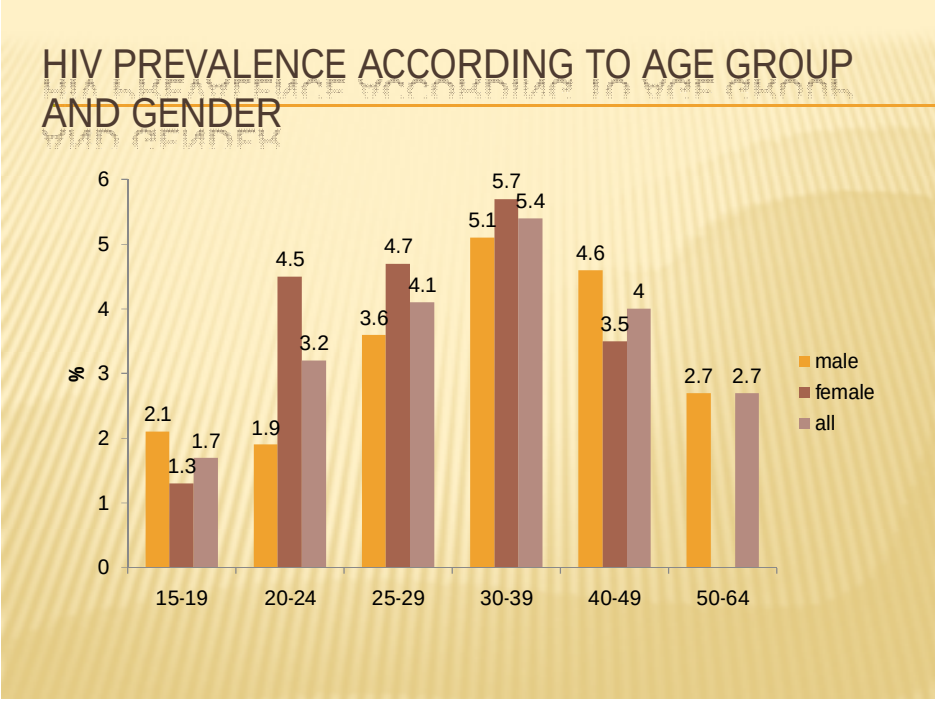

Diagram 2: HIV Prevalence According to Age Group and Gender.
Source: NACA

After South Africa and India, Nigeria has the third highest number of people living with HIV/AIDS. As of 2008 they were over 2.95 million people living with HIV/AIDS in Nigeria. [400] There are several factors that contribute to the spread of HIV/AIDS in Nigeria such as culture and religion. The marriage practices in Nigeria which are sometimes based on culture violate women's rights and have been identified as one of the factors that contribute to the growing HIV prevalence among women and girls.[401] In Nigeria there are three different legal systems, namely civil, customary, and Islamic laws.[402] A Muslim man is allowed to marry as many as four wives. Previously in Nigeria there was no law as to the minimum age a girl could attain before she is given

[400] 2008 National HIV Sero-Prevalance sentinel Survey Among the Antenatal Clinic Attendees. Preliminary Findings
[401] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development pg. 30
[402] Center for Reproductive Law and Policy (CRLP). 2001. Women of the World: Laws and Policies Affecting their Reproductive Lives (Anglophone Africa). New York: CRLP.

away in marriage. Some young girls are married off as early as 10 years and may be married off to men who are more than 50 years older than they are. The northern part of Nigeria has some of the highest rates of early marriage in the world. The Child Rights Act, passed in 2003, rose the minimum age of marriage to 18 for girls. However, the Nigerian federal law can be implemented diversely at the state level (Nigeria has a three tiers of government system. The first which is the federal level includes the Executive, Legislative and Judiciary. The second tier contains 36 States of the federation, and the local government which has 774 local governments) and up until now not many of the 36 states in the country have begun the process of implementing the law.[403] Young girls are therefore at danger of contracting sexual transmittable diseases such as HIV/AIDS, and basically have no protection from the law from being married off at a very young age. (See Diagram 3) Statistics show that 20 percent of girls were married by age 15, and 40 percent were married by the age of 18.[404] Child marriage is extremely prevalent in some regions; in states such as Borno, Yobe, Jigawa and Gombe 48 percent of girls were married by the age of 15.[405] Young girls that are married at such a tender age do not only face the fear of being infected with HIV/AIDS and other STDs but face obstetric fistulas which are a result of prolonged and obstructed labour that is associated with girls giving birth at young ages.[406] The FMOH indicates that between 200, 000 to 400,000 girls are presently living with fistulas, with 100,000 occurring annually.[407]Fistula is a medical condition where there is an abnormal connection between the rectum and the vagina. The diseases can be extremely debilitating.[408]

[403] Corinne Whitaker, personal communication, 2004.
[404] Ibid
[405] http://www.popcouncil.org/pdfs/briefingsheets/NIGERIA.pdf
[406] Yolah, Hajia Kindin.(2001) *Epilogue to childhood encounter*," http://www.unfpa.org/news/news.cfm?ID =268&Language=1, accessed 20 April 2007
[407] Ibid
[408] Wikipedia. The Free Encyclopedia. http://en.wikipedia.org/wiki/Rectovaginal_fistula http://en.wikipedia.org/wiki/Rectovaginal_fistula

Statistics also show that girls between the ages of 15–24 are about twice as likely as boys the same age to be infected by HIV.[409] Married girls due to their age, lack of education and low status in the Nigerian society usually have less knowledge about HIV than unmarried girls. They are less likely to have heard of HIV and are less likely to know that HIV can be transmitted from mother to child.[410] The prevalence rate for HIV varies from state to state with the highest statistic being Cross River (12.0%), Benue (9.3%) and Adamawa (7.5), however the elements that contributes to the spread of the disease is the same. (See Diagram 4) Consequently, the heterosexual route of infection accounts for 82% of all transmission and despite the sexual behaviour of the population, sex is generally a "hush-hush" subject and many people do not discuss it freely.[411] Sex has in the past been perceived as something dirty or evil particularly by religious leaders who often view morality as being determined by a higher order from above.[412] Although the FMOH and the Nigerian Educational Research and Development Council (NERDC) have added sexual education on school curriculums to improve the entire package of development as well as teacher training for schools and family-life programmes, effective sexual education has still remained elusive and almost unattainable in many parts of the country. The inability to implement sex education in some parts of Nigeria through free and open discussions between adults and the younger generations has continued to foster myths and misconceptions about HIV/AIDS and hence and contributed to rising HIV transmission in some communities.[413]

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[409] Estimates range from 4.7 percent to 7.0 percent for girls aged 15–24, and from 2.4 percent to 3.6 percent for boys. UNAIDS. 2002. Report on the Global HIV/AIDS Epidemic 2002. Geneva: UNAIDS.
[410] NDHS 1999. Data are for 15–19-year-olds.
[411] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development. pg 29
[412] Adepoju, Adunola, (2005) *Sexuality and Life Skills Education*. London: PenPress Publishers
[413] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development pg 29

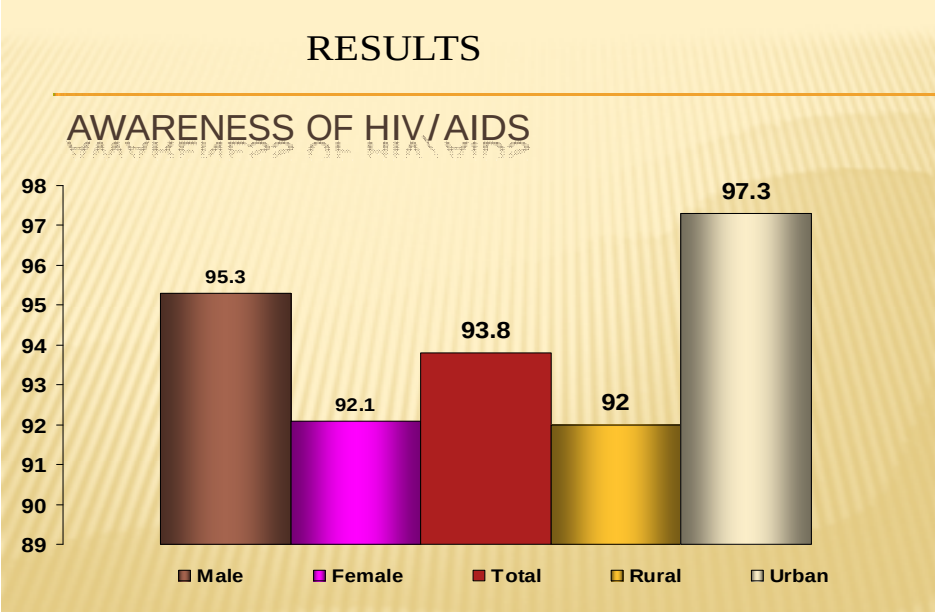

Diagram 3: Awareness of HIV/AIDS

Source: NACA

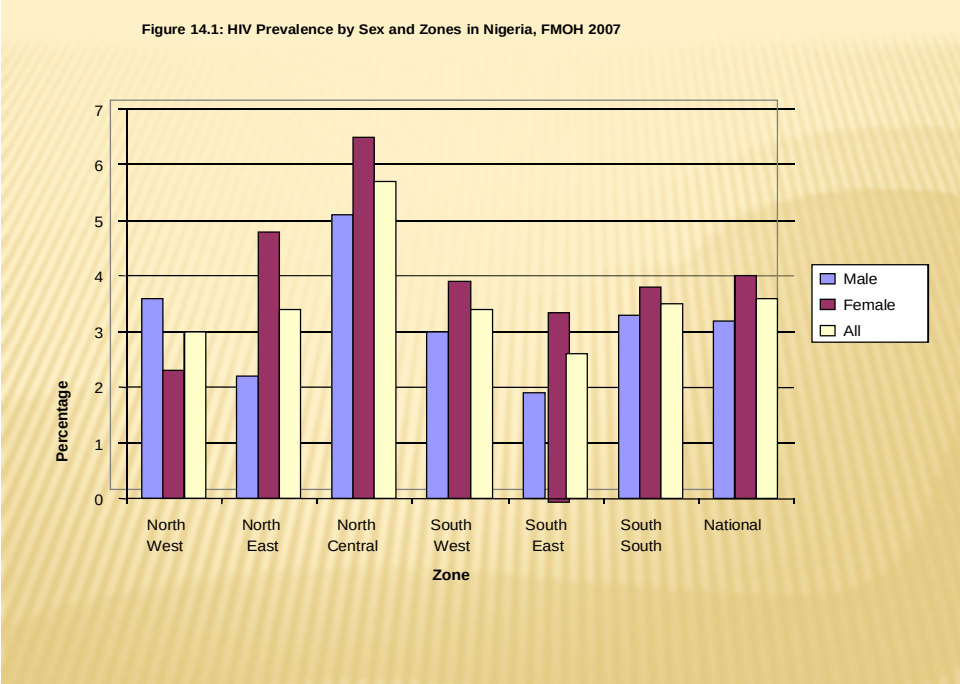

Diagram 4: HIV Prevalence by sex and Zone in Nigeria, FMOH 2007

Source: NACA

5.3 HIV/AIDS crisis in Nigeria put in Human Rights Perspective

Most people living with HIV/AIDS in Nigeria (PLWHA) have therefore been deprived of almost every fundamental human right because they are seen as the "outcast in society", "the lepers", "and the dead among the living". A person living with HIV/AIDS in Nigeria, especially in the rural parts of the country suffer hate, discrimination, rejection, neglect, harassment, humiliation and various acts of unprofessional conduct by health care workers such disclosure of patient records without their consent. They have no one to turn to for reassurance and usually die alone rejected by society. The trepidation of HIV/AIDS stems from the lack of medicines for people infected with the disease. A status quo, some have argued is compounded by the high cost of patented medicines; which is directly linked to article 33 of the TRIPS Agreement..[414] This allows the patent holders charge whatever price they wish, even if the majority of customers cannot afford it. The stigma against the disease is so much so that they are various myths surrounding how to gain access to medicines or protect oneself against the disease. In 2002 a man in Johannesburg was sentenced to life in prison for raping a nine-month old baby. He allegedly raped the baby because he believed the myth that a person can be protected against AIDS if he has sex with a virgin, even if it is a baby.[415] Such myths are not only exclusive to developing countries. Studies by the Henry J. Kaiser Foundation showed that one quarter of Canadians believe that HIV can be transmitted through kissing, mosquito bites, casual contact, coughing and sneezing.[416] However by far the biggest myth that exacerbates such beliefs is that if a person is diagnosed with HIV/AIDS they will die when in fact many people can and do live normal, happy, healthy productive lives with the right medical treatment.[417]

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[415] http://www.thebody.com/content/whatis/art20708.html July, 29, 2002. South Africa Man Jailed for Life for Baby Rape

[416] http://www.thebody.com/content/whatis/art11316.html One-Quarter of Canadians Believe HIV can be Transmitted Through Kissing, Mosquito Bites, Poll says. Accessed 3, December 2005

[417] http://aids.about.com/cs/aidsfactsheets/tp/hivmyths.htm

Many people in Nigeria have no incentive to be tested for HIV or even informed about the result of their assessment if the result is positive, because they feel that they are not likely to have access to antiretroviral. The plight of a person living with HIV/AIDS in most parts of the developing world is very different from people in the developed world. Available medication has given those with HIV/AIDS in the developed world hope thereby prolonging their lives. Among the available medication is the availability of five different kinds of antiretroviral medicines in the form of a complex combination of cocktails. The first is the Reverse transcriptase inhibitors (RTIs), this targets the structure of the viral DNA by slowing down the activity of the reverse transcriptase, the second is the Protease inhibitors (PIs), this targets the viral structure by inhibiting the activity of protease, an enzyme used by HIV to reduce nascent proteins for the final assembly of new virons, the third is the Fusion inhibitors, this blocks HIV from fusing with a cell's membrane to come in and infect it. At present there is only one FDA-approved drug in this class, enfuvirtide, which is marketed as Fuzeon. The fourth is the Integrase inhibitors, this stops the enzyme integrase, which is responsible for the integration of viral DNA into the DNA of the infected cell and lastly the Entry inhibitors which blocks HIV-1 from the host cell by binding CCR5, a molecule on the host membrane termed a co-receptor that HIV-1 normally uses for entry into the cell together with a primary receptor. These antiretroviral drugs disrupt the setting in of the HIV infection, thereby allowing an infected person's immune system to recover.[418] The latter two anti-retroviral are currently under clinical trial and are not commercially available to the public as of yet.[419]

[418] Gustin L.O & Hodge, J.G Jr (1998) *The "Name Debate": The Case for National HIV Reporting in the United States*, 61 Alb. L. Rev. 679, 700
[419] http://en.wikipedia.org/wiki/Antiretroviral_drug

5.4 Violation of the Human Right to Health in Nigeria

Ever since the discovery of HIV in Nigeria, there has been widespread abuse of human rights and violation of fundamental liberties that are essential for a person to live with human dignity and equality. Remarkably however is the fact that section 33 of the Nigerian Constitution 1999 guarantees the right to life of every citizen of the Federal Republic of Nigeria. Some have therefore interpreted this as including the right to healthcare. Section 17 (3) (d) provides that there shall be "adequate medical and health facilities for all persons". The Nigeria government has ratified most human rights treaties and instruments, including the African Charter on Human and People's Rights (ACHPR)[420] which became domestic law by means of the African Charter on Human and People's Rights (Ratification and Enforcement Act, Cap 10, LFN 1990). [421] Article 16 of the Charter also stipulates that state parties to the Charter must take all necessary measures to protect the health of all citizens and ensure that they receive medical attention when they are sick. Nigeria is also a member of the Organisation of African Union (OAU) and ECOWAS, and both regional treaties contain provisions protecting the basic rights of individuals as an essential part of the agreement; other international charters that Nigeria have subscribed to include the UN Charter and the WHO constitution. Both have human rights as their core obligation. In this regard it is fair to say that the right to health is a fundamental part of the fabric of the Nigeria society.

Another violation of the right to health for PLWHA in Nigeria is the fact that is not unusual for people living with HIV/AIDS to be denied treatment because they are carrying the virus. The stigma that comes with the disease means that a person with HIV/AIDS may sometimes be refused treatment by doctors and other health care workers because some medical staff are afraid of being exposed to the diseases. Expired ARVs is another major cause of concern in

[420] This was ratified by Nigeria on 22 July 1983
[421] HIV/AIDS and Human Rights in Nigeria. Background Paper for HIV/AIDS Policy Review in Nigeria. Prepared by the Centre for the Right to Health for the Health for the POLICY Project. September 2003

Nigeria, thus access to medicines should mean access to the right drugs, for example in November 2003, a report showed that expired ARVs were found in 64 per cent of health care facilities. The financial loss amounted to an estimated sum of 19,953,510 Naira[422] (equivalent to $146,717).[423]

5.5 ARV distribution in Nigeria

The Nigeria government commenced procuring ARVs in 1997, and by 2003 there were 25 ARVs that had been collected sporadically of which 9 were patented and 16 were generics.[424] Indeed the effect of patents and the avalibility of medicines in Nigeria cannot be lost on the reader. Nigeria does not have a fully developed pharmaceutical industry like India or Brazil and must therefore rely on importation of ARVs from countries like India and China. Indeed ARVs in Nigeria are procured by the government and stored at the Central Medical Store at Oshodi in Lagos, Nigeria, and on the Essential Medicine List for Nigeria are 8 antiretroviral drugs namely Diadanosine, Lamivudine, Stavudine, Zidovudine, Nerirapine, Indinavir, Nelfinavir and fixed dose combination of lamivudine, Stavudine and Nievirapine.[425] Health facilities throughout the country are required to collect their share of the ARVs from the Central Medical stores in Lagos. Although procurement of ARVs have been done mainly by the government, thus between 2001 and 2004, the Nigerian government spend a total of 2.1 billion naira ($19 million). Charity organisations, international organisations and institutions have also been instrumental in the fight to get ARVs to people suffering from HIV/AIDS. The World-Bank initiated a HIV/AIDS program Development Project to form the structure of the HIV/AIDS Emergency Action Plan (HEAP) for 2001-2004. The main purpose of the project has been to help Nigeria curtail the spread and lessen the impact of HIV/AIDS epidemic that was beginning to take a toll on

[422] The US Dollar was equivalent to 136 Naira at the time of the study.
[423] Situation of ARV Drug Use in Nigeria. November 2003. The Federal Ministry of Health in coloration with World Health Organization.
[424] Ibid
[425] Ibid

the country. The total credit from the World Bank was US$90.3 million, this was to be shared proportionately between 18 (out of the 36) states and the Federal Capital Territory in Abuja, Nigeria.[426] Although it must be noted that this has now been extended to the remaining 14 states. Another such initiative is the Global Fund for AIDS, Tuberculosis and Malaria which as of 2005 had committed $66.46 million Naira to halt and reverse the HIV/AIDS epidemic. [427] The fund was initiated to expand the country's ARV program, to develop six centres of excellence for the Prevention of Mother to Child Transmission (PMTCT), and to sponsor the successful contribution of the Nigerian Civil Society Organisations (CSOs) in the national response to HIV/AIDS.

Britain's Department for International Development (DFID) has also been a major force in providing access to medicines for people living with HIV/AIDS in Nigeria. It has in fact been at the forefront of two HIV/AIDS programme in Nigeria: Promoting Sexual and Reproductive Health for HIV/AIDS Reduction (PSRHH) and Strengthening the National Response to HIV/AIDS (SNR). The latter began in 2002 and will remain functional until 2009.[428] The program aims at sexual and reproductive care among the poor, vulnerable and marginalised people in Nigeria.[429] The programme has set up three agencies: Population Services, SFH, and Action Aid with Nigeria as their chief implementing bodies.

SNR was established in Nigeria in 2004 and is a $25 million 5 year project.[430] Family Health International (FHI) is another program that has taken the lead to

[426] World Bank. Nigeria: HIV/AIDS Program Development Project Appraisal Document, P070291. Washington, D.C: World Bank. 2001.
[427] Global Fund for AIDS, Tuberculosis and Malaria. Portfolio of Grants in Nigeria. Accessed at www.theglobalfund.org/search/portfolio.aspx?lang=en&countryID=NGA on July 1, 2005
[428] Department for International Development. DFID Programmes in Nigeria. London: Department for International Development, May 2005;14
[429] Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD*. Harvard Center for Population and Development
[430] Department for International Development. DFID Programmes in Nigeria. London: Department for International Development, May 2005;14

work with Action Aid-Nigeria and other voluntary Services as collaborating partners in the halt of HIV/AIDS. The program is being implemented in six high prevalence states with the goal of reducing "the impact of HIV/AIDS on the lives and livelihood of poor people in Nigeria."[431] The objective of these organisations and programs has been the continued effort to implement a multi-sectoral, human-rights-based Nigerian response to the epidemic, focusing on selected, high priority locations where DFID's input has made a real difference to improve the situation.

5.6 Nigeria's Response to HIV/AID compared to other Countries that have successfully confronted the Diseases.

Nigeria has set a target year of 2010 to reverse the spread of HIV by a minimum of 25%,[432] the fact however remains that Nigeria needs more access to cheap affordable medicines and an unparalleled motivated national response to quieten the spread of HIV/AIDS. Appraising how some low and middle income countries have been successful in implementing programs and enacting legislation to curtail the spread of HIV/AIDS is a good starting point to evaluate the suitability of Nigeria's response to HIV/AIDS. A good example of a country which has been able to implement a somewhat successful HIV/AIDS management program is Uganda who as early as 1986 developed a behavioural change strategy that has led to the reduction of the HIV prevalence.[433] President Yoweri Museveni[434] was remarkable in instigating a policy that led to a complete revolution in the way HIV/AIDS is responded to and tackled in Uganda. He championed an open, honest and ingenuous discussion on the subject of HIV/AIDS and placed it on the political agenda as an issue to be

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[431] Ibid
[432] Federal Government of Nigeria. *National Policy on HIV/AIDS.* Abuja: Federal Government of Nigeria,
2003. See also Adeyi. O, Kanki.P.J, Odutolu, O, Idoko, J.A (2006) *AIDS IN NIGERIA: A NATION ON THE THRESHOLD.* Harvard Center for Population and Development
[433] Ibid
[434] who became the president of Nigeria since 29 January 1986

addressed and resolved.[435] President Museveni also applied a policy where all pregnant women would be tested for HIV/AIDS, consequently one of the strategies implemented by Museveni to fight AIDS was the ABC program, which stands for "Abstain, Be faithful, or use Condoms if A and B are not practiced. This program was mainly headed by Janet Museveni, the wife of the Ugandan President as part of George Bush's ABC strategy for curbing the spread of the epidemic who said "Giving young people condoms is tantamount to giving them a licence to be promiscuous; it leads to certain death". However this approach does not go without its criticisms, Hillary Benn, the UK's International Development Secretary who was in charge of Britain's fight against AIDS abroad,[436] stated that the ABC program ignores the fact that HIV/AIDS has long been associated with several human rights abuses. For example, in many developing countries where women are considered subordinate in society, they face the dangers of rape and engaging in unsafe sex. Hillary Benn's unease was made unequivocal in a statement in 2006 when he said "I wish we could have been a bit more frank in our declaration about telling the truth that some groups – like sex workers, drug users and men who have sex with men [who] are more at risk… This is not a time for telling it straight because it is about saving people's lives".[437] Critics have asserted that any discriminatory allocation of medications or funding for medications would constitute a violation of the obligation to respect the right to health.

In 2003 the Bush administration introduced the President's Emergency Plan for AIDS Relief (PEPFAR) with the aim of saving the lives of people infected with HIV by providing them with essential medicines and implementing initiatives to curb the spread of AIDS. However like the ABC programme it has been criticised for its emphasis on abstinence and faithfulness being the

[435] Kaleeba N, Kadowe JN , Lalinaki D, Williams G. Open Secret; People Facing
[436] http://www.commondreams.org/headlines04/0711-03.htm
[437] UK Mission To the United Nations New York (2006) 'Statement by Mr. Hilary Benn MP - Follow-up to the outcome of the twenty-sixth special session', 2 June

core of the programme. Surprising as it may seem, even in the 21st century many people still believe that HIV/AIDS is a punishment from God for sexual immorality and a reprimand against gay people from a higher authority, thus in "Launch a Jihad Against [people with] AIDS", the author writes that "The AIDS pandemic should not be considered simply as a disease for which a cure may sooner or later be discovered; it must be viewed in general as a serious sign and a grave warning for adopting a lifestyle of sexual abandon and drug intake, and that even if a cure or vaccine is discovered, new viral mutations will almost certainly surface if rampant promiscuity, homosexuality and drug abuse are not checked."[438] Critics have argued that governments should stop adopting policies that are ideologically and morally based, and begin to adopt scientific and rights based policies that will encourage access to medicines as a human rights for people living with HIV/AIDS. Although it is important to note that in 2008, the Bush Administration passed another legislation pledging 50billion in funding through PEPFAR for AIDS, tuberculosis and malaria over a five year program. The legislation removed the controversial abstinence clause that had previously been sown into the 2003 law.

Evidence suggests that governments which have an open and all-inclusive access to medicines policy are more likely to reverse the spread of HIV/AIDS and other opportunistic diseases. A good example of a country which has been successful in curbing the spread of HIV/AIDS is the Brazilian's government with its policy on free and worldwide access to anti-retroviral medicines (ARVs) for people living with HIV/AIDS.[439] Since 1996, the Brazilian government initiated a program where free generic AIDS drugs have been made available to Brazilian citizens and death rates have fallen by more than

[438] http://www.sodomylaws.org/usa/wackos/wacko034.htm
[439] Galvão J. Brazilian. (2002) policy for the distribution and production of antiretroviral drugs: a privilege or a right? [in Portuguese.] *Cad Saúde Pública*. 18:213–219, Galvão J. Community mobilization and access to medicines: the Brazilian non-governmental responses for the HIV/AIDS epidemic. Text presented at: Harvard Forum on Human Rights in Brazil, Brazil Human Rights Series: Rights to Health; November 3, 2003; Boston, Mass.

half. Likewise opportunistic infection has fallen by 60 - 80 percent and continues to fall dramatically. [440] In 1997, an estimated 35,900 people infected with HIV/AIDS in Brazil were receiving treatment, this number increased to 55,600 in 1998. By 2001 the number increased to 105,000, it further increased to 140,000 in 2004.[441] What has made Brazil stand out as a champion for protecting, enhancing and encouraging human right to health and access to medicines is that although Brazil is a middle-income country with a far smaller gross domestic product (GDP) than countries like the US, and lower per capita health expenditures and technological investments than the UK.[19] The Brazilian government provides ARVs to its citizens free of charge, an act which signifies the government's total commitment towards halting the spread of HIV/AIDS and making the right to health care in the world a priority.

Previously in Brazil, access to health care including medicines was based on "regulated citizenship",[442] a system whereby social rights like retirement pensions and medical coverage were restricted to private sector workers who were paid regular wages. The Brazilian government had created a system of social security based on obligatory contributions by employers and employees that was restricted to those that had a job.[443] By doing this the majority of the population were ignored including people in sectors like agriculture,[444] what this inevitably meant was that Brazil had to run a health care sector which resembled a private health sector. Thus the system was based on the Eloi Chaves Law, and this effectively limited universal and equal access to medicines, however in the 1980s several health care experts and health reform advocates got into government positions and began to reform the health care

[440] See Stephen Buckley (2000) Brazil Becomes Model in Fight Against AIDS, Wash. Post, at A22
[441] Avert: http://www.avert.org/aidstarget.htm
[442] Santos WG. *Cidadania e Justiça*. Rio de Janeiro, Brazil: Campus; 1979.
[443] Paulo Eduardo M. Elias, PhD, and Amelia Cohn, PhD. *Reform in Brazil: Lessons to Consider*.
http://www.ajph.org/cgi/reprint/93/1/44?ijkey=bbcad7e5d31614a75eb6b3def1b973245dfcd907
[444] Ibid

sector by way of decentralizing the health care system. Change came in 1988 when the Brazilian public health system was reorganised with the adoption of a new constitution. [445] The new Constitution brought with it the Unified Health System (Sistema Único de Saúde [SUS]).[446] The SUS was instrumental in offering free comprehensive health care to the entire population, regardless of employment status or access to other forms of health insurance. To sustain this policy, the government had to limit the drug high cost by producing some ARVs domestically and by consulting with international pharmaceutical companies to import other ARVs.[447] The Brazil government response to HIV/AIDS has been phenomenon and the steps it has taken are seen as bold and ambitious by many and this has resulted in domestic industries producing at least five generic HIV/AIDS medicines.[448] Not only that, but recently Brazil also made full use of the flexibilities within the TRIPS Agreement in the form of compulsory license.

In April 2007 Brazil issued a statement stating that it would be issuing a compulsory license to import Merck's Efavirenz from India. Note that it is estimated that 210,000 people live with HIV/AIDS in Brazil and 180,000 are receiving free antiretroviral from the government, 38 percent of them use Efaviirenz.[449] Efavirenz had been identified as one of the best choices for the initial treatment of HIV Treatment.[450] The Brazilian government's strategy for

[445] Elias PE, Cohn A. (2003) *Health reform in Brazil: lessons to consider*. *Am J Public Health*.;93:44–48.
[446] Mattos RA. Os sentidos da integral-idade: algumas reflexões acerca dos valores que merecem ser defendidos. In: Pinheiro R, Mattos RA, eds. *Os Sentidos da Integralidade na Atenção e no Cuidado à Saúde*. Rio de Janeiro, Brazil: IMS/UERJ/ABRASCO; 2001: 39–64., Souza RR. *O Sistema Público de Saúde Brasileiro*. Brasília, Brazil: Ministry of Health; 2002. Available at: http://dtr2001.saude.gov.br/editora/produtos/livros/pdf/02_0784_M.pdf. Accessed April 4, 2005.
[447] Oliveira-Cruz V, Kowalski J, McPake B. (2004) *Viewpoint: the Brazilian HIV/AIDS 'success story'—can others do it*? Trop Med Int Health. 9: 292–297
[448] James Thuo Gathii. (2001) *Construing Intellectual Property Right and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-end Consumers*. 53 Fla. L. Rev. 727
[449] *Brazil Takes Steps to Import Cheaper AIDS Drugs Under Trade Law* . IP_watch
[450] *Abigail Zuger*. AZT/3TC/Efavirenz Is a Good Choice for Initial HIV Treatment. Journal Watch (General) *January 20, 2004*

providing access to medicines and controlling the costs of HIV/AIDS medicines has not been without challenges from the US and pharmaceutical companies. In 2001 Brazil was involved in an international dispute about its program of access to AIDS medicines. [451]In that year, the World Trade Organization (WTO) accepted a request for a panel by the United States, which was challenging Brazil's patent laws. These laws in a nutshell permitted the compulsory license of patents under special conditions. At its heart, the US challenge brought into question Brazil's commitment to producing ARVs nationally. The United States was concerned about the likely patent violations that would occur as a result of Brazil's program, the dispute was however resolved amicably.

The South Africa government faced a similar upheaval in 1997 when it attempted to pass its Medicines and Related Substances Act in order to allow the governments regulate the marketing and distribution of medicines in South Africa. The law sought to allow the use of compulsory licensing and parallel importation of cheaper drugs and generic substitution for brand name drugs from countries such as Brazil and India. At the time there were at least 4.2 million people living with HIV/AIDS in South Africa [452]and the price for antiretroviral cocktails could cost between $10,000 to $15,000 per year, a price which was far more than what an average person living with HIV in South Africa could afford to pay.[453] The issue was compounded when the pharmaceutical companies refused to provide the drugs to South Africans at a lower price or to allow them manufacture cheaper generic versions. The group of pharmaceutical companies argued that the Medicines and Related Substances Act would violate their ownership of drug patents and their intellectual property rights. The pharmaceutical companies further argued that

[451] Galvão J. (2002) *Access to antiretroviral drugs in Brazil.* Lancet.;360: 1862–1865
[452] http://www.bmj.com/cgi/content/full/322/7284/447?view=full&pmid=11222409
[453] See Gathii, J.T (2002) *Rights, Patents, Markets and the Global AIDS Pandemic,* Florida Journal of International Law, 14 : 261-352

such infringement could undermine the funding of future scientific research.[454] When the South African government went ahead and passed the law, the Pharmaceutical companies filed a law suit against the South African government to prevent them from implementing the Act. There was of course an international public uproar and pharmaceutical companies were forced to drop the law suit in order to preserve their public image.[455] The concern of many activist at the time were twofold, firstly they sought to confront the effects that intellectual property was having on access to AIDS drugs. Secondly they wanted to see a situation where governments in developing countries would be allowed to use the flexibilities within the TRIPS Agreement to gain access to cheap drugs for all epidemics that were confronting their nations. Access to medicines in this case became not only a human rights issue, but a constitutional one. South Africans had the constitutional right to human dignity, life and health care. The South African government felt the need to meet its obligation of realizing its citizen's right to health care.

Nigeria has no manufacturing capacity to produce any of the antiretroviral for PLWHA and must therefore enter into agreements with countries that produce generic AIDS medicines such as Brazil and India. In 2001, Nigeria entered into an agreement with an India-based manufacturer to offer low priced treatment to many HIV/AIDS patients despite resistance from multinational pharmaceutical companies. [456] Nigeria faces a grave situation with its fight against HIV/AIDS hence of the 600,000 people who are in need of

[454] Ibid at 271
[455] Barbara Noah (2003) *AIDS and Antiretroviral Drugs in South Africa: Public Health, Politics, and Individual Suffering: A review of Brian Tilley's my life*. 31 J.L. Med. & Ethics 144
[456] Chris McGreal, Defiant Nigeria to Import Cheap Copies of AIDS Drugs, THE GUARDIAN, Dec. 11, 2001, at 2 available at http://www.guardian .co.uk/aids/story/0,7369,616827,00.html.

antiretroviral medicines only 20,000 is receiving it.[457] Nigeria is still struggling to establish the appropriate policies and approaches to deal with the HIV/AIDS crisis, some commentators assert that it is the Nigerian government's national response that has fuelled the HIV/AIDS epidemic and other opportunistic diseases rather than the TRIPS Agreement. Senegal for example also recorded the presence of HIV/AIDS in their nation in 1986, the same year that Nigeria did. However they have managed to keep their HIV/AIDS prevalence level at a low of 2%.[458]

5.7 The Nigerian Government's National Response

The government's national response has passed through different stages in Nigeria. Real efforts and government commitment began in 2001 after the Doha Declaration, when the government began to allocate human and financial resources to prevent of the halt the epidemic. The Nigerian civil society organisations (CSO) and other international organisations became involved in finding a solution to the health crisis. Consequently the HIV/AIDS Emergency Action Plan (HEAP)[459] was established in 2001 which pursued a multisectoral national response to HIV/AIDS. The program provided for HIV prevention intervention, research efforts and demonstration service delivery projects which were at the time seen as the solution to a successful national response of any country HIV/AIDS management program.[460]

The response was divided into a public and civil society national response. The public sector response to the HIV/AIDS epidemic began with the FMOH co-ordinating the national response. The health sector HIV/AIDS strategy was co-

[457] AIDS Funding on the Ground in Nigeria http://www.npr.org/templates/story/story.php?storyId=4701306
[458] UNAIDS, UNAIDS report for 2003: most deaths and new infection ever; some good news. AIDS Treatment News, 2003;396:2
[459] Federal Government of Nigeria. National Policy on HIV/AIDS. Abuja: Federal Government of Nigeria, 2003
[460] AIDS in Nigeria: A Nation on the Threshold. 2006. Harvard Center for Population and Development Studies. Pg 243

ordinated by the Department of Disease Control and the major focus was on prevention and health promotion (this involved offering support for the advancement of broad-based programs to teach the general population about HIV/AIDS, targeting intervention to high risk groups), treatment (this involved increasing access to services to diagnose and manage STIs) health standards and health systems (this involved setting up national standards for the public, private and community-based delivery of HIV/AIDS prevention, health promotion, and treatment and care) and informed policy and strategic development (which consisted of establishing and strengthening and behavioural surveillance for HIV and other STIs and rallying communities, NGOs, People living with HIV and AIDS (PLWHAs), vulnerable groups, and other business sector).

However the change of strategy came when the Nigerian government sought to concentrate on a multisectoral national HIV/AIDS response under HEAP 2000-2004. HEAP involved the development of national policies, monitoring HIV/AIDS and other sexual transmitted diseases, co-ordination of development partners, blood safety and more importantly access to medicines for people that were already living with HIV/AIDS as well as PMTCT. The HEAP was fundamentally successful because for the first time in Nigeria, political commitment and co-operation was given to alleviate the epidemic by the president, politicians and other governmental officials without question or reluctance. This was immediately after the re-establishment of democracy in the form of a civilian rule under President Olusegun Obasanjo in 1999. The president established the Presidential Committee on AIDS which include several governmental ministries and technical experts. At the federal level National Action Committee on AIDS (NACA) dealt with HIV/AIDS prevention and control, at the state level co-ordination was done through state action committee on AIDS (SACAs) and on the local level this was managed by the local Action committee on AIDS (LACAs). Some of the features that

made the HEAP successful were the development of skills and the availability of resources. Nigeria was able to attract funding from the World Bank, USAID, DFID, the Bill and Melinda Gates Foundation, and the Ford Foundation. The government was able to attract a budget to the tune of $236million, apart from the $40 million national government contribution that budgeted over a three to five year period.[461] The fact that several international projects began in the country at the same time meant huge success and more access to ARVs for people with HIV/AIDS. Nevertheless HEAP was again reviewed in 2004 where many gaps were identified. Access to services for PMTCT and ARV treatment were found to be lacking; states were not adequately motivated to action, and co-ordination in the centre was insufficient. A new plan known as the National HIV/AIDS Strategic Framework was thereby established in 2005. Also worth noting is the Nigerian National Response Information Management System for HIV/AIDS (NNRIMS) which was set up by NACA to monitor, evaluate and report on HIV/AIDS initiatives and their impact on the country. Such initiatives point to a struggling nation undergoing a "national emergency" and fighting to provide help to her citizens and access to medicines regardless of the cost of medication and health services. [462]

Mother to child transmission of HIV was and still is a huge major public health crisis in Nigeria. In 2001, the FMOH initiated a national PMTCT programme and the service provision began in July 2002 in eight tertiary institutions in the six geo-political zones of Nigeria (namely North West, North East, Central North, South East, South West, and South South) with the assistance of the AIDS Prevention Initiative in Nigeria (APIN) and United Nation Children Fund (UNICEF), although by 2005 and with the help of the United States, the

[461] Ibid at 249
[462] Federal Ministry of Health. Nigeria National Response Information Management System (NNRIMS) Guidelines and Indicators. Abuja: Federal Ministry of Health, 2004

number of sites had increased to 66 sites.[463] The co-ordination of the program is principally done by the FMOH, the task team which comprises of obstetrics, gynaecologist, paediatrics and nurse, and core partners provide technical and financial assistance to the program. The program has one of the most efficient monitoring and evaluation systems and provides nevirapine prophylaxis which is essential in reducing transmission, although it has been suggested that ARV regimen has to be reconsidered in the breastfeeding population, whilst the use of the triple therapy –zidovudine, stavudine, and nevirapine of highly active antiretroviral therapy (HAART) for HIV positive women. The goal of the National PMTCT Programme in Nigeria is to reduce the transmission of HIV from mother to child. The objectives of the programme include: to ensure that 50% of HIV positive pregnant women and their babies access ARV by 2010 for PMTCT; to increase access to obstetric practices that reduce the risk of mother to child transmission of HIV by 50% by 2010 and ensure that all HIV positive mothers, their partners and all HIV infant gain access to ARV.

Interestingly, the Federal government response to HIV was considered to be efficient, so much so that by 2001, the national AIDS program in Nigeria was proclaimed the largest antiretroviral treatment program in Africa with an annual allocation of $3.7 million for the procurement of ARVs from India. [464] In 2002 the Nigerian government started an ambitious ARV treatment programme to get 10,000 adults and 5000 children unto ARV within a year.[465] An initial $3.5 million worth of ARV were imported from India and delivered at subsidized monthly cost of $7 per person. In 2004, the programme suffered a major setback when it was hit by a shortage of drugs. This meant that some

[463] SCALE UP PLAN On Prevention of Mother to Child Transmission (PMTCT) of HIV in Nigeria. Federal Ministry of Health. 2005

[464] See Abantu for Development. Empowering Youth Through Comprehensive Reproductive Health Programs. London/Accra: Abantu for Development,(2004) and ActionAid/Nigeria. Mapping Civil Society's Involvement in HIV/AIDS Programmes in Nigeria. Abuja: Action Aid, 2001

[465] Odutolu, O, Ahonsi, B.A, Gboun, M & Jolayemi, O.M (2006) AIDS in Nigeria: A nation on the threshold'. Chapter 11: The National Response to HIV/AIDS. Harvard Centre for Population and Development Studies.

people did not receive treatment for up to three months. Eventually, another $3.8 million drugs were then ordered and the programme resumed. In 2001, Ranbury Nigeria, a subsidiary of Ranbury India, India's largest pharmaceutical company signed an agreement with the Nigerian government to supply ARVs manufactured at its plant in Lagos. In the same light, in 2004 Archy Pharmaceutical also set up a plant to manufacture ARVs in Lagos. These efforts were made to increase the availability of ARVs to people in Nigeria and other West African Countries.[466] The significance of these establishments cannot be overstated because it shows a commitment to confronting the problem of a lack of medicines for people living with HIV/AIDS. Similarly developments have shown the possibility of a widespread therapy for HIV/AIDS in the country. The price of advanced antiretroviral (ARV) drugs which can effectively suppress the AIDS virus in infected people has fallen from $12,000 to under $200 per year. In addition, ARV treatment regimens have been greatly simplified by decreasing dosing and monitoring requirement and decreased toxicity.

The Nigerian government has in recent time's demonstrated clear and solid commitment to providing antiretroviral (ARV) treatment to people living with HIV/AIDS. Public health expenditure increased from 0.3 percent of GDP in 1996, the lowest of any country in the world, to 0.5 percent of GDP in 2000.[467]. However despite Nigeria's staunch efforts in fighting the disease, there is still much to be done in scaling up HIV/AIDS services. AS at 2004, few Nigerians still had access to basic HIV/AIDS prevention, care, support or treatment services. Around 520,000 people are estimated to require ART (antiretroviral therapy) and only 170,000 are currently receiving treatment. As 2004, there were 50 treatment sites for HIV/AIDS in Nigeria.[468] According to Luppe's report, patients lucky enough to be included in Nigeria's national

[466] Reuters News Media 2004
[467] (UNDP 2003)
[468] PlusNews, 2005

treatment programme paid 1,000 Naira (US $7) per month for their ARV drugs.[469] However, this fee did not cover the cost of drugs required to treat opportunistic infections, nor frequent laboratory tests which were necessary and had to be paid for separately. Although, there have been substantial efforts from international organizations, one of such organisations is the Ford Foundation which has worked closely with national governments to create deep talent pools of professional and community leaders knowledgeable about the best practices for preventing and treating HIV/AIDS and supporting them in taking action to assist those living with the diseases; in so doing ensuring equal access to HIV prevention.[470] Other international efforts to provide ARV to people living with HIV/AIDS include PEPFER's pledge to put 120,000 people on ARV between 2006 and 2011, and the Global Fund grant which has been instrumental in giving people living with HIV/AIDS hope.

Another major channel through which Nigeria has sought to confront HIV/AIDS epidemic is through civil societal interventions. Such intervention has come mainly from faith-based and community based organisations that operate on a small-scale care and welfare system.[471] Other interventions have come from Nigerian civil society organisations. A good example is the STOPAIDS which is a Lagos based CSO launched an HIV prevention education which branches in Onitsha, Lagos, and Port-Harcourt for long-distance truck drivers. The civil society areas of concentration have been mainly focused on condom use promotion, youth-focused intervention, people living with HIV/AIDS care and support, including organising for self-help and advocacy, HIV prevention and VCT among high-risk groups, mass media engagement, training and mobilization and legal reform advocacy and legal aid

[469] Plus News, 2005
[470] FORD FOUNDATION. HIV/AIDS. http://www.fordfound.org/fields/hivaids/overview
[471] Ahanihu E. Closing Ranks: An Account of Nigeria's Response to HIV/AIDs, 1986-2003. Ibadan: Spectrum Books. 2005 and Touray KS. Mapping of Support Groups for People Living with HIV/AIDS (PLWHAs) in Nigeria: National Report. Abuja: National Action Committee on AIDS, 2005

for people living with HIV/AIDS. The Nigerian chapter of the Society Women and AIDS in Africa (SWAAN) has also provided prevention education, voluntary HIV counselling and community home-based HIV care service among low-income women across Nigeria, including sex workers.[472] The media has also played a huge part in promoting access to medicines for people living with HIV/AIDS. Also worth mentioning has been the work done by the Journalists Against AIDS (JAAIDS). JAAIDS was formed in 1997 and sought to contribute to the prevention, care and control of HIV in Nigeria by educating and building the skills of media professionals reporting on AIDS and pursing media-based advocacy. The most significant advocacy campaign embarked by JAAIDS has focused on the issue of access to HIV treatment and community participation in stigma reduction. These efforts still have a long way to go in making a real difference when compared with the prevalence of HIV/AIDS in the sub-Sahara.[473]

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[472]See Mba ND. Youth for Youth, Gender and Development NGOs: Report of a mapping Exercise Prepared for the Ford Foundation. Ford Foundation, 2004 and Society for Women and AIDS in Africa Nigeria. SWAAN Profile. 2003

[473] Table below is from AVERT http://www.avert.org/subaadults.htm and it states that an estimated 22 million adults and children were living with HIV in sub-Saharan Africa at the end of 2007. The estimated number of adults and children living with HIV/AIDS, the number of deaths from AIDS, and the number of living orphans in individual countries in sub-Saharan Africa at the end of 2007 are shown below.

Country	People living with HIV/AIDS	Adult (15-49) rate %	Women with HIV/AIDS	Children with HIV/AIDS	AIDS deaths	Orphans due to AIDS
Angola	190,000	2.1	110,000	17,000	11,000	50,000
Benin	64,000	1.2	37,000	5,400	3,300	29,000
Botswana	300,000	23.9	170,000	15,000	11,000	95,000
Burkina Faso	130,000	1.6	61,000	10,000	9,200	100,000
Burundi	110,000	2.0	53,000	15,000	11,000	120,000
Cameroon	540,000	5.1	300,000	45,000	39,000	300,000
Central African Republic	160,000	6.3	91,000	14,000	11,000	72,000
Chad	200,000	3.5	110,000	19,000	14,000	85,000
Comoros	<200	<0.1	<100	<100	<100	<100
Congo	120,000	3.5	43,000	6,600	6,400	69,000
Côte d'Ivoire	480,000	3.9	250,000	52,000	38,000	420,000

Whilst both the public and private sector of Nigeria can be commended for its courageous and ambitious HIV/AIDS programs which have contributed to

Dem. Republic of Congo	400,000-500,000	1.2-1.5	210,000-270,000	37,000-52,000	24,000-34,000	270,000-380,000
Djibouti	16,000	3.1	8,700	1,100	1,100	5,200
Equatorial Guinea	11,000	3.4	5,900	<1,000	<1,000	4,800
Eritrea	38,000	1.3	21,000	3,100	2,600	18,000
Ethiopia	980,000	2.1	530,000	92,000	67,000	650,000
Gabon	49,000	5.9	27,000	2,300	2,300	18,000
Gambia	8,200	0.9	4,500	<1,000	<1,000	2,700
Ghana	260,000	1.9	150,000	17,000	21,000	160,000
Guinea	87,000	1.6	48,000	6,300	4,500	25,000
Guinea-Bissau	16,000	1.8	8,700	1,500	1,100	6,200
Kenya	1,500,000-2,000,000	7.1-8.5	800,000-1,100,000	130,000-180,000	85,000-130,000	990,000-1,400,000
Lesotho	270,000	23.2	150,000	12,000	18,000	110,000
Liberia	35,000	1.7	19,000	3,100	2,300	15,000
Madagascar	14,000	0.1	3,400	<500	<1,000	3,400
Malawi	930,000	11.9	490,000	91,000	68,000	560,000
Mali	100,000	1.5	56,000	9,400	5,800	44,000
Mauritania	14,000	0.8	3,900	<500	<1,000	3,000
Mauritius	13,000	1.7	3,800	<100	<1,000	<500
Mozambique	1,500,000	12.5	810,000	100,000	81,000	400,000
Namibia	200,000	15.3	110,000	14,000	5,100	66,000
Niger	60,000	0.8	17,000	3,200	4,000	25,000
Nigeria	2,600,000	3.1	1,400,000	220,000	170,000	1,200,000
Rwanda	150,000	2.8	78,000	19,000	7,800	220,000
Senegal	67,000	1.0	38,000	3,100	1,800	8,400
Sierra Leone	55,000	1.7	30,000	4,000	3,300	16,000
Somalia	24,000	0.5	6,700	<1,000	1,600	8,800
South Africa	5,700,000	18.1	3,200,000	280,000	350,000	1,400,000
Swaziland	190,000	26.1	100,000	15,000	10,000	56,000
Togo	130,000	3.3	69,000	10,000	9,100	68,000
Uganda	1,000,000	6.7	520,000	110,000	91,000	1,000,000
United Rep. Of Tanzania	940,000	5.4	480,000	130,000	77,000	1,200,000
Zambia	1,100,000	15.2	560,000	95,000	56,000	600,000
Zimbabwe	1,300,000	15.3	680,000	120,000	140,000	1,000,000
Total sub-Saharan Africa	22,000,000	5.0	12,000,000	1,800,000	1,500,000	11,600,000

reducing in ARV prices globally. Other challenges that Nigeria has had to face in providing access to medicines include budgetary shortfalls and discontinuous release of funds, inventory control and distribution problems, inadequate laboratory backstopping, human resource scarcity and training deficiencies, health care infrastructure deficits, inadequate involvement of people living with HIV/AIDS and related community groups, poor technical guidance, support and co-ordination for all treatment centres to forge a comprehensive ARV program[474] and counterfeit medicines.[475]

5.8 NACA

One of the most recognised efforts that have been made by the Nigerian government to combat the HIV/AIDS epidemic is through the work of National Action Committee on AIDS (NACA). The advert of democracy in 1999 in Nigeria brought with it a renewed commitment to tackle the public health problem of the nation and in 2001, the government set up a three-year HIV/AIDS Emergency Action Plan (HEAP). In the same year, the government hosted OAU's first African Summit on HIV/AIDS, Tuberculosis, and Other Related Infectious Diseases[476]. Both gestures indicated an unprecedented national response to the HIV/AIDS epidemic that was ravaging the country at the time. In 2004, NACA launched a five year behavioural change communication strategy to combat the spread of HIV/AIDS through the National Strategic Framework (2005-2009), NACA has also set up Nigerian National Response information Management System Operational Plan, which has 9 Specific Objectives that are listed below**:**

[474] Ibid at pg 257
[475] This will be discussed in detail below.
[476] Adeyi et al. (2006) *AIDS in Nigeria: A nation on the threshold'*. Chapter 2: The epidemiology of HIV/AIDS in Nigeria. Harvard Center for Population and Development Studies.

1. 1. To develop the requisite infrastructure for monitoring and evaluation in Nigeria
2. To develop the required human resource capacity across levels of the national response.
3. To harmonize indicators and standardize data tools and collection systems.
4. To coordinate and strengthen second generation surveillance and HIV/AIDS operational research.
5. To develop a database or clearing house for all strategic information on the national response.
6. To define clear roles and responsibilities in monitoring and evaluation across different levels and sectors of the system
7. To facilitate efficient data transmission and feedback flow
8. To outline how data collected by NNRIMS should be used
9. To mobilize adequate financial and material resources to support full operationalization of the monitoring and evaluation plan (2007- 2010)

NACA's response to the HIV/AIDS has been nationwide and is done through a multi-sectoral platform of network activity which involves the National Policy on AIDS, the BBC Strategy, Work Place Policy, The Vaccine Plan, the Policy on Ethics for Human Research, the Policy Environment –Sectoral Plans, the Health Sector Plan, the Education Sector Plan, the AFPAC policy and Plan, the Ministry of Internal Affairs Plan –Prisons, Immigration and Civil Defence, the National Commitment, NEEDS and SEEDS.

NACA also has the full support of other international organisations including: The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), The World Bank – MAP and the Malaria Initiative, US President's Emergency Plan for AIDS Relief (PEPFAR) & US President Malaria programme, The Bill and Melinda Gates Foundation and other development partners - DFID, JICA, The French Cooperation, CIDA and other international bodies who are committed

to helping the Nigerian government reverse the Spread of HIV/AIDS in the country.

NACA has also sought to raise awareness that AIDS is real through campaigns targeted at Behavioural CHANGE including FLHE, zip up, condom,. It has set up condom vending machine as well as voluntary counselling and testing; other efforts include PMTCT, providing treatment in the form of OIs, ARVs.

NACA has promoted its campaign through the National Youth Network, CISHAN, NEPWHAN, Faith Based Advisory Council and the public sector which comprises of 28 line ministries and the Primary Health Care Development Agency. Interesting enough NACA has recorded results in Increasing 85% in both urban and rural areas. NACA has recorded behavioural changes, for example the ages in which young people are first having sexual intercourse has risen, the number of people using condoms when have extra marital sex has risen to 61%, sex workers have increased the usage of condoms to 83%, and there are now over 160 ART Sites. Indeed the new government under the presidency of Umaru Musa Yar'Adua which began in 2007 has continued to work already began by the last administration of trying to tackle the HIV/AIDS epidemic. Whether the national response of the Nigerian government will amount to a reversal of the HIV/AIDS epidemic remains to be seen and will be judged by the target it has set itself of reducing HIV prevalence by 25% by 2010, preventing 55% of new HIV infections by 2010, placing 550,000 HIV positive persons on treatment by 2010 and providing care and support services for 1.6 million HIV positive persons by 2010.

5.9 Summary

The Nigerian government has struggled to come to terms with initiating ways of tackling the HIV/AIDS epidemic, nevertheless there continues to be a high percentage of people living with the diseases. The issue of HIV/AIDS is

clearly a human rights issue which is supported by section 17 (3) (d) and 33 of the Nigerian Constitution, however the government has in the past struggled to fulfil these obligation with regards to providing medicines for its citizens. Although the government must be commended for adopting a miltisectoral approach which has sought to get international bodies, private charities, NGOs, civil societies, private sectors and private individuals involved in the fight for access to medicines, it still has some way to go before it can reach its NACA objectives of reducing HIV prevalence by 25%, preventing 55% of new HIV infections, placing 550,000 HIV positive persons on treatment and providing care and support services for 1.6 million HIV positive persons by 2010 or the Millennium Development Goals (MDGs) of access to medicines for all HIV/AIDS patients by 2015.

Empirical evidence of countries that have succeeded in drastically reducing the prevalence rate of the HIV/AIDS epidemic show that countries must put in place laws so that the rule of law and due process can be the cornerstone of all its policies and initiatives. This in turn enables the government to meet its obligation. The Brazilian government has succeeded in curbing the spread of HIV/AIDS with its policy on free and worldwide access to anti-retroviral medicines (ARVs) for people living with HIV/AIDS.[477] To sustain this policy, the Brazilian government had to limit the drug high cost by producing some ARVs domestically and by consulting with international pharmaceutical companies to import other ARVs. Today Brazil domestic industries produce at least five generic HIV/AIDS medicines. Although Nigeria relies on help from international organisations and donors in order to purchase ARV medicines, the question remains will it continue to rely on them to provide medicines for the millions of people that will need access to medicines? If Nigeria amended

[477] Galvão J. (2002) *Brazilian policy for the distribution and production of antiretroviral drugs: a privilege or a right?* [in Portuguese.] Cad Saúde Pública. 18:213–219, Galvão J. Community mobilization and access to medicines: the Brazilian non-governmental responses for the HIV/AIDS epidemic. Text presented at: Harvard Forum on Human Rights in Brazil, Brazil Human Rights Series: Rights to Health; November 3, 2003; Boston, Mass.

its patent laws and became TRIPS compliant, it would be able to take advantage of the flexibilities within the TRIPS Agreement to meet its human rights obligations, which in my opinion is a great place to start to meet all other obligations that may arise with ensuring access to medicines for Nigerians.

6 NEGLECTED DISEASES, DRUG COUNTERFEITING AND HUMAN RIGHTS

6.1 Introduction

The human rights community is becoming increasingly aware of neglected diseases and addressing problems associated with access to drugs.
Professor Paul Hunt

The most dangerous goods on the market are counterfeit drugs and 'People are interested in getting a profit, but this is a human rights issue...the consequences of this business are really immense... a person with severe malaria: if he or she cannot access the genuine drug, then it means they may die.
Edith Ngirwamungu, president of the Medical Association of Tanzania.

This chapter seeks to address neglected diseases and counterfeit medicines as human rights issues in the access to medicine debate. It seeks to do this in order to identify whether these are the real obstacles to accessing medicines as opposed to the TRIPS Agreement. In doing this, the chapter examines what challenges other jurisdictions have encountered in solving the problem of neglected diseases as well as confronting the problem of counterfeit medicines. The way that it seeks to do this is by confronting the issues as two distinct international issues that need an all round response by both states and non-state actors such as NGOs and the private sector. By examining the problem of counterfeit medicines on a state by state level, the reader is able to better appreciate the access to medicine problem as an international problem which needs international solution.

Recently the international community has called for the issue of neglected diseases to be given more consideration and solutions found. Thus in April 2003, the UN Commission and the UN General Assembly passed a human rights resolution on neglected diseases to specifically recognise the need for

"further international corporation and research to promote the development of new drugs, vaccines and diagnostic tools for diseases causing a heavy burden in developing countries, and stresses the need to support these countries in their efforts in this regard, taking into account that the failure of market forces to address such diseases has a direct negative impact on the progressive realization in these countries of the right of everyone to the highest attainable standard of physical and mental health"[478] In the same manner the international community has called out for solutions to be found for the global trading in counterfeit drugs which has claimed the lives of so many.

Whilst many commentators have called for WHO to actively get involved in counterfeit medicines as a serious public health crisis, concerns that counterfeit can only be tackled as a violation of IP rights issue have remained unanswered. Paraguay on behalf of the Latin American and Caribbean countries (GRULAC) put it succulently when she said" Counterfeit is an infringement of an IP right [and] injures a rights holder of a trademark ... the typification of this infringement does not include health criteria."[479] That being said the fact that counterfeit is a human right to health issue that cannot in my opinion be ignored. The confusion extends to the direction that the international law enforcement agency INTERPOL and IMPACT should be following in order to tackle the problem. Whilst reports shows that INTERPOL is investing more effort and attention to Africa as the main target markets for counterfeit traders because of the high level of corruption, unregulated medicines and poverty, evidence point to the fact that most counterfeit medicines come from China and other Asian countries where the penalty for trading in counterfeit medicines is not efficiently checked by the government. Whilst Nigeria has played a tremendous role in reducing the trade of counterfeit drugs in Nigeria through the work of NAFDAC and its active role in IMPACT, a lot still

[478] UN General Assembly, A/C.3/58/L.53, 17 November 2003, para.13.
[479] Mara. K (2008) Hope for Consensus on WHO And Counterfeits Moves To May Assembly. Intellectual Property Watch. 9 December 2008.

remains to be done in order to completely eradicate the trade in counterfeit drugs. The situation is made more serious by the fact that China is becoming a world power[480] and has began to form strong ties with Nigeria and many other African countries. Thus as Chinese government and companies sign more contracts with African leaders to build more roads, import goods and mine natural resources, the fear remains that there will be more avenues for the influx of counterfeit medicines if the situation is not tackled in the near future. It is with this background in mind that this chapter tackles the access to medicines problem.

6.2 Neglected Diseases: a Symbol for Neglected People

Neglected diseases are a group of tropical disease that are deadly and widespread, yet have no sufficient treatment and affect a large number of people who are often deprived and live in low income developing countries.[481] People suffering from neglected diseases often lack affordable or easy to use drug treatment because they are usually too poor and cannot afford to pay for medications.[482] What makes the case for neglected diseases more disturbing is that most of the diseases that affect low income developing countries can be treated or prevented with medicines, however pharmaceutical companies have in the past been reluctant to conduct R&D into neglected diseases.[483]The inability for poor countries to pay for the medication generally has acted as a deterrent for pharmaceutical companies who have no interest in investing in a market where they cannot make financial profits.[484] Whilst the pharmaceutical industries have generally tried to stay away from investing in neglected diseases, they have found R&D into life-style drugs (life style drugs is a term

[480] Reports show that China will rival US as world power by 2010. Chinadialy.com.cn. Updated 2006-06-02 . http://www.chinadaily.com.cn/china/2006-06/02/content_607496.htm
[481] Hunt, P. (2003) *Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations. Health and Human Rights* Working Paper Series No 4.
[482] Yamey. G. (2002) *The world's most neglected diseases Ignored by the pharmaceutical industry and by public-private partnerships*. BMJ; 325:176-177 (27 July)
[483] J Drews, trans D Kramer (2003) In Quests of Tomorrows Medicines : 234
484 Neglected Diseases. http://www.answers.com/topic/neglected-diseases

which is generally used by the media to target "medical conditions" which are considered unworthy of treatment. Lifestyles medicines includes medications which treat conditions such as baldness, impotence, wrinkles, and obesity) particularly attractive.[485]

Pharmaceutical companies have also found it particularly attractive to invest in "evergreening". Thus the EGA report on patent-related barriers has expressed concern that the 'evergreening' technique can and is being used as a way to have follow-on patents and keep generic competitors off the market. These follow-on patents are often weak or trivial and, upon careful examination should not be granted patents)[486] and modification of chemical entities marketed by competitors to obtain a drug in an existing market.[487]

Neglected diseases fall amongst the three categories of diseases affecting the world today. The other two are global diseases (like cancer, diabetes and cardiovascular diseases which affect people both in developed and developing nations and usually forms the major focus of pharmaceutical industries around the world) and most neglected diseases which are totally ignored by pharmaceutical companies and public- private partnerships.[488]

Statistics show that between 1975 to 1999, only 13 drugs out of 1,393 New Chemical Entities (NCE) marketed were aimed at neglected diseases.[489] Out of the 13 drugs, only 4 were for the treatment of malaria and nine for other neglected diseases.[490] By 2003 only 26 NCE for neglected diseases had been

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[485] Wikipedia http://en.wikipedia.org/wiki/Lifestyle_drug.
[486] EGA REPORT | May 2008. *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*
[487] Holmer, A.F (31 May 2002) *Innovation is Key Mission*' USA Today
[488] Yamey. G (2002) *The world's most neglected diseases Ignored by the pharmaceutical industry and by public-private partnerships*. BMJ; 325:176-177 (27 July)
489 Deficient market and a public-health policy failure. See Trouiller, P. et al. (2002) Drug development for neglected diseases: a deficient market and a public-health. Lancet, 359, 2188–2194:
490 Ibid

developed from a total of 1556 NCEs produced between 1975 and 2004. It follows that investments in health R&D have never been higher nevertheless only a small percentage of that money has actually been spent on developing medicines for tropical diseases. This has raised much concern for human rights activists and academics alike. Similarly global spending on health research has increased from US$30 billion in 1990 to US$105.9 billion in 2001. Further statistics also show that tropical diseases which often fall in the category of neglected diseases account for 90% of the global disease burden, but only 10% of the world's health budget was spent on it.[491] Of the 10%, kudos must go to India and China who have some of the biggest generic industries because most of the NCEs were derived from their efforts and the fact that they also face the same health issues and have had to find medicines for neglected diseases has added to their minor R&D interest.

Although, India has demonstrated some interest in developing NCEs for neglected diseases through its strong innovative capabilities in developing manufacturing processes and has increased its R&D into new drug development. On the down side is the fact that India is not engaged in the entire process of drug development because they lack the skills and resources to do so. This has made India follow the bandwagon of MNCs and made the Indian pharmaceutical companies focus on drugs that are targeted at diseases that affect high-income countries as opposed to neglected diseases that affect poor developing counties.[492] Another major factor that has contributed to the lack of medicines for neglected diseases is the fact that the pharmaceutical environment is a highly competitive global market place and this has turned drugs from being used as a public health tool into a profit making

491 Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, et al. (2002) *Drug development for neglected diseases: A deficient market and a public-health policy failure*. Lancet 359:2188–2194.
492 Chaudhuri, S (2005) *R&D for Development of New Drugs for Neglected diseases How Can India Contribute* March 31

commodity.[493] Thus the absence of R&D into medicines to treat diseases that affect mainly people in developing countries are evidence of the fact that the priorities of pharmaceutical companies are highly guided by market prospects and benefits[494] and the attitude of "no profit - no cure" has become the norm.[495]

6.3 R& D for Neglected Diseases

Drug production has been left mainly in the hands of the private sector has compounded the problem of lack of R&D for medicines that are needed in many poor countries.[496] Jeffrey Sachs stated that "poor country governments lack the means to subsidize R&D, and patent protection means little when there is no significant marketer at the end of the process. The result is that the R&D for diseases specific to poor countries tends to be grossly underfinanced. The poor countries benefit from R&D mainly when the rich also suffer from the same diseases."[497]

In the early twentieth century neglected diseases posed a constant threat to armies during the wars, foreign settlers, and European business communities who were stationed in developing countries were also at risk from tropical diseases. Overcoming tropical diseases was therefore a vital necessity that concerned the colonial 'masters'. It was with this objective that the London and Liverpool Schools of Tropical Medicine were established in 1899 to study tropical disease to treat the many British citizens who were dying of tropical

493 Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, et al. (2002) *Drug development for neglected diseases: A deficient market and a public-health policy failure.* Lancet 359:2188–2194

494 Ibid

495 Els Torreele, Martine Usdin, & Pierre Chirac. 31 July 2004. *Needs- based pharmaceutical R&D Agenda for Neglected diseases.* http://www.who.int/intellectualproperty/topics/research/Needs%20based%20R&D%20for%20neglected%20diseases%20Els%20Pierre%20Martine.pdf

496 Fisher W.W and Syed. T (2007) *Global Justice in Healthcare: Developing Drugs for the developing world.*. 40 U.C. Davis L. Rev. 58

497 Commission on macroeconomic and Health, Macroeconomics and Health: Investing in Health for Economic Development (2001) 77.

diseases This case is clearly pointed out by the availability of medicines for malaria and tuberculosis (note the word used is availability not affordability).[498]For example many people in developing countries cannot afford to pay for malaria drugs, however most of the westerners that travel to developing countries can. In the same way, many people who have tuberculosis in developing countries may not be able to pay for treatment but there are sufficient patients in developed countries to persuade pharmaceutical companies to invest in medicines for tuberculosis. All the same, developing countries still find it difficult to gain access to medicines for diseases suffered in both developing and developed countries. Thus statistics show that 611,000 people die from measles each year, 155,000 from syphilis, and 1,778,000 from diarrhea in developing countries. Note that in developed countries people rarely die from such diseases, they are more likely to die from global diseases such as cancer and heart diseases [499] The fact that people affected by neglected diseases are therefore at the mercy of the pharmaceutical industry that set the agenda for drug development and R&D is therefore undisputed.

It follows that whilst HIV/AIDS, tuberculosis and malaria (known as the Big Three) receive a lot of media attention as neglected diseases which more R&D and the attention of the international community, the argument follows that other neglected diseases need the same level of media attention as well. Thus Professor Molyneux argues that political and media attention over the last few years have led to resources to conduct R&D being transferred to fight the "big three" which only has a limited chance of success, other disease such as Kala-azar (Leishmaniasis), African Sleeping Sickness (African trypanosomiasis), Chagas disease (American trypanosomiasis) , Lymphatic Filariasis (elephantiasis) , Onchocerciasis (river blindness) , Drancunculiasis (guinea worm) , helminthiases:, Ascariasis (roundworm) , Trichuriasis

[498] Yamey. G (2002) *The world's most neglected diseases Ignored by the pharmaceutical industry and by public-private partnerships*. BMJ; 325:176-177 (27 July)
[499] Fisher, W W and Syed T. (2007) *Global Justice in Healthcare: Developing Drugs for the developing world*. 40 U.C. Davis L. Rev. 581

(whipworm), Hookworm , Leprosy, Buruli ulcer and Trachoma are being ignored.

6.4 Tuberculosis

Tuberculosis is one of the most widespread diseases in the developing world and one of the leading infectious killers after HIV/AIDS, thus it puts the serious need to find medicines for neglected diseases into perspective. In 1993, WHO confirmed that tuberculosis presented a global health emergency, by 2006 many developing countries including the federal government of Nigeria had declared the diseases a national emergency.[500] The WHO Global tuberculosis Control Report in 2006 showed that they were approximately 9.2 million new cases of tuberculosis,[501] the same report showed that 1.7 million people had died of tuberculosis in 2006 of which 14% were HIV-positive.[502]

Tuberculosis is the leading killer of people living with HIV/AIDS and the inadequacy of tools to diagnose and treat tuberculosis has been a major threat to the health and lives of HIV/AIDS and tuberculosis co-infected people.[503] At the 17th International Conference in Mexico, respondents called for new strategies such as expanded screening in health care setting to have early diagnosis of HIV and tuberculosis.[504] Reuters report notes that patients with HIV/AIDS are 50 times more likely to develop tuberculosis than those who do not have HIV, however the Report showed that only 314,394 people had been tested for tuberculosis out of the supposed 33 million HIV-positive people who had the disease worldwide.[505] A report showed that $900 million needs to be

[500] Abubakar Sani. Nigerian Newsday. Nasarawa Weekly Newspaper
[501] GLOBAL HEALTH REPRORTING. ORG http://www.globalhealthreporting.org/tb.asp
[502] Ibid
[503] WHO REPORT 2008 Global Tuberculosis Control. SURVEILLANCE, PLANNING, FINANCING
[504] Alice Carver. Tuberculosis, a Threat for People Diagnosed with HIV/AIDS. August 8th 2008. http://www.efluxmedia.com/news_Tuberculosis_a_Threat_for_People_Diagnosed_with_HIV AIDS_21827.html
[505] Ibid

invested annually in the development of new tools for tuberculosis, but only $206 million was invested in 2005, and the funding gap is expected to widen over time. As recently as 2008 a WHO report showed that in the US, only $20 million was spent on clinical trials for drugs for tuberculosis, in comparison to the $300 million that was being spent on HIV drugs annually, this point out the disparity of the financial resources allocated to different diseases. Thus a report showed that a dramatic funding increase is needed to support R&D tuberculosis. Interestingly diseases like leishmaniasis, a parasitic and highly infectious disease spread by sand flies hardly gets any allocation even though it is endemic in 88 countries however the most commonly used drug is now 70-years-old and toxic.[506]

Many have expressed surprise at the lack of R&D into diseases that affect poor countries, stating that interpreted to suit developing countries, the TRIPS Agreement, at least in theory provides incentives that encourage R&D that ensures that drugs are manufactured to treat neglected diseases. Article 7 of the TRIPS states that the "protection and enforcement of the intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conductive to social and economic welfare, and to a balance of rights and obligations".[507]

Whilst the TRIPS envisages that technological advances would increase the pharmaceutical industry's ability to control infectious diseases worldwide, there has been little or no progress towards drug discovery and development aimed at neglected diseases in poor countries. It is therefore important that more is done to ensure collaboration among scientists, drug developers, care providers, and affected individuals in both developed and developing

506 MSF Report
507 TRIPS AGREEMENT

countries, and develop a global priority research agenda to eradicate tuberculosis.

6.5 Partnership Initiatives into R&D for Neglected Diseases

Regardless of the foregoing, many speculators have recorded some progress in confronting the lack of medicines for neglected diseases. In this regards, there has been some positive response by the pharmaceutical industry and charitable organisations to bring medicines to the "neglected patients" of the world. Indeed there has been many diseases control initiatives by numerous international partnerships and many of these programs have been successful in curtailing tropical diseases.[508] Until recently riverblindness was a major problem confronting the African continent but has gradually been eradicated with the help and cooperation of the pharmaceutical industry.[509] By 1974, the first control program known as the Onchocerciasis Control Program (OCP) was launched and treated over 30 million people. By 1992 another control initiative program called the Onchocerciasis Elimination Program for the Americas (OEPA) was formed; subsequently in 1995, the African Programme for Onchocerciasis Control (APOC) was formed and provided medicines for millions of people living with Onchocerciasis.[510] However by far the most far reaching strategy to eliminate the spread of Onchocerciasis was the initiative by Merck in 1988 which sought to provide ivermectin to millions of people in eleven countries, thus statistics suggest that at least 65 million people receive ivermectin annually and this has near enough brought the diseases under control.[511]

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[508] Molyneux DH. (2004) Neglected" diseases but unrecognized successes -- challenges and opportunities for infectious disease control. Lancet ;364:380-383
[509] Chibuzo Odigwe. (2003) River Blindness. Student BMJ : 11:437-480 December
[510] Boatin BA, Richards FO Jr. (2006) *Control of Onchocerciasis.* Adv Parasitol ;61:349-394
[511] Hotez PJ, Ottesen E, Fenwick A, Molyneux D (2006) . *The neglected tropical diseases: the ancient afflictions of stigma and poverty and the prospects for their control and elimination.* Adv Exp Biol Med;582:22-33.

Similarly, other renowned pharmaceutical companies have begun to take note of the need to provide more medicines to fight neglected diseases. For example Pfizer has partnered with the International Trachoma Initiative to donate azithromycin as part of a comprehensive program to eliminate trachoma.[512] GlaxoSmithKline's coalition with WHO, Merck, and the Global Alliance to eliminate lymphatic Filariasis has led to the control of lymphatic filariasis which was a public health problem in Egypt, Samoa, and Zanzibar.[513] Patent pools are another way which pharmaceutical companies have sought to conduct more R&D into neglected diseases. A good example of this is the U.S FDA priority review voucher. This legislature was passed in order to create an incentive to register NCEs for most neglected diseases. Whilst there are no PRVs traded yet, some have stated that a PRV is worth more than 300 million dollars.[514] UNITAD has created a patent pool for second generation AIDS drugs whilst Gilead, J&J and Merck have agreed to negotiate with them.

Interestingly GSK has taken a low profile on the UNITAID proposal and refused to plainly exclude HIV/AIDS in their announcement and are limiting their proposal to an upstream R&D proposal. This has led many public health experts to interpret this as a sign that GSK is not interested in the model presented in the UNITAID patent pool. Nevetheless it is important to note that GSK, AstraZeneca PLC, Novartis AG and other major pharmaceutical companies have made commitments to tackle neglected diseases, and set up research institutes to specifically focus on neglected diseases. A recent report indicated that pharmaceutical companies have launched more than 60 projects

[512] Kumaresan J. (2005) Can blinding trachoma be eliminated by 20/20? Eye;19:1067-1073.
[513] Molyneux DH.(2006) *Elimination of transmission of lymphatic filariasis in Egypt.* Lancet;367:966-968 and Mohammed KA, Molyneux DH, Albonico M, Rio F (2006) Progress towards eliminating lymphatic filariasis in Zanzibar: a model programme. Trends Parasitol;22:340-344 and Ramzy RMR, El Setouhy M, Helmy H, et al. Effect of yearly mass drug administration with diethylcarbamazine and albendazole on bancroftian filariasis in Egypt: a comprehensive assessment. Lancet 2006;367:992-999 and Levine R, What Works Working Group. Controlling trachoma in Morocco. In: Millions saved: proven successes in global health. Washington, DC: Centre for Global Development, 2004:83
[514] James love. KEI reaction to GSK announcement on patent pool for neglected diseases. 19. February 2009

to treat neglected diseases and the report is optimistic that nine or ten medicines could become available by 2010.[515] Whether or not this will become a reality remains to be seen.

Apart from the partnership initiative, India's pharmaceutical companies plays a very important role in global R&D for NCEs but most of their R&D is conducted into diseases affecting high-income countries. The India pharmaceutical industry also faces the challenge of finding partners to collaborate with in order to undertake successful R&D investments in manufacturing new drugs. They have had to depend on its government, R&D institutions, academic institutions such as universities and colleges and international agencies to provide funding for R& D. Chauduri points out that the government and the higher education sector account for 78 per cent of R&D expenditure, whilst the remaining 22 per cent comes from the private sector. Pharmaceutical R&D expenditure in India between 1998-1999 was estimated at 6000 million of which 63 per cent of it was contributed by the pharmaceutical industry.[516] Commentators have therefore raised the question of why the pharmaceutical industry around the world, especially in the developed world have continuously lobbied to make stronger patent rules applicable in developing countries if they consider the markets in third world countries to be inconsequential and unprofitable. One of the best answers to this question is that MNC want to prevent price leakage of cheap pharmaceuticals from developing world into developed countries; a scenario which usually occurs with parallel importation.[517]

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[515] Justin Gills. (2006) *Cure for Neglected Diseases: Funding Large Doses of Donations Will Lead to New Drugs.* Washington Post Staff Writer. Tuesday, April 25, , Page Q01. http://www.washingtonpost.com/wp-dyn/content/article/2006/04/24/AR2006042401570.html

[516] See Laxman Prasad (2002) Drugs & Phama Research in India – Govt Initiatives". Paper presented at the Workshop on TRIPS Pharmaceutical Industry and Health, October 7-8, Indian institute of Management Calcutta. Prasad is Advisor, DST, which publishes the R&D Statistics in India.

[517] This will be discussed in a latter chapter.

Commentators assert that the allocation of resources to R&D should be reformed to address the health crisis of the developing world in order to safeguard the economic, health and security interest of the developed world.[518] Questions such as whether the profits of manufacturing a drug is more important than finding cures of diseases if they can be found have arisen in recent times.[519] The idea that an era of globalisation should bring with it a level of integration in all sectors including health care that transcends countries and borders has added value to the access to medicines debate.[520] Thus the increase in international travel and tourism has unavoidably increased the possibility that diseases will pass from developing countries to the developed world if not halted. Some of the most prevalent diseases that have had a spill over effect on developed countries are HIV/AIDS, Malaria and Tuberculosis, hence the situation is made more dire especially as new resistance to previous inoculations or treatments have become more pronounced;[521] nevertheless there is the argument that the spill over effect of diseases from the developing world to the developed world only carries weight with diseases that are contagious. That argument does not hold when one considers the financial burden that neglected diseases have on the healthcare systems of many developed countries.

In 2007, Jon Snow did a program on the BBC showing the effects of immigration on the UK. The program showed that it cost NHS millions of to treat tuberculosis, HIV/AIDS that came from developing countries. The lack of medicines to treat infections in developing countries has also been linked to the spread of terrorism in the developed world. Indeed poor health and underdevelopment are interrelated, thus commentators have argue that the

[518] Fisher W.W and Syed. T (2007) *Global Justice in Healthcare: Developing Drugs for the developing world.* 40 U.C. Davis L. Rev. 581
[519] Randhawa. G.K (2006) *Orphan Dieases and Drugs.* Ind J Pharmacol; 38: 171-76)
[520] This not to say that health care or medicines should be free, that would not make sense, however it should be equally available and affordable.
[521] See Working Group 2 of the Comm'n on Macroeconomics and Health, World Health Org., Global Public Goods for Health 4-11, 47-57, 50 tbl 3.1. (2002)

eradication of poverty in developing countries might diminish the threat of terrorism which some believe is a direct result of poverty and resentment. Branko Milanovic comments that "resentment breeds terrorism"[522] Hatred of the west has been the bedrock of terrorist activities and this has led some to argue that this is fuelled by the "unfair trading system" between developing countries and developed countries. The genesis of this is usually affiliated with the key periods of European colonization between the 1500 and 1900s and the post- World War II era of decolonization manifested by an international structure in which Western dominance has been affixed in the power of the US.

The US spends roughly 50 Billion dollars on pharmaceutical research per year, which is approximately half of the world expenditure on pharmaceutical research.[523] However the question is not what the world spends on R&D but how much should it spend on R&D for neglected diseases for nations that cannot afford to pay for their own R&D. For example the richest 1 percent of the world (50 million people) receives as much income as the bottom 57 per cent (2.7 billion) of the world.[524] Such clear disparity promotes an inequality of global resources that could be targeted towards R&D for neglected diseases. This had led commentators to assert that R&D dollars should be allocated in the manner that will achieve results in the access to medicines problem for the majority of the world.

In 2001 at the 37th Summit of the OAU (Organisation of African Unity) formally adopted the strategic framework document known as New Partnership for Africa's Development (NEPAD). The NEPAD strategic framework

[522] Larry Elliott & Charlotte Denny, Top 1% Earn as Much as the Poorest 57%, Guardian (London), Jan. 18, 2002, at 21.
[523] William W. Fisher & Talha Syed, Drugs, Law, and the Health Crisis in the Developing World (forthcoming
[524] See Branko Milanovic, (2002) *True World Income Distribution, 1988 and 1993: First Calculation Based on Household Surveys Alone*, 112 Econ. J. 51-92

document arose from a mandate given to the five initiating Heads of State (Algeria, Egypt, Nigeria, Senegal, and South Africa). NEPAD was an undertaking by African leaders to maintain a common vision and a firm and shared conviction, that they have a pressing duty to eradicate poverty and to place their countries, both individually and collectively, on a path of sustainable growth and development and, at the same time, to participate actively in the world economy and body politic. The Programme is anchored on the determination of Africans to extricate themselves and the continent from the malaise of underdevelopment and exclusion in a globalising world. What stood out through the formation of NEPAD was that it constituted a bold and unprecedented declaration of African responsibility for Africa's future.[525]

At Kananaskis in Canada, African leaders also presented the NEPAD document to the G8 for endorsement and support. The African leaders had a main objective of finding ways into inciting pharmaceutical research into neglected diseases. Although criticized for not dealing specifically with epidemic diseases, the NEPAD document recognizes that "unless the epidemics of AIDS, tuberculosis and malaria are brought under control, real gains in [African] development will remain an impossible hope." Indeed, the African leaders have asserted that nothing short of a massive international initiative can even begin to contain and control HIV/AIDS, tuberculosis and malaria.

Likewise other commendable efforts to tackle lack of R&D for neglected diseases include the DNDi (Drugs for Neglected Diseases initiative) which was set up in 2003 to promote co-operation between developing countries and developed countries in developing new drugs, raising awareness for neglected

525 AFRICA: A RISK WORTH TAKING Presentation by Ms. Connie Freeman
Regional Director for Eastern and Southern Africa,
Canada's International Development Research Centre (IDRC)2002 National Policy Research Conference
Ottawa (ON), October 24, 2002

diseases, and building public responsibility and leadership in addressing needs of patients. [526] Part of the DNDi's agenda included developing new drugs by building a portfolio that will make better use of drugs, raise awareness of the need for R&D for neglected diseases and build up existing capacity in disease endemic countries. It capitalized on existing, fragmented R&D capacity, especially in the developing world, and complemented it with additional expertise as needed.

Amongst all the international efforts that has been put forward to tackle the issue of lack of medicines for people living with neglected diseases, one of efforts that stand out the most include the product-development partnerships in drug R& D set up by certain individuals and philanthropic organisations. . A survey carried out in April 2005 showed that a total of US$212 million had been donated for R&D into neglected diseases, 78.5% of which came from the Bill & Melinda Gates Foundation although public funding in R&D for neglected diseases was still as low as 16%. Worthy of mention also is the fact that the British Government announced in March, 2006 that a substantial additional funding of 17 million pounds (or about $30 million) would be donated for R&D into neglected diseases, a funding gap of several hundred million dollars is still needed in order for there to be adequate R& D into neglected diseases.[527]

Lack of R&D is a serious issue that needs to be confronted so that people living in the developing world can have more hope for the future. Indeed most countries in the developing world have a population of people suffering from neglected diseases who have no access to medicines, it is also their

526 2003 by five public sector institutions – the Oswaldo Cruz Foundation from Brazil Indian Council for Medical Research, the Kenya Medical Research Institute, the Ministry of Health of Malaysia and France's Pasteur Institute; one humanitarian organisation, Médecins sans Frontières (MSF); and one international research organisation, the UNDP/World Bank/WHO's Special Program for Research and Training in Tropical Diseases (TDR

[527] .P Chirac , E . Torreele. Global framework on essential health R&D . The Lancet , Volume 367 , Issue 9522 , Pages 1560 - 1561

responsibility to ensure that their governments made concrete efforts to invest in developing their local pharmaceutical industries and improving the use of their traditional medicines for therapeutic purposes where applicable.[528] A report by WHO's Commission on Intellectual Property Rights, Innovation, and Public Health, released April 3, 2005 urged WHO to develop a Global Plan of Action to secure enhanced and sustainable funding for developing and make accessible products to address diseases that disproportionately affect developing countries.[529] The bitter reality nevertheless remains that although it may not make economic sense for pharmaceutical companies in the developed world to invest in R&D for medicines for neglected diseases, the terrible reality of people suffering around the world and the fact that half of the world population is perishing without access to medicines is a public responsibility for the governments of the world.

6.6 Drug Counterfeiting

WHO's definition of a counterfeit drug is: "a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."Note that Article 51 of the TRIPS Agreement allows suspension of release by customs authorities of goods suspected to be counterfeit.

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[528] Sudip Chauduri. (2005) *R&D for Development of New Drugs for Neglected Diseases. How Can India Contribute.*

[529] WORLD HEALTH ORGANIZATION EXECUTIVE BOARD. EB117/9. 117th Session 22 December 2005. Provisional agenda item 4.10 Intellectual Property rights, Innovation rights, Innovation and Public Health.,; Donor funding priorities for communicable disease control in the developing world. Shiffman *Health Policy Plan*...2006; 21: 411-420; Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? Attaran and Gillespie-White *JAMA*.2001; 286: 1886-1892.

Counterfeit drugs are a public health problem and therefore a serious hazard that endangers people's lives and prevents access to genuine medicines in developing world. In 2003, the World Health Organisation (WHO) report showed that 10 % of all medicines worth $32 billion sold worldwide were fake and counterfeit drugs. Other studies have also showed that the pharmaceutical industry losses approximately $46 billion a year to counterfeit drugs.[530] The harms of counterfeit drugs in Nigeria and other developing countries cannot be underestimated, thus the former Director General of National Agency for Food and Drug Administration Control (NAFDAC), Dr Dora Akunyili compared counterfeit drugs to "terrorism against public health [and] an act of economic sabotage".[531] The Center for Medicines in the Public Interest predicted that counterfeit drug sales will reach $75 billion globally by 2010, a more than 90 percent increase from 2005. One of the major reasons for this is that the laws and enforcement agencies in many countries are so lax that in Argentina for example, it is not a crime to change the expiration date on a drug unless it is proven that doing so will damage someone's health. There is strong evidence to suggest that counterfeit drugs are slowing leaking into the supply chains of western countries, thus there are 70,000 packages of counterfeit drugs hidden inside legitimate medicines that are smuggled into the United States through the JFK and Miami airports every day.[532] Similarly in February 2009, over 70,000 packets of fake medicines which originated from China were discovered to have been distributed by the NHS.[533]

The developing world is where most counterfeit drugs are manufactured and where most victims live. Statistics show that in some of these countries up to

[530] Counterfeit Drugs: Infected with Greed. http://www.inthesetimes.com/article/2845/
[531] Keynote Address by Prof. Dora Akunyili, Director General National Agency for Food and Drug Administration of Heads of West Africa Drug Regulatory Agencies Held at the ECOWAS Secretariat, Asokoro, Abuja, on 17th March 2006.
[532] Ibid
[533] Joel Taylor. Thousand given fake drugs by NHS. METRO newspaper. February 3, 2009

half the drugs are counterfeit.[534] Majority of these counterfeit medicines are produced in countries like China, India and other parts of South East Asia. The destructive nature of the unlawful trade in counterfeit drugs are well recognized, thus the report from the EC states that "the marketing of fake goods does considerable damage to [patent] rights holders, as well as law-abiding manufacturers and traders and more and more attention is being drawn to the dangers to the consumers' health and safety." Counterfeit drugs cause serious injury and death and lead to drug resistance which inevitably undermine the effectiveness of legitimate drugs. All these are a basic violation of the right to medical care under Article 25 of the UDHR and the right to health under 12 of the ICESCR. What makes the situation more poignant is that people in the developing world already face a host of public health problems and do not have the economic power to purchase medicines, however counterfeit drugs worsens the existing burden of poverty.

Counterfeit drugs have killed a lot of people in Nigeria. Dr Dora Akunyili stated that "The evil of fake drugs is worse than the combined scourge of malaria, HIV/AIDS and armed robbery put together. This is because malaria can be prevented, HIV/AIDS can be avoided and armed robbery may kill a few at a time, but counterfeit/fake drugs kill in mass. The social problem posed by hard drugs, cocaine, heroine etc. cannot also be compared with the damage done by fake drugs, because illicit drugs are taken out of choice, and by those that can afford them, but fake drugs are taken by all and anybody can be a victim".[535] Thus Nigeria has a long history of problems with counterfeit drugs. The first well reported case of deaths caused by counterfeit medicines was in

[534] International Policy Network. (IPN) http://www.policynetwork.net/main/press_release.php?pr_id=103 .
[535]Prof. Dora N. Akunyili (D.G of NAFDAC) Strategies employed in combating Drug Counterfeiting in Nigeria, A workshop organised by World Health Organisation (WHO) in Collaboration with Italian Medicines Agency (AIFA) and the International Federation of Pharmaceutical Manufacturers and Association (IFPMA), held in Rome, Italy, 16th-18th February. 2006

the 1980's when the malaria drug for children, chloroquine syrup killed many children in the University of Nigeria Teaching Hospital in Enugu. In 1990, 109 children died in Ibadan and Jos from taking paracetamol syrup which contained a poisonous substance ethylene. Similarly in 1996, a clinical trial was conducted in Kano by Pfizer for Trovan during the outbreak of the meningicoccal meningitis during which 200 people died. It was further reported that at least 15,000 Africans died as a direct result of the clinical trial conducted by Pfizer.

Pfizer's illegal clinical trial in Nigeria was also a violation of Nigerian law and the international Declaration of Helsinki that regulates ethical medical research and the U.N. Convention on the Rights of the Child.[536] The Nigerian Federal Government consequently filed a law suit against them demanding for N890bn ($6.9bn) damages, however the case was eventually settled out of court in 2007. Another case of counterfeit drugs causing deaths took place in 2003, when the counterfeit cardiac stimulant (adrenaline) killed 3 children during an open heart surgery. In 2004, hospitals in Nigeria also reported that 4 Nigerian companies were producing contaminated infusions; further investigation confirmed that the infusions produced by the companies were contaminated with microorganisms. In the case of fake antiretroviral medicines there were reports of counterfeit antiretroviral in Zidovudine, Lamivudine, Indinavir in Cote d"Ivoire in 2003. Regardless of the foregoing by far the most common counterfeit drugs in Nigeria are antibiotics, malaria drugs and vitamins.

6.6.1 The Need to have a Common Definition for Counterfeit Drug

Commentators have asserted that in order to fight the war against counterfeit drugs successfully, there should be a consensus on the definition of the term counterfeit drugs. There should also be an effective collection and comparison of data with the goal of implementing the necessary measures to combat

[536] http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338.html

counterfeit drugs. Under Nigerian law counterfeit and fake drugs are defined as " any product which is not what it purports to be; or b) any drug or drug product which is coloured, coated powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labelled in the prescribed manner or which label or containers or any thing accompanying the drug bears any Statement, design or device which makes a false claim for the drug or which is false or misleading; or c) any drug or drug product whose container is so made, formed or filled as to be misleading; or d) any drug product whose label does not bear adequate direction for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe usage or methods or duration of use; or e) any drug product which is not registered by the agency in accordance with the provisions of the Food, Drugs and Related Products Decree 1993, as amended."

Pakistan's Manual of Drug Laws defines a counterfeit as "a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive the label or outer packing of a drug manufacturer"

The US defines counterfeit drugs as : "a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, of device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than, the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

The Philippines definition of counterfeit medicines is similar to WHO's definition, it states that "...medicinal products with correct ingredients but not in the amounts as provided there under, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity, a counterfeit drug is deliberately and fraudulently mislabelled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products"[537]

All the various definitions of counterfeit drugs have led some commentators to suggest that there is need for an international convention on counterfeiting of pharmaceuticals, just as there is a common consensus on the definition of narcotics and psychotropic substances. This it is believed will ensure a harmonized regulation of pharmaceutical products in international commerce. It follows that the severity of the problems of counterfeit medicines is a huge international problem that must be tackled collectively, if it is to be tackled effectively and trans-national counterfeiters caught and persecuted sooner than later

6.6.2 Counterfeit drugs: a Flourishing Business in Developing Countries in South America

The trade in counterfeit is particularly attractive for criminals and this has enabled the trade flourish and provide a lucrative venture for fraudsters. One of the reasons why the business of counterfeits drugs is growing is because most regulatory oversight and law enforcement agencies in developing countries are weak.[538]According to Peru's Association of Pharmaceutical Laboratories in Peru the sale of counterfeit drugs rose from an estimated US$ 40 million in

[537] The Republic Act No. 82036
[538] Deadly Imitations. http://www.paho.org/English/DD/PIN/Number23_article3.htm (Accessed 23 April 2008)

2002 to a US$ 66 million.[539] Evidence gathered from South American countries reports that recent developments in Pan American Health Organizations (PAHO) show a high activity in counterfeit drugs. These data comprise drugs that enter the country as contraband, contaminated, expired, counterfeits with altered or mislaid labels and those stolen from warehouses.[540] In the Dominican Republic, roughly 50 per cent of all medicines operate illegally. Thus in 2005, 10 percent of medicines imported were counterfeits.[541] In Lima the numbers of illegal pharmaceutical stores dealing in counterfeit medicines in 2002 were estimated to be as high as 18,000. Thus trading in counterfeit medicines was so rampant that the Lima General Directorate of Medicines, Supplies and Drugs of the Department of Health seized approximately 460,000 expired medicines in 2005.

Mexico has also had to tackle the problem of counterfeit drugs infiltrating the markets. In the case of Mexico, the case for counterfeit medicines is more crucial because of the thousands of Americans who cross the border every year to buy medicines in order to save money buying prescription drugs in the US.[542] For this reason trading in pharmaceuticals is an extremely lucrative business in Mexico, and the estimated total sales to foreigners exceeds two hundred million dollars annually. In 2002, the number of illegal pharmacies selling counterfeit medicines increased from approximately 200 to 1,800. In 2004, Mexican federal agents apprehended 60 tons of stolen, expired, and counterfeit medicines in two states - Michoacán and Jalisco. That same year

[539] WHO. See http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html (Accessed 25 April 2008)
[540] Deadly Imitations http://www.paho.org/English/DD/PIN/Number23_article3.htm (Accessed 12th April 2008)
[541] According to the Ministry of Public Health.. Deadly Imitations http://www.paho.org/English/DD/PIN/Number23_article3.htm (Accessed 23 April 2008)
[542] The People's guide to Mexico. http://www.peoplesguide.com/1pages/chapts/health/buymed/cheapmed1.html (Accessed 23th June 2008)

reports indicated that counterfeit medicines represented approximately 10 percent of the pharmaceutical market nationally.

El Salvador, one of the smallest countries in Central America also has the problem of counterfeit drugs turning up in the market. The fact that there was a civil war in the country that ended in 1992 made the situation worse. The irony in the case of El Salvador is the fact that there is only one school of pharmacy in San Salvador, the capital of El Salvador and it has been able to carry out experiments and develop its pharmaceutical industries. Some of the experiments carried out in El Salvador's laboratory have been compared to those carried out by British pharmacy students.[543] Tragically the problem of lack of infrastructure and corruption has contributed to encouraging the trade in counterfeit medicines.[544] In 2005, a WHO report showed that the business of counterfeit and fake drugs in the country generated economic losses to the country's pharmaceutical industry to the tune of approximately $40 million.

In 2001 Colombia's National Institute for the Supervision of Foods and Medication (INVIMA) discovered a thriving trade in Bosa, a poor neighbourhood in Bogota where more than 20,000 counterfeit tablets of flu druds, Dristan (a generic aspirin known as Dolex), and Ponstan 500, a popular painkiller of Pfizer were being produced. In 2000, Columbia confiscated 6 million doses of counterfeit Voltaren, a Novartis anti-arthritic medicine. The fact that the amount far exceeded the annual consumption of Voltaren in Colombia, signified that the fakes were created for export.[545] Note that most counterfeit drugs are not produced for consumption in the country of origin, rather it is made for the purpose of export. In 2004, the Association of Colombian Pharmaceutical Industries (ASINFAR) estimated that US$ 60

[543] Ibid
[544] http://www.pjonline.com/Editorial/20000902/forum/ipsf_counterfeit.html (Accessed 16th April 2008)
[545] http://www.businessweek.com/magazine/content/01_25/b3737153.htm (Accessed 19th April 2008)

million, which represented 5% of the total annual market of drugs sold in Colombia were contraband, counterfeit or adulterated. The criminal trade in counterfeit is so dangerous that Dr. Miguel Rueda, the General Director of INVIMA has received many death threats for trying to crack down on the activities of counterfeiters. In 2001, Dr Rueda estimated that 10% of the $1.2 billion worth of drugs sold in Colombia every year was counterfeit drugs.

6.4.3 Counterfeit Drugs: a Flourishing Business in Developing Countries in Asia

Another major source of counterfeit medicines are countries in Asia. WHO has identified the "greater Mekong sub region," which includes Vietnam, the Lao People's Democratic Republic, Cambodia, China, Myanmar, and Thailand as the major sources of counterfeit drugs.[546] China for example is the chief counterfeit manufacturing centre in the world. In 2001 it was reported that China had 500 illegal factories where counterfeit medicines were being produced.[547] That same year the China's Research and Development-based Pharmaceutical Association estimated that about 8% of over-the-counter drugs sold in China were counterfeit.[548] The productions of counterfeit drugs in china is so rampant that the drugs are manufactured from different locations ranging from one-room shacks in shanty towns to large, modern factories in the city.

The exact data on the effects that the production of counterfeit medicines in China has had on victims around the globe is difficult to ascertain, however the official Chinese estimate suggest that 100,000 people in China die every year from taking counterfeit drugs.[549] In 2001, the Chinese authorities sealed off

[546] Stephen Pincock WHO tries to tackle problem of counterfeit medicines in Asia. *BMJ* 2003;327;1126- doi:10.1136/bmj.327.7424.1126-a
[547] http://bmj.bmjjournals.com/cgi/content/full/327/ 7424/1126-a (Accessed 16th July 2008)
[548] WHO. http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html (Accessed 9th June 2008)
[549] DRUG BUSTERS. CSO MAGAZINE- NOVEMBER 2005. http://www.csoonline.com/read/110105/counterfeit.html (Accessed 16th April 2008)

1,300 factories whilst investigating a staggering 480,000 cases of counterfeit drugs worth $57 million.[550] In 2006 fake drugs containing wrong active ingredients for the antimalarial medicine, artesunate was traced back to an illegal factory on the outskirts of Puning, a city in Guangdong Province. In 2006 and 2007 a factory in Yangtze Delta, China also sold counterfeit glycerin in Panama that ended up killing 120 people.[551]

Although a research conducted by Professor Jin Shaohong, director of China's National Institute for the Control of Pharmaceutical and Biological Products showed that the trade in counterfeit drugs in is reducing, the improvement has not been as much as the international community would like. His research showed that in 1998, 14% of drugs were estimated to be counterfeit; however by 2008 the percentage had fallen to 10.[552]

Indonesia has also been on the headline news as one of the manufacturers of counterfeit medicines. In 2005 Indonesia's International Pharmaceutical Manufacturers Group (IPMG) approximated that counterfeit drugs represented 25% of Indonesia's $2 billion pharmaceutical market.[553] In 2008, an international pharmaceutical industry group claimed that 40 per cent of all drugs sold in Indonesia may be counterfeit.[554] Cambodia is also facing a similar public health crisis, in 2002 a Health Ministry survey conducted revealed that 13% of drugs on the domestic market were counterfeit or substandard, including anti-malaria drugs and antibiotics. In 2003, a WHO

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[550] Fackler M (2002 July 29) China's fake drugs kill thousands. San Francisco Examiner
[551] WALT BOGDANICH and JAKE HOOKER Battle Against Counterfeit Drugs Has New Weapon: Pollen. February 12, 2008
[552] Asia's dealy Counterfeit Drugs. June 5, 2008. http://www.feer.com/politics/2008/june/Asias-Deadly-Counterfeit-Drugs (Accessed 23rd January 2008)
[553] Counterfeit Medicines. Fact sheet N°275. http://www.who.int/mediacentre/factsheets/fs275/en/ (Accessed 12th March 2008)
[554] Claims 40 per cent of Indonesia drugs counterfeit. Fri Jul 18, 2008 1:33pm AEST. http://www.radioaustralia.net.au/news/stories/200807/s2307503.htm (Accessed 11 March 2008)

report revealed that Cambodia had 2,800 illegal pharmacists and 1000 unregistered medicines on the market.[555] Evidence suggests 33% of Artesunate (a major drug for malaria) sold in Cambodia, Thailand and Vietnam contained no active ingredients. The D&MD's Prescription Drug Counterfeiting report showed that of thirty medicines named in a list of drugs especially susceptible to counterfeiting, twenty-three are used in treating HIV/AIDS and cancer.[556]

A WHO report showed that Laos had approximately 2100 illegal drug outlets, while in Thailand, substandard medicines account for approximately 8.5 per cent of the total market.[557] In late 2006 and early 2007, the interim military government of Thailand issued compulsory licenses for three Western-owned pharmaceuticals. In each of its applications, the government claimed that the price of these drugs undermined its commitment to provide universal healthcare to its citizens, however this move makes the suspecting spectator to question if this will not lead to more counterfeit drugs in Thailand because of its weak regulatory agencies. In 2003, The Philippine's Bureau of Food and Drug (BFAD) reported that 30% of drug store outlets visited by food and drug deregulation officers carry and sell counterfeit drugs.

6.6.4 Counterfeit Drugs from India

India is a very important area that must be tackled if the fight against counterfeiting drugs can be successful in Nigeria. Apart from the similar colonial history which Nigeria and India has and the fact that they both passed the Patent Act , and which has been identified throughout this thesis. Nigeria derives most of its drugs from India. At a conference in Lyon, France, Dr Dora

[555] http://www.who.int/entity/bulletin/volumes/81/12/ WHONews.pdf (Accessed 13th April 2008)

[556] http://www.bioportfolio.com/cgi-bin/acatalog/Prescription_Drug_Counterfeiting.html (Accessed 2 March 2008)

[557] http://www.who.int/entity/bulletin/volumes/81/12/ WHONews.pdf (Accessed 1st April 2008)

Akunyili stated that most counterfeit drugs in Africa came from India.[558] Thus a report by the European Commission (EC) alleged that of the 2.7 million counterfeit drugs seized by its customs department in 2006, India was the largest source of counterfeit medicines.[559] In 2003, Mr Ranjit Shahani, President of the Organisation of Pharmaceutical Producers in India (OPPI), on the modus operandi of spurious drugs manufacturers in India pointed out that "India is fast becoming the capital for counterfeit drugs and accounts for one-third of the counterfeit drugs produced worldwide"[560]

According to WHO, 35% of counterfeit produced in the world originate in India. Statistics show that only a few of the 15,000 generic manufacturers in India operate illegally, however this has put India on the top list of countries to watch out for when it comes to counterfeit production of medicines. In 2003, Nigeria threatened to ban all pharmaceutical products from India because most of the counterfeit drugs that were coming into the country originated from there.

The Indian pharmaceutical industry has expressed fears that such a reputation could harm India as the supplier of inferior, counterfeit and adulterated quality drugs.[561] One of the ways in which India has attempted to deter the production of counterfeit drugs has been to introduce the death penalty for selling fake drugs that cause grievous harm.[562] The Indian Health Minister Sushma Swaraj said "Profiting from spurious drugs that might harm or kill innocent people is

[558] Nigeria Calls for Convention Against Counterfeit Medicines. 16 November 2005. http://www.ip-watch.org/weblog/index.php?p=138&res=1280&print=0 (Accessed 4th March 2008)
[559]http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/India_hub_of_counterfeit_drugs_EC/articleshow/2142855.cms (Accessed 4th March 2008)
[560] http://www.thehindubusinessline.com/2003/08/03/stories/2003080301260500.htm (Accessed 1st April 2008)
[561] Ibid
[562] India to introduce death penalty for peddling fake drugs BMJ 2003;327:414 (Accessed 23 August 2007)

equivalent to mass murder,",[563]The committee recommended that the maximum penalty for the sale or manufacture of fake medicines that cause grievous harm or death should be changed from life imprisonment to the death penalty and that the minimum prison sentence for these offences should be increased from five years to 10 years. The committee has also called for higher fines for those convicted for trading in fake drugs.[564] Dr Mashelkar said Penalties should be "severe, sure and swift," , quoting from the `Technical Expert Group on Patent Law Issues' report he had chaired three years ago. [565]

Like many Asia countries facing the threat of counterfeit medicines, one of the major problems that India has in combating counterfeits is the loop holes in domestic regulations. India lacks a federal drug agency its state regulators are often influenced by political considerations and plagued by corruption, a problem that many developing countries face. Nigeria has nevertheless begun serious work to eradicate the problem of counterfeit through NAFDAC which will be discussed in turn.

6.7 NAFDAC

NAFDAC was established as a Parastatal of the Federal Ministry of Health by the Decree No. 15 of 1993.[566] Its role and duties included regulating and controlling the quality standards for foods, drugs, cosmetics, medical devices, chemicals, detergents and packaged water imported, manufactured locally and distributed in Nigeria. However in 2001, under the new leadership of Dr Dora Akunyili, NAFDAC's role in the fight for access to genuine and authentic medicines and its war against counterfeit drugs dramatically changed the landscape of the fight against counterfeit drugs internationally. In 2009, Dr

[563] Ibid
[564] Ibid
[565] http://www.thehindubusinessline.com/bline/2007/07/16/stories/2007071651130300.htm (Accessed 6th April 2008)
[566] http://www.nafdacnigeria.org/ (Accessed 23rd March 2008)

Paul Orhii took over as Director General of NAFDAC and has continued to champion the fight against counterfeit medicines.

In the 1990's counterfeit drugs in Nigeria was a severe problem. Thus, Adeoye Lambo,the former WHO Deputy Director reported that 54% of drugs in pharmacies' in Lagos were counterfeit drugs, a figure which rose to 80% in 1991.[567] However since 2001 the amount of counterfeit drugs in circulation in Nigeria has plummeted from a national average of over 41% in 2001 to 16.7% in 2006.[568] NAFDAC has been a key instrument in the fight against counterfeit drugs and has sought to tackle the problem by using the following key eradication strategies.

The first has been to tackle the "double standard" that exist [569] in some countries in the regulatory status of drugs. The double standards have allowed pharmaceutical industry to dump pharmaceuticals which are restricted or banned in developed countries.[570] It is well known that some countries have stronger regulation for drugs consumed indigenously but have less stringent regulations for drugs exported to other countries. An example of the kind of double standard which may occur is the case of a combination medicine known as Deanxit (flupenthixol and melitracen) which was used for the treatment of

[567] Ibid
[568] Prof. Dora Akunyili. Keynote Address, NAFDAC at the International Conference of Heads of West African Drug Regulatory Agencies held at the ECOWAS Secretariat, Asokoro, Abuja, 17th March 2006

[569] Double standards: in the regulatory status of pharmaceuticals enable the pharmaceutical industry to dump to third world countries medicines whose use is restricted or banned domestically. Numerous initiatives have been taken at the international level to tackle the problem, namely by the World Health Organisation. The European Community remained for a long time silent and promoted a laissezfaire policy, thereby giving carte blanche for the uncontrolled export of pharmaceuticals. However, a change of the European Community's attitude towards the export issue seems to be in the offing.
[570] Roger Bate, Kathryn Boateng. Bad Medicine in the Market. HEALTH POLICY OUTLOOK. June 20 2007. http://www.aei.org/publications/pubID.26368/pub_detail.asp and Nigeria leads fight against "killer' counterfeit drug. WHO Report. Volume 84, Number 9, September 2006. 685-764. http://www.who.int/bulletin/volumes/84/9/06-020906/en/index.html. KnujOn http://www.knujon.com/rx.html#imageonly

depression and anxiety. The drug was rejected in Denmark twice by the Danish Medicines Authority but exported to countries with weaker regulatory authorities such as Sri Lanka. The Danish authority did not need to give the exporters or importing country a certificate stating that it had been rejected by the pharmaceuticals in the Danish market.[571] Thus the Danish Medical Agency (DMA) has been accused of operating "double standard" when it comes to the regulation of pharmaceuticals, hence a product of lower standard may be exported but not sold in Denmark. Kristen Myhr pointed out that what made the case more bizarre was the drug was also registered in other European countries like Switzerland, Spain, Italy, Austria and Belgium,[572] and not just in developing countries. This kind of practice is possible in Europe because the regulatory position with regards to Good Manufacturing Practice (GMP) certification is not mandatory; consequently there is usually only a prospect of an examination of plants. The responsibility for quality and safety rest with the pharmaceutical companies, thereby making the industry self-regulatory.[573] Note that European Community has promoted a policy of laissez-faire, and some have argued that this has given a leeway for the uncontrolled export and donation of banned or substandard pharmaceuticals.[574] In contrast to this, in the US, all suppliers of Active Pharmaceutical Ingredients (APIs) are licensed and inspected by the Food and Drug Administration (FDA), although this increases the prices it also reduces the number of suppliers to those that can implement Good Manufacturing Practice (GMP)[575] standards, and quality.[576]

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[571] Kristen Myhr [e- drug] Double or dubious standards for regulation and export? 10 April 2002 http://www.essentialdrugs.org/edrug/archive/200204/msg00035.php
[572] http://www.dsr.dk/sygeplejersken/ (Accessed 20th March 2008)
[573] Ibid
[574] Ruth Macklin "Double Standards in Medical Research in Developing Countries" Cambridge Law Medicine and Ethics (No 2)
[575].Good Manufacturing Practice (GMP) is defined as "That part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use." The principles and guidelines for GMP are stated in Directives; Directive 2003/94/EC for medicinal products and investigational medicinal products for human use. See also See *Good Manufacturing Practices for Pharmaceutical Products (GMP)*, WHO Technical Report Series, No. 823, 1992, Annex 1, pp. 77-79
[576] Hevione head seeks level playing ground. 13/12/2004 http://www.in-pharmatechnologist.com/news/ng.asp?id=56745-hovione-head-seeks

Consequently, statistics show that in Europe, 70 per cent of the APIs used in medicinal products are sourced from plants based in countries in Asia that have perhaps never been inspected for GMP by a European Union official. This has put developing countries are at a disadvantage all round because they sometimes depend on inspection done in EU countries as many countries in the third world do not have strong regulatory authorities. Similarly the FDA in the US is required to certify all AIPs for consumption in the US, manufacturers that produce only for export are not inspected unless somebody asks for it. In order to counter the problem that come with pharmaceuticals "For export only", the NAFDAC management has prohibited the importation of products marked "For export only" into Nigeria, and thus any product that cannot be consumed in its country of manufacture is officially prohibited from being exported into Nigeria.[577]

In an attempt to ensure stricter registration procedures NAFDAC reports that it has set up collaboration with food and drug regulators in almost all continents in order to control pharmaceutical products that come into Nigeria[578] NAFDAC has also established serious communication with neighbouring West African countries' Food and Drug Regulatory Authorities. It has done this in order to monitor, share strategies and ideas to eradicate counterfeit is the sub-region and prevent counterfeiters from establishing a haven and outlet into Nigeria or other West African countries.[579] Dr Dora Akunyili's work and vision has been commended by the international community and she has consistently urged an adoption of an international convention of pharmaceutical.

[577] Prof. Dora Akunyili. Keynote Address, NAFDAC at the International Conference of Heads of West African Drug Regulatory Agencies held at the ECOWAS Secretariat, Asokoro, Abuja, 17th March 2006
[578] Ibid
[579] Ibid

NAFDAC has also attempted to tackle the problem of counterfeit medicines by strengthening its registration processes. NAFDAC has strengthened the registration process by outlining some organizational guidelines to ensure a strong and effective regulation scheme which will prevent the dumping of counterfeit or restricted pharmaceutical products. These guidelines include: all pharmaceuticals must comply with laboratory standards and inspection requirements before they are registered; all drugs on the Nigerian market must be registered again after every five years; all herbal medicine must also be registered again every year; all drugs in circulation in Nigeria must have a NAFDAC Registration Number that has been certified by NAFDAC to enable the public identify counterfeit drugs and finally so as to encourage transfer of technology, drugs can only be imported for ten years period of which importer must begin producing locally.[580]

NAFDAC has registered success in its campaign to eradicate counterfeit drugs. As of 2006, it measured its achievements by reducing counterfeits by 90% from what it was in 2001. Between April 2001 and July 2005, NAFDAC raided over 1000 illegal locations of counterfeiters and destroyed many of their outlets.[581] The most notorious market for the production of counterfeit drugs in the East of Nigeria known as the Onitsha market is the headquarters of counterfeit drugs in Nigeria and has the biggest warehouses where counterfeit drugs are stored in Nigeria. Whilst other counterfeit markets exist in Kano and Aba, Onitsha has posed the biggest problem for NAFDAC.

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[580] Prof. Dora N. Akunyili (D.G of NAFDAC) Strategies employed in combating Drug Counterfeiting in Nigeria, A workshop organised by World Health Organisation (WHO) in Collaboration with Italian Medicines Agency (AIFA) and the International Federation of Pharmaceutical Manufacturers and Association (IFPMA), held in Rome, Italy, 16th-18th February. 2006

[581] Ibid

[581] http://ec.europa.eu/development/ICenter/Pdf/05-03_7%20Consultation_Rago.pdf (Accessed 12th February 2008)

Whilst trying to deal with the Onitsha problem, in 2002, NAFDAC closed down the Aba market for 6 months and the Kano market was sealed off in 2004/2005 for a period of three months to halt the activities of counterfeit traders. Although this caused a lot of hardship to the indigenous people of the states and the customers, NAFDAC was determined to put the safety and good quality of medicines first. Subsequently on 6 March 2007NAFDAC also successful closed down the Onitsha market. Some commentators have wondered why it took NAFDAC so long to deal with the counterfeit problem in Onitsha. Some of the reasons for the delayed were the size of the market and determination of the counterfeit criminals in the Onitsha market. Onitsha market is one the biggest markets in Nigeria, and it has many accesses and outlets, so in order to avoid a gang war when closing down the market, NAFDAC needed to recruit a large and prepared security force to raid the premises. Several days after the market closure, NAFDAC was able to apprehend and destroy a seven 20feet container of fake drugs and large quantities of packaging materials. Other fake labels for various products of highly reputable companies were seized, whilst an illegal clinic which produced fake injections and infusions was also destroyed.

Another major accomplishment of NAFDAC in reducing the presence of counterfeit drugs in the Nigerian market has been the successful implemented and registration of drugs; at present the statistic of registered drugs in Nigeria stands at 89%.[582] Thus in comparison to the level of unregistered drugs in 2001, this is an enormous achievement.

Another major accomplishment of NAFDAC in its fight against counterfeit drugs is the introduction of the Ahura Tru Scan which has made it easier to identify counterfeit medicines. The Ahura Tru Scan is named after Ahura

[582] Prof. Dora Akunyili. Keynote Address, NAFDAC at the International Conference of Heads of West African Drug Regulatory Agencies held at the ECOWAS Secretariat, Asokoro, Abuja, 17th March 2006

Scientific, its United States manufacturer. This device is a chemical identification hand machine. It puts accurate and traditional lab based instruments in portable systems and is designed for field use. The device is effective in making it possible to distinguish between genuine and counterfeit medicines.[583]

Another major improvement that NAFADC has achieved in the fight for access to safe and good quality drugs is to ensure that some drugs are obtained strictly on prescription. Thus the irrational use of drugs without prescription encourages drug counterfeiting. Whilst this was not the case in the past, today all injections and sedatives in Nigeria can only be purchased on prescription. Kenya also faces the problem of counterfeit drugs infiltrating the markets due to its practice of buying medicines without prescription. [584] The Kenyan population like many Nigerian practice a lot of self medication. Thus many drugs which are used in the treatment of opportunistic diseases including HIV/AIDS can easily be accessed by consumers over the counter. The harmful effects of this cannot be overstated, some commentators have used the term manslaughter to describe the illicit lethal trade in counterfeit drugs, indeed, some have even called it murder. Dr Dora Akunyili described her outrage by declaring that "criminals are making these fakes in the full knowledge that their ineffective product might kill people who would otherwise survive [many infections and diseases]."[585] Statistics show that 60% of the population practice self medication, especially in the rural areas where the lack of infrastructure,

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[583] Fake drug detection made easy. Daily Trust. Tuesday, February 2, 2010.
[584] Counterfeit drugs continue to flood markets
Board warns of devastating impact of narcotics as trafficking continue unabated
2 March 2007 - Zachary Ochieng
Source: NewsfromAfrica
http://www.newsfromafrica.org/newsfromafrica/articles/art_10823.html (Accessed 9 May 2008)
[585] Prof. Dora Akunyili. Keynote Address, NAFDAC at the International Conference of Heads of West African Drug Regulatory Agencies held at the ECOWAS Secretariat, Asokoro, Abuja, 17th March 2006

clinics and un-stocked hospitals force the communities to rely on “dukas” and kiosks.

In order to better understand the seriousness of the problem of counterfeit medicines in Nigeria, a look at other African countries like Kenya and Liberia is necessary to show that Nigeria is not the only country in Africa facing the problem of counterfeit medicines in the region. The reason for choosing Kenya is that it has one of the most advanced generic industries in Africa and is regarded as a powerhouse for the manufacture and distribution of drugs in the sub-Sahara.. What happens in Kenya is therefore important in accessing the African situation.Kenya has a number of pharmaceutical companies that are producing medicines for the local population of Kenya.The local drug manufacturers is represented by the Industry Association and The Kenya Federation of Pharmaceutical Manufacturers. These association have pharmaceutical companies such as Biodeal Laboratories Ltd, whose Managing Director is the Chairman of Association, Universal Limited, GlaxoSmithKline East Africa Limited, Ellys Chemical Industries Limited, Pharmaceutical Manufacturing Company Limited, Cosmos Limited, Regal Pharmaceutical Limited, Dawa Pharmaceuticals Limited, Beta Healthcare International Limited and almost 30 other manufacturers and a host of authorized firms for international brands and generic manufacturing. These companies come second only to South Africa in the Sub-Saharan Africa region in the manufacturing and distribution of drugs. This has made them a formidable force in the east and central Africa region.

Despite commendable progress Kenya has made in developing its pharmaceutical companies to provide access to medicines for its local populations, a report by WHO showed that Kenya is still struggling with a growing network of counterfeit drug dealers. An assessment conducted by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons

Board stated that approximately 30% of all the drugs in Kenya are counterfeit. Further figures provided by the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical commodities account for roughly $130 million annually in sales in the country.[586]

The Pharmacy and Poisons Board, Kenya's drug regulatory body which performs the same functions as NAFDAC in Nigeria was set up under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya as a parastatal of the Ministry of Health to tackle the trade in counterfeit;[587] however it has not been as successful as NAFDAC in confronting the counterfeit criminal gangs in the country. The Pharmacy and Poisons Board mission statement is to regulate pharmacy through the following routes namely: manufacturing and trading in drugs and poison with the central aim of achieving the highest standard of safety, efficacy and quality of drugs, chemical substances and medical devices; and locally manufacturing importing, distributing, selling and using medicines to ensure the protection of the consumer.[588] The Board has nevertheless found itself struggling because the Board is seriously understaffed with only 20 inspectors to monitor and control over 3000 chemists, pharmacies kiosks and dukas in the country. At the same time, Kenya is the hub of regional trade in East and central Africa, and this has served to attract drug dealers. This status quo is further compounded by Kenya's slackness in supervising the flow of international drugs.[589]

The trade in counterfeit drugs has continued to grow through the misrepresentation of products and identity. Some of which include misdiagnosis, misconduct, failures by physicians to examine charts, the

[586] Around the world: reports of counterfeit medicines http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html (Accessed 14th March 2008)
[587] Pharmacy and Poisons Board. Ministry of Health, Kenya on boardkenya.org/index.php?id=14
[588] Ibid
[589] OTC Healthcare in Kenya. http://www.euromonitor.com/OTC_Healthcare_in_Kenya

persistent dispensing of medications dangerous to fastidious health conditions and the dispensation of the wrong prescriptions by pharmacy personnel to patients.[590]

On the other end of the spectrum is Liberia. The reason for choosing Liberia is not only is it neighbours with Nigeria but it too faces the problem of counterfeit medicines, This along with the problem of poverty and civil wars in the region have made the challenge of meeting the healthcare needs of its population near enough impossible to meet. Liberia is a small west African country with a population of approximately 3 million people.[591] It was locked in a brutal civil war for fourteen years between 1989 until the signing of the Accra Comprehensive Peace (CPA) in August 2003. During that period more than 250,000 died and over a million people were displaced, this figure included the hundreds of thousands of refugees who fled the country. During that time many of the hospital facilities were destroyed and looted. The war led to many trained and qualified health professionals fleeing the country to other neighbouring countries. This has in the long run led to a shortage of healthcare staff which has further compounded the public health crisis of the country. Before the war, there were 296 primary health care facilities of which 164 were destroyed. Similarly there were 18 hospitals and presently only 12 hospitals which are located in mainly urban areas exist.[592] The effect of this is the clearly flourishing environment in which counterfeit trading can flourish. In the 1990's a surge of "health care professionals" form the Democratic Republic of Congo (DRC) came into Liberia, eighty percent of the physicians

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590 Health Care in Liberia: fake doctors, counterfeit drugs, and no alternative for patients By: Nyankor Matthew The Perspective. Atlanta, Georgia. February 7, 2007 http://www.theperspective.org/articles/2007/0207200701.html

591 Liberia: Health/Nutrition Sector report. WHO report 29 Nov 2003 http://www.reliefweb.int/rw/rwb.nsf/AllDocsByUNID/0be90e8ce8c5fe65c1256df700474ee0 Prof. Dora Akunyili. Keynote Address, NAFDAC at the International Conference of Heads of West African Drug Regulatory Agencies held at the ECOWAS Secretariat, Asokoro, Abuja, 17th March 2006

592 Africa Development Forum (ADF-V) Liberia Country Brief Presented by the Ministry of Youth & Sports November 2006 http://www.uneca.org/adf/docs/Report_Consultation_Liberia.pdf

who came into Liberia from the 1990's to seek professional certification from the Angolan Physicians Association were impostor. Due to the lack of fake diploma detection mechanisms, these individuals were given certification to practice medicine have continued to practice medicine in the country.[593]

Counterfeiting and medical imposters are not the only contributory factors to the lack of access to medicines in many sub-Saharan countries. In the case of Liberia the destructive nature of the prolonged civil war has had a catastrophic nature on Liberia's physical, social, political and economic infrastructure, as such its human development indicators mirrors the frightening stipulation of the population. Over 80% of Liberia's population is illiterate and lives below the poverty line.[594] The unemployment rate exceeds 70%. Thirty-five percent of Liberians are malnourished, only 28% are fully immunized, 25% have access to safe drinking water, and only 36% have access to sanitation facilities. The prevalence of transmittable diseases such as HIV/AIDS, TB and River Blindness continues to escalate at an alarming rate.[595] In Liberia, HIV/AIDS is estimated to affect 8.2% of the population between the ages of 15-49 years. According to the Ministry of health statistics, between 1986 and 2002, the AIDS cases increased among young people from 4.2% to 12.9%. The lack of knowledge, exacerbated by poverty, and multi-sexual behavioural practices continue to pose great challenges for the survival of young adolescents especially females who have been the main victims of rape and sexual abuse throughout the civil war.[596] Female Genital Mutilation (FGM), teenage pregnancy, abortions and prostitution are closely associated with the healthcare problems facing Liberia and women in particular. These factors are all contributory factors to the successful trade in counterfeit drugs and criminal

[593] According to the (Angola Press Agency, 2006-04-24)
[594] Liberia: Health/Nutrition Sector report. WHO report 29 Nov 2003 http://www.reliefweb.int/rw/rwb.nsf/AllDocsByUNID/0be90e8ce8c5fe65c1256df700474ee0 (Accessed 20th June 2008)
[595] Ibid
[596] Ibid

activity. The international community and national governments are aware that efforts must be codified to arrest the spread of counterfeit drugs internationally, and one of the most effective ways it has sought to do this is through the work of IMPACT.

6.8 The Fight against Counterfeit

The fight against counterfeit medicines and its destructive nature have led to various organisations been set up both internationally and by individual states. A good example of this is the primary universal partnership known as International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT) which was set up on 26 February 2006 by WHO to fight counterfeit drugs and mobilize attentiveness and action to tackle the issue of counterfeit medicines. At a conference to advance the global prevention, tracking and detection of counterfeit medicines, Dr Howard Zucker, the WHO assistant Director-General for Health Technology and Pharmaceuticals said the purpose of IMPACT is to ensure that counterfeit medicines are "tackled not only through global efforts but also by a truly collaborative, cross-cutting approach involving medicine regulatory authorities, health professionals, enforcement officials, law-makers and industry.'[597] This assertion demonstrates the imperative of the need to eradicate the plague of counterfeit medicines through a multi-sectoral approach.

IMPACT is made up of 193 WHO member states on a voluntary basis and includes international organizations such as the World Bank, the World Trade Organisation and the International Federation of Pharmaceutical Manufacturers Associations, enforcement agencies such as Interpol, the World Customs Associations, patients' , national drug regulatory authorities, customs and police organizations, non-governmental organizations, associations

[597] http://www.manufacturing-chemist.info/story.asp?storycode=44340

representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups. These groups have come together with the sole aim of improving organization and coordination between countries so that eventually the manufacture, trading and selling of fake medicines can be eliminated. To accomplish this mandate, IMPACT has decided to focus on the following five key areas: legislative and regulatory infrastructure; regulatory implementation; technology and risk communication.

IMPACT held its first public meeting in Singapore, 13-15 February 2008 with the forum theme "Combating Counterfeit Medicines: Where the Regulatory and Technology Roads Meet".[598] In the meeting it was agreed that technology is imperative as one of the key ways of confronting counterfeiters. Advanced technology will help manufacturers upgrade their standards, and enable regulatory authorities strengthen the screening and testing of local and imported products.[599] In March 2007, more than twenty technology companies responded to a call to support the fight against counterfeit medicines.[600] Speaking in her capacity as Chair of the IMPACT Working Group on Regulatory Implementation, Dr. Bernstein commented: "Anti-counterfeiting technologies are evolving fast and the field is an increasingly complex one. Pharmaceutical manufacturers and regulators have an interest to keep themselves informed about developments and this IMPACT Forum should provide a handy means of doing so." [601]

The US FDA. has recently recommended the use of Radio Frequency Identification Technology (RFID) as a way of tracing drugs. As such numerous pharmaceutical companies are experimenting with RFID and Optically

[598] Ibid
[599] Pincock. S (2003) WHO tries to tackle problem of counterfeit medicines in Asia**.** BMJ. November 15; 327(7424): 1126
[600]Zucker, H. "WHO Coalition Examines Technology to Prevent Fake Drugs." Emaxhealth.com. 19 Mar. 2007
http://www.emaxhealth.com/94/10339.html (Accessed 23rd March 2008)
[601] World Health Organization, Geneva. Counterfeit medicines

Variable Devices (OVDs) or using Bar Codes or other technologies such as web portals that can help track and authenticate the drugs.[602] Other RFID recommendations include putting electromagnetic chips and tags that have a unique serial number into cartons and individual drug products, and using anti-counterfeiting technologies such as colour-shifting inks, holograms, and chemical markers built-in into a drug or its label.[603] Many pharmaceutical companies have agreed that this is the way forward in ensuring that problem of counterfeit drugs is eradicated. By utilizing the broad partnership from health agencies to pharmaceutical manufacturers and distributors, IMPACT has proposed to help develop innovative solutions.

Another key way in which IMPACT intends to halt the spread of counterfeit medicines is by putting in place regulatory reforms.[604] In many countries, poverty and lack of political have created a market for counterfeit products.[605]IMPACT has sought to identify the means by which regulators can take action and implement ways to tackle counterfeit medicines. These measures include revised approaches to ensure that standards for quality, safety and efficacy are implemented and distribution chains are effectively controlled. Because regulatory oversights of pharmaceuticals are ineffective, especially in distribution channels. Coordinated action at the local level is essential between health authorities, police, customs, and judiciary institutions to ensure proper regulation, control, investigation and prosecution.[606] Medicines need to be safe, effective and of good quality in order to generate the anticipated remedial effect. Guarantee these properties requires equipping skilled national drug

[602] . World Health Organization, Geneva. Counterfeit medicines. Revised February 2006; Fact sheet No.275.
[603] 19. U.S. Food and Drug Administration. Protecting consumer from counterfeit drugs, consumer magazine. http://www.fda.gov/
[604] Ibid
[605] Counterfeit Medicines – The Global Hazards. http://www.pharmainfo.net/reviews/counterfeit-medicines-global-hazard
[606] Valerio Reggi. IMPACT, WHO. Counterfeit medicines: an intent to deceive. WHO Pharmaceuticals and Stephen. P (2003) WHO tries to tackle problem of counterfeit medicines in Asia. BMJ. 15 November. 327: 1126, European Federation of Pharmaceutical Industries and Associations. Counterfeit Medicines.

regulatory authorities with the necessary human and other resources to control the manufacture, importation, distribution and sale of medicines.[607] IMPACT has pledged to help countries with weak regulatory systems to strengthen them by improving collaboration and drawing from the experience, capacity and resources of all IMAPCT stakeholders.

Through enforcement, IMPACT asserts that it will help to identify and coordinate action between customs, police and the judiciary of different countries to monitor borders, track counterfeit goods and apprehend counterfeiters. By working with the World Customs Agency, INTERPOL, and informal networks of enforcement officers IMPACT aim to facilitate communication between enforcement and health authorities, improve international collaboration and develop appropriate mechanisms that will enable importing countries, especially in the developing world. This it is emphasized will trigger investigation and identification of the actual source of counterfeit medicines plaguing markets throughout the world.

Risk communication, education and awareness programmes are also ways by which IMPACT is directing its efforts towards combating counterfeit drugs. IMPACT has resolved to identify and create the most coordinated and effective mechanisms required to respond and alert key audiences, stakeholders and the general public about counterfeits in communities all over the globe. Commentators have endorsed this approach by citing ways that this can be achieved namely by setting up information campaigns through radio and TV advertisements, banners, billboard adverts, publicity shows, events and even facebook.[608] International information networks can also be created and reinforced to monitor the traffic of goods, exchange information, issue alerts from country to country and region to region. Increased public information is

[607] Ibid
[608]Counterfeit Medicines – The Global Hazards.
http://www.pharmainfo.net/reviews/counterfeit-medicines-global-hazard

essential for patients, dispensers, and doctors who have a right to know if there are suspect goods on the market but must also contribute to detecting counterfeits by reporting and helping to investigate suspicious cases.[609] Special initiatives can also be launched to make internet users aware of the risks they run when purchasing medicines from unknown sources and to address consumers in extremely poor and rural areas where patients may be unable to make informed choices and may not be aware of their rights.[610]

Given the disparities between the level of technological access in industrialized and developing countries, IMPACT plans to help facilitate the transfer of technology across both developed and developing countries. Technology it is asserted can contribute creative tools and in some cases leapfrog lengthy legal and administrative processes to provide faster solutions.

In 2007, a working group at the WHO came up with a draft "The Principles and Elements for National Legislation against Counterfeit Medical Products", it outlined the necessary legislative steps that must be taken if counterfeit medical products were to be addressed, and that was "through different bodies of legislation: on intellectual property protection and enforcement, on pharmaceutical and medical devices regulation and control, and criminal law".[611]

Some of the legal problems that have been identified is the fact that legal systems throughout the world are not well equipped to deal with the serious consequences of counterfeit medicines. The latter coupled with the fact that the penalties for counterfeiters are not severe enough have all encouraged the

[609] Ibid
[610] Counterfeit Drugs Kill. http://www.who.int/impact/FinalBrochureWHA2008a.pdf MAY 2008
[611] The Principles and Elements for National Legislation against Counterfeit Medical Products in Lisbon, 12 December 2007. http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf. (Accessed 23rd April 2008)

existence of counterfeit trading throughout the world.[612] IMPACT has asserted that stronger legislation will help empower those who have to deal with counterfeits and counterfeiters in the course of their work; namely, the police, customs officials and the judiciary. Laws in all countries need to enacted or reviewed to meet these global challenges that the world has had to contend with in making sure that access to authentic medicines is met. IMPACT has also pledged to focus on developing a set of principles for the establishment of appropriate legislation and penal sanctions including a clear legal definition of counterfeit medicines.[613]

Another main organisations used to confront counterfeit medicines is the World Customs Organisation (WCO) which represents 171 customs administrations and is the main source of technical assistance to customs administrators. WCO has worked within WCO Standards Employed by Customs for Uniform Rights Enforcement (SECURE) to develop 'Model Provisions for National Legislation to Implement Fair and Effective Border Measures Consistent with the TRIPS Agreement'.[614] Despite the ambition of the WCO, critics have argued that some of the measures used are TRIPS plus. Some of which include having the ability to suspend counterfeit goods destined for export. Another critisim is that its definition 'infringing goods' exceed counterfeiting goods under Article 51 of the TRIPS Agreement. On the other hand the model provisions has been identified as lacking the authority to enforce policies that contradict the WTO.[615] Indeed commentators have argued that the role of the WCO should be limited to training and capacity building of customs officials.[616]

[612] Ibid
[613] Ibid
[614] See http://www.wcoipr.org.wcoipr/gfx/ModelLawfinal.doc
[615] Duncan Matthews. (2008) The Fight against Counterfeiting and Piracy in the Bilateral Trade Agreements of the EU. Policy Department External Policies.
[616] Ibid

The US Strategy on Targeting Organised Piracy (STOP) is co-ordinated by teh US government and seeks to encourage its trading partners to seize counterfeit goods at US borders. Their major outlets are to ensure that there are laws which protect IPRs and they are in turn enforced. To ensure that these laws are enforced the USTR is working in union with foreign governments through treaties, the promotion of best practices, technical assistance, the G8, the OECD, the US-EU summit, Asia-Pacific Economic Cooperation (APEC) forum and teh Security and Prosperity Patnership (Canada and Mexico).[617]

Importantly too is the Anti Counterfeiting Trade Agreement (ACTA) which has been described as a response to "to the increase in global trade of counterfeit goods and pirated copyright protected works'.[618] Accordingly, teh USTR has pointed out that teh agreement would not bring about changes to the TRIPs Agreement. It intends to set up a higher standard of enforcement that can be joined on a voluntary basis. Although the ACTA would address the problem of counterfeit products more than has been done so far, some have expressed concerns that it will require many signatories to undertake such a widescale expansion of customs and policing of goods and information.[619]

The case for access to medicines for HIV/AIDS, malaria and tuberculosis requires that patients receive the correct authentic medication to treat their ailments and it requires that counterfeit medicines be fought on all levels. It also requires that collaboration be instigated on a national, regional and international level. It must include all stakeholders such as patients, health professionals, manufacturers, distributors, lawmakers and law enforcement agencies.

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[617] See Tekeste Biadgleng, E. And Munoz Tellez, V., 2008, The Changing Structure and Governance of Intellectual Property Enforcement, South Centre, Geneva,

[618] Ministry of Economic Development of New Zealand (2008). "On Anti-Counterfeiting Trade Agreement".

[619] Shaw, A., 2008, "The Problem with the Anti-Counterfeiting Trade Agreement (and what to do about it)," *KEStudies*.

6.9 Summary

Many developing countries including Nigeria are saddled with both problems of neglected diseases and counterfeit medicines which contribute to preventing access to medicines. Nevertheless the fact that TRIPS Agreement has contributed to increasing the prices of medicines for the majority of the population cannot be ignore, still it cannot be blamed for the criminal activities of counterfeit traders nor the fact that some diseases are considered by MNC not to be profitable enough to invest in. It is therefore the responsibility of Nigeria and other developing countries to tackle the problem of neglected diseases and counterfeit drugs. One of the ways that Nigeria can get around this is by engaging in R&D for neglected diseases.

By engaging in their own R&D, Nigeria will have the flexibility of setting its own agenda to research into neglected diseases that affect them rather than being at the mercy of pharmaceutical companies in the industrialised world who are reluctant to conduct R&D for diseases that affect poor people who cannot afford to pay for the medicines. In setting their own agenda, Nigeria will be able to concentrate on finding more anti-retroviral drugs, malaria medicines and other medicines for dieases which are peculiar to the indigenes but are not lucrative avenues for MNCs. Although it is true that some pharmaceutical companies have begun to conduct more R&D into neglected diseases and have provided some partnership initiatives to fight neglected diseases, some of these initiatives have not gone far enough in tackling many of the diseases that are exclusive to poorer counties such as dracunculiasis and chagas diseases.

One of the ways in which Nigeria can conduct more R&D into neglected diseases is through partnerships between the local industries and the universities. Such partnerships are being undertaken all over the world especially between US universities and pharmaceutical companies. Only

recently AstraZeneca announced a strategic partnership with Peking University in China. Such partnerships are invaluable in the way that they enhance local clinical research capabilities and speed up access to new medicines that may in turn benefit Nigerian patients. The Nigeria governments should also continue to use NAFDAC to fight counterfeit drugs as a way of gaining access to medicines. Indeed one of the ways it may further deter such activities in Nigeria is by criminalising the production of counterfeit drugs or the sell of fake drugs that causes grievous bodily harm or death.[620] Fines and severe penalty can also be used as a way of sending a clear signal that the Nigerian government will not condone such practices.

[620] India to introduce death penalty for peddling fake drugs (2003) BMJ ;327:414 (23 August)

PART III

7 THE FLEXIBILITIES WITHIN THE TRIPS AGREEMENT EXPOSED

7.1 Introduction

Eight million people die every year for the price of going out with your friends to the movies and buying an ice cream. Literally for about $30 a head per year, you could save 8 million lives. Isn't that extraordinary? Preventable disease - not calamity, not famine, nothing like that. Preventable disease - just for the lack of medicines. That is cheap, that is a bargain.

Bono

Target 6b: Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it.

- 6.5 Proportion of population with advanced HIV infection with access to antiretroviral drugs.

Millennium Development Goals

This chapter presents a critical analysis of the background of the Doha Declaration in light of the clarifications which it brought to the flexibilities within the TRIPS Agreement. When the Declaration was first adopted in 2001, many commentators praised it for being one of the most important achievements and victories for public health in developing countries. However, less than a decade after, many begun to question its achievement in bringing about access to medicines as it was intended to do. In the wake of the US and EU pressure to enforce TRIPS-Plus measures in regional and bilateral agreements, the cracks in the Doha Declaration had begun to show. For many countries like Nigeria who face consistent pressure to introduce a TRIPS plus regime the battle rages on.[621]

[621] An example of TRIPS plus pressures from the EU include the EU-West Africaxxiii EPA where West Africa was encouraged to ratify or accede to UPOV (1991) and comply with

In examining the flexibilities in the TRIPS Agreement and the victory of the Doha Declaration, a detailed analysis of what compulsory licenses and parallel importation mean to developing countries and how successful they have been in using them will be carried out. This chapter will also look at the operation of compulsory licenses and parallel importation in developed countries in a bid to show the inequality of the multilateral trading regime that has been successfully implemented through the WTO. It will also carry out a detailed anaylsis of the way in which parallal imporatation has been interprettaed in the US courts in a bid to show whether or not the usage and interpretation of parallel importation by developing countries can be problemeatic\

7.2 What Brought About the Doha Declaration?

The Doha Declaration on the TRIPS Agreement and Public Health (of November 14, 2001) was adopted in response to the outcry of developing countries and least developing countries that TRIPS had brought an end to the era of access to medicines. The Declaration sought to clarify and reiterate the options and flexibilities within the TRIPS Agreement that developing and least developing countries could take advantage of, in order to circumvent the unmistakable public health crisis that had arisen in the form of the HIV/AIDS epidemic in many developing countries.[622] The first special discussion on intellectual property and access to medicines was spearheaded at the request of the African Group on 20 June 2001.[623] Developing countries wanted reassurance that they could use compulsory licenses and parallel importation in

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various provisions of the Budapest Treaty. In Cotonou Agreement 2000, the parties are obliged to recognize the need to ensure adequate and effective protection of patents on plant varieties and on biotechnological inventions.

[622] Heimel. A.Y (2004). *THE POWER OF A PATENT: THE IMPACT OF INTELLECTUAL PROPERTY IN THE FREE TRADE AREA OF THE AMERICAS AGREEMENT ON THE PLIGHT OF PRESCRIPTIONDRUG AVAILABILITY AND AFFORDABILITY IN CENTRAL AND SOUTH AMERICA*. 16 Pace Int'l L. Rev. 447

[623] Sun. H (2004). *THE ROAD TO DOHA AND BEYOND: SOME REFLECTIONS ON THE TRIPS AGREEMENT AND PUBLIC HEALTH*. 15 Eur. J. int'l L. 123

the wake of strong pressures from pharmaceutical industry not to do so.[624] It was therefore necessary to clarify that the flexibilities within the TRIPS Agreement could be interpreted in a way which would allow members to comfortably establish the link between intellectual property rights and access to medicines.[625]

Zimbabwe issued a statement on behalf of the African Group which stated that "We propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health".[626] What appeared apparent was the fact that developing countries saw the need to have one voice if they wanted to be clear that they were prepared to take the necessary steps to protect and advance their fundamental interest in gaining access to medicines. The members of the Africa Group were headed by Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.[627] The African group was concerned that the public health problems facing many developing countries were escalating without a solution to the problem. One of the most worrying problems confronting them was how to halt the spread of the HIV/AIDS epidemic. Sub-Sahara has one of the highest percentages of people who are living with HIV/AIDS and yet lack access to medicines because of the high cost of medicines; yet not a lot of countries from the sub-

[624] See WTO NEWS, 'Moore: Countries Must Feel Secure That They Can Use TRIPS' Flexibility'. 20 June 2001. Also note that there are other flexibilities within the TRIPS Agreement such as data exclusivity and novelty criteria, but the group of developing countries paid more attention to parallel importation and compulsory licensing.
[625] TRIPS Public Health', Submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka. Thailand and Venezuela, 29 June 2001, IP/C/W/296.
[626] See WTO Council for Trade-Related Aspects of Intellectual Property Rights, Special Discussion on Intellectual Property and Access to Medicines 4, WTO Doc NO IP/C/M/31 (Restricted) (July10, 2001) [on File with CJIL]
[627] Advance Copy (Unrestricted-IP/C/W/296), Council for TRIPS, 19 June 2001 (final text available at http://www.wto.org).

Sahara were present at the African group. The absence of many active Member states from the sub-Saharan region during the Doha Ministerial discussions raises some interesting questions about why they were also underrepresented at the GATT.

The fact that HIV/AIDS is one of the leading causes of death in many developing countries has led many to assert that developing countries were right to have been at the forefront at Doha demanding and calling for changes and clarifications on the flexibilities within the TRIPS Agreement which would in turn provide increased access to medicines. Developing countries had been accused of not asserting themselves during the Uruguay rounds, indeed most of them where seen as 'quiet bystanders' who lacked the expertise or political representation to partake wholly.[628] Another explanation that has been pointed out that explains why many countries from the sub-Saharan were not appropriately represented at the GATT is the comparative lack of resources among developing country delegations in Geneva which has consistently led to underrepresentation.[629]

The European Union for example administers local operations through democratic local governance, decentralisation and territorial development sometimes with the objective of developing and pursuing policy positions in international agreements. [630] By so doing, the EU as a bloc usually find that they have sufficient personnel to attend international meetings where specialized representation is needed. Many developed countries have always had a significant advantage over developing countries when it comes to being

[628] Wilkinson R and Scott. J(2008) Developing country participation in the GATT: a reassessment. World Trade Review
[629]Abbott. F. M (2002) *THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO* 5 J.Int'l Econ. L. 469
[630] Juergen K Binder, Peter Slits, Remi Stoquart, Dr. Jospeph Mullen and Carlos Buhigas Schubert. Towards an EU approach to democratic local governance, decentralisation and territorial development. Background Paper. Project No. 2007/147439 – Version 1 See: http://www.deleri.ec.europa.eu/whatsnew/Background%20paper.pdf

represented at the WTO ministerial meetings. Whilst many developed countries tend to have permanent representatives at international organisations, developing countries on the other hand had very few delegates who were competent enough to be permanently situated at Geneva. Even when they were competent personnel, they are hardly permanently stationed in Geneva as they are usually other international institutions and meetings that required their attention.

Regardless of the foregoing, it must be noted that international efforts have been made by several organizations to ensure that developing countries are fully represented at the WTO. Note that the Advisory Centre on WTO Law (ACWL) was established in July 2001 to give free advice on the WTO laws to all members of the WTO; and alleviate the difficulties faced by developing countries and LDC in gaining expert knowledge on the TRIPS Agreement.[631] Since 2004, the Agency for International Trade Information and Cooperation (AITIC) established in 1998 has been transformed into an intergovernmental organization to enable LDC gain from globalization through the multilateral trading system.[632] Nevertheless when it comes to the responses of individual countries to the Geneva-capacity problem,[633] a few developed countries have taken concrete actions to readdress the situation.[634] Netherlands and Norway have also provided funding to help in the formulation of developing country

[631] See Advisory Centre on WTO Law. How to Use the Services of the ACWL. A Guide for Developing Countries and LDCs. http://www.acwl.ch/pdf/how_to.pdf
[632] Business for Development. Fostering Trade through Private –Public Dialogue. A Business-Government Forum in Hong Kong. Hong Kong, China, 11-12 December 2005. http://www.intracen.org/hongkong/docs/Concept-Paper.pdf
[633] Abbott. F.M (2002) *THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO*. 5 J.Int'l Econ. L. 469
[634] The U.S. government and U.S.-based IP private industries provided extensive training for foreign officials and nationals; Nigeria was one of participants in the program. Allison Areias. INTELLECTUAL PROPERTY TRAINING AND TECHNICAL ASSISTANCE PROGRAMS. http://usinfo.state.gov/products/pubs/intelprp/training.htm

policy papers, and assisted them in arranging a system where they can exchange views and opinions freely.[635]

Developed countries on the other hand encompassing countries like Australia, Canada, Japan, Switzerland and the US have consistently aligned themselves together at the WTO.[636] Characteristically, during the Doha rounds, the US took the US PhRMA position that patents do not lead to increased prices.[637] It also reiterated that compulsory licence should be used restrictively, and asserted its position that the TRIPS should not be interpreted in a manner which would allow Members to establish its policy on parallel importation.[638] The emergence of a strong group of delegates from developing countries enunciating and advocating an intelligent position at the Doha declaration made a difference. Although initially it was not very clear which direction the pendulum would swing, the second Ministerial Council meeting on 25 July 2001 was held, with a third and fourth meeting scheduled for 19 and 21 September 2001.[639] During the meetings the African group presented their paper to the TRIPS Council. Interestingly, observers have noted that the group of developing countries were more active at the Doha rounds because they had learnt their lesson from the Uruguay rounds. The price of being 'ordinary observers' at the Uruguay rounds were far too costly to repeat the same mistake again. For it had put the prices of medicines outside their reach by introducing the 20 year patent term which had put the prices of medicines outside their reach.

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[635] The Quaker United Nations Office (QUNO) has actively provided logistic support for developing country delegations.
[636] Sun. H (2004). *THE ROAD TO DOHA AND BEYOND: SOME REFLECTIONS ON THE TRIPS AGREEMENT AND PUBLIC HEALTH*. 15 Eur. J. int'l L. 123
[637] Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN (01)/DEC/2, 20 November 2001.
[638] Abbott. F,M (2002) *THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO*. 5 J.Int'l Econ. L. 469
[639] A brief summary of the meetings can be found at http:// www.wto.org.

7.3 Demands of the Developing Countries during the Doha Declaration.

Five major issues arose as the main crux of the African group's demands. Firstly they wanted Public health to be considered in a broader context. They wanted HIV/AIDS, tuberculosis, malaria and other epidemic to be acknowledged as a serious health crisis.[640] This was essentially the content of Para 1 of the Declaration on the TRIPS agreement and public health as adopted on 14 November 2001. Commentators have suggested that by demanding the recognition and significance of the public health problems facing the developing and least developed countries, the Doha Declaration broadened the scope of public health problems that developing countries could address. It also compelled Member states to confirm the relevance of the objectives (Article 7)[641] and principles (Article 8)[642] for the interpretation of the TRIPS Agreement. This was in accordance with the customary rules of interpreting public international laws based on Articles 31 and 32 of the Vienna Convention.[643] Art 31 and 32 requires each provision of the TRIPs Agreement to be read in the light of the object and purpose of the Agreement as expressed in its objectives and principles.[644]

Secondly, developing Members wanted the flexibilities available in the TRIPS Agreement such as compulsory licensing and parallel importation reiterated in

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[640] DOHA WTO MINISTERIAL 2001: TRIPS WT/MIN(01)/DEC/2. 20 November 2001 Declaration on the TRIPS agreement and public health. Adopted on 14 November 2001

[641] Article 7 states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

[642] Article 8 *states that* "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

[643] See Appellate Body Report, *US – Gasoline*, WT/DS2/AB/R, p.17 and Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, p.10.

[644] Gathii, J.T (2002) *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 Harv. J.L. Tech. 296- 98

the Doha Declaration. It follows that the Doha Declaration was able to clarify that Article 31 of the TRIPS gave each Member the right to grant compulsory licences and the independence to determine the grounds upon which such licences are granted' (Paragraph 5(b)). Impressively at the time the Declaration was also able to clarify that Members may grant licenses not only during a) national emergency b) public non commercial use, c) anticompetitive practices, but had the autonomy to stipulate the grounds upon which such licenses may be granted. This was considered a major breakthrough.[645]The Doha Declaration went on to assure developing countries that they had the freedom to grant compulsory licenses in order to combat nearly all public health crisis, thus Para 5(c) allows each member dealing with public health problems including HIV/AIDS, tuberculosis, malaria and other epidemics to determine whether they are facing a national emergency or circumstances of extreme urgency.

Thirdly, developing countries wanted the members of the WTO to acknowledge that despite the fact that enhanced patent protection leads to innovation in the development of new medicines, at the same time it increases the price of medicines beyond what the average patient in a poor country can afford. Unsurprisingly, developing countries have always had serious concerns about whether patent protection encourages R&D on drugs for diseases that directly affect them. To address this concern, developing countries attempted to address the lack of directive in the TRIPS Agreement to pharmaceutical companies to focus on R&D in diseases that affect poorer countries in the developing and least developing world.

Fourthly, developing countries wanted to be given the assurance in Doha that they could adopt legislation in order to allow parallel imports without the

[645] Matthew D (2004) *The Decision on Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health: A Solution to the access to Essential Medicines Problem*. 7 J. Int'l Econ. L 73

consent of the patent holder. This stance genuinely epitomized the declared interest at Doha in helping developing and least developing countries obtain low-cost access to pharmaceutical medicines. Although this self-sufficiency to parallel import however is subject to the most favoured nations (MFN) and the national treatment provisions in Article 3 and 4 of TRIPS.[646] Commentators have suggested that the authorization to permit parallel importation may be based on the consent of the patent holder; nevertheless the Doha Declaration does not elaborate on that. Paragraph 5(d) leaves each Member "free to establish its own regime for such exhaustion without challenge", and that is the stance that most developing countries prefer to take.

The fifth issue that the African group sought to resolve at the Doha Declaration was an extension of the transition periods for Members of the least developing counties to implement the TRIPS Agreement and pharmaceutical patent.[647] When the idea that the transition period for the implementation of the TRIPS Agreement be extended from 2006 to 2016, the United States sought an explanation as to why least developed countries might want to do this. The underlying principle for demanding such clarification was that such least developed countries were not required to implement the pharmaceutical patent protection until 2006 and therefore should not be concerned about the impact until then. Although the group succeeded in extending the deadline for LDC providing pharmaceutical patent protection and enforcing those rights until 1

[646] Article 3:1 states that "Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits". Article 4 states that "With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members" See also Haochen Sun. THE ROAD TO DOHA AND BEYOND: SOME REFLECTIONS ON THE TRIPS AGREEMENT AND PUBLIC HEALTH. 2004. Eur.J.Int'L.123

[647] Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001.

January 2016,[648] some thinkers have suggested that the transition period should not only be limited to pharmaceutical products but to all aspects of the Agreement.[649] Further arguments along those lines suggest that even by 2016, it is uncertain whether LDCs and other low income countries should adopt the full range of the TRIPS Agreement. What has however been suggested is that each LDC or low income country be looked at on a case by case basis in order to avoid certain burdensome aspects of the TRIPS Agreement affecting countries adversely.[650] Thus Constantine Michalopoulos writes that it is inappropriate to force LDCs and other low income countries to a fixed deadline. What developing countries need is the declaration by developed countries that technology transfer and technical assistance programs will be put in place to assist those countries towards economic and technical advancement. Technology transfer occurs when one firm transfer technology information from one firm to another, or from one country to another.[651] Arguments have been also been put forward that the TRIPS Agreement fosters the slow flow of technology transfer to developing countries.[652] Hence technology transfer has been identified as being an important aspect of sustainable development. The argument follows that for there to be successful transfer of technology emphasis should be laid on the transfer of technology from developed countries to developing and LDCs.[653] In order for there to be sufficient transfer

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[648] Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Fourth Session, Doha, Adopted on 14 November 2001, WT/MIN(01)/ DEC/2.

[649] Constantine Michalopoulos. *Special and Differential Treatment of Developing Countries in TRIPS*. 2000. Published by: Quaker United Nations Office (QUNO), Geneva, Quaker International Affairs Programme (QIAP), Ottawa Project undertaken with the financial support of the Government of Canada provided through the Canadian International Development Agency (CIDA) Available at http://www.quno.org/geneva/pdf/economic/Issues/Special-Differential-Treatment-in-TRIPS-English.pdf

[650] Ibid

[651] Keith Maskus. (1998) *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*. Duke J. Comp. & Int'l L. 9: 109

[652] Correa, Carlos. (2002.) *Managing the Provision of Knowledge: the design of Intellectual Property Laws*. In Inge Kaul et al, Providing Global Public Goods, Oxford University Press, New York

[653] Aaron Cosbey *The Sustainable Development Effects of the WTO TRIPS Agreement: A Focus on Developing Countries*. International Institute for Sustainable Development. Winnipeg, Canada.

of technology, patent holders must set up factories in developing countries for domestic production.[654]

Pharmaceutical companies however prefer to export their goods to other countries, rather than set up factories in the recipient countries.[655][656] Declaring the above, the successes of the Doha declaration must not be overlooked. By extending the dead line for the implementation of the TRIPS Agreement, to 2016 least developing countries will be free to increase their own capacity to manufacture generic drugs or obtain low-priced drugs imported from other Members. The extension of the dead line gave LDCs the chance to adopt the necessary measures to use test data protection before the 2016 expiry date. In addition LDC now has until 2016 to propose and shape their national Intellectual property legislation in a way that will allow them to improve access to medicines by importing generic medicines and probably producing it.

Developing countries seeking to make full use of the flexibilities within the TRIPS Agreement contend that data protection should not be used as a back door route to patent protection[657]. One of the concerns developing countries hoped to clarify at the Doha Ministerial meetings was whether Article 39 establishes broad interpretations for national rules which allows member states to apply different types of protection or whether under Article 39 exclusive rights are given for test data.[658] Before the TRIPS Agreement, countries had the option to choose whether to grant protection on test data or not, however Article 39.3 of the Agreement requires countries to protect test data against

[654] Ibid
[655] Ibid
[656] See Ryan. M (1998) *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, Brookings Institution, Washington DC, pp.67-72.
Source: http://brookings.nap.edu/books/0815776535/html/
[657] Abbott. F.M (2002) THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO. 5 J.Int'l Econ. L. 469
[658]http://trade.busiaanessroundtable.org/trade_2006/wto/decision.html

"unfair commercial use".[659] The difficulty however remains that the term "unfair" commercial practice is not defined in the Agreement, the interpretation will depend on what the society believe it is at any particular given time.[660] Additionally other language in Article 39 remains unexplained. Languages such as "new chemical entity", "unfair commercial use", "undisclosed test or other data" are open to interpretation. These shortcomings were not addressed at the Doha. Whilst some developed countries such as the

US argue for a minimum period of exclusivity, this argument is not supported by the TRIPS Agreement For there to be access to medicines in accordance with the TRIPS Agreement, developing countries were aware that there has to adequate transfer of technology. At the Doha ministerial meetings, developing countries expressed their disappointment that developing countries had not provided the incentives to promote technology transfer to assist their business and organizations in accordance with Article 66.2. Although some developed countries have provided different forms of technical assistance on IPR-related issues, some issues have arisen. Developed countries have been accused of providing unsuitable and unsafe technical assistance to them by advising countries to implement policies that are harmful to health.[661]. For example, the US Agency for International Development (USAID) has been funding the US Commerce Department to provide technical assistance to Nigeria in re-writing its patent laws.[662] The patent law draft legislation demanded for stronger intellectual property laws than TRIPS required. Such measures included laws

[659] Humaira Mufti. Data Protection in compliance with Article 39 of the TRIPS Agreement: Draft Amendment to the Drugs Act 1976. WIPO National Seminar on Flexibilities under the TRIPS Agreement
27-28th November, 2007.
[660] Ibid
[661] Médecins Sans Frontières Briefing Note . August 2003. ONE STEP FORWARD, TWO STEPS BACK? ISSUES FOR THE 5TH WTO MINISTERIAL CONFERENCE (CANCÚN)
[662] For more information on the shortcomings of WIPO technical assistance, see: MSF, Consumer Project on Technology, Oxfam International and Health Action International. "Conference Report: Implementation of the Doha Declaration on the TRIPS Agreement and Public Health. Technical Assistance—How to Get it Right." March 2002. <www.accessmed-msf.org>

to criminalisation patent infringement. Medecins Sans Frontieres objected to this stating that such a law would lead to more difficulty for the country gaining access to affordable generic drugs.[663] Correa states that little or no action has been taken by developed countries to specifically implement their obligations under Article 66.2. [664]

Importantly, the Doha Declaration reaffirms the commitment of technology transfer made by developed country Members, whilst reiterating the need for developed countries to support and encourage technology transfer to least-developed country members. The Ministers at Doha responded by setting up a Working Group under the patronage of the General Council to look at the relationship between trade and transfer of technology, in order to make achievable recommendations on steps that might be taken within the of the WTO to increase technology flows to developing countries. Ultimately the Doha Declaration was seen as a breakthrough for developing countries and their public health agenda, [665] thus it was the first time that international health and development was discussed at every level of the WTO governance.[666]

Some commentators have suggested that the Declaration gave sufficient discretion to Member states in deciding how to counteract the negative effects of the TRIPS Agreement and its effect on prices. Part of the rationale for such an assertion is based on the fact that the final text of the Doha Declaration has more similarities to the draft that the developing countries has proposed when

[663] Schroeder.M (2003) *Drug Patents Draw Scrutiny as Bush Makes African Visit*." The Wall Street Journal.
[664] Correa. C. (2002) *'Implications of the Doha Declaration on the TRIPS Agreement and Public Health*'. WHO Health and Economics Policy Paper. EDM Series No. 12 at 36.
[665] Matthew D (2004) *The Decision on Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health: A Solution to the access to Essential Medicines Problem*. 7 J. Int'l Econ. L 73
[666] Mercurio. B. (2004) *TRIPS, Patents, and Access to life saving Drugs in the Developing World*. 8 Marg. Intell. Prop. L. Rev. 211

compared to the developed countries draft.[667] When one cast their mind back to the surrounding issues and events of 2001, it does perhaps seem unsurprising that the US government became so lenient towards the position of developing countries. One of such events was the tragic incident of the World Trade Centre. On 11 September 2001, several days before the second TRIPS Council meeting scheduled for 19 September 2001 was held, the World Trade Centre was attacked and bombed by terrorist claiming more than 5,000 US lives.[668] The Pentagon was also attacked and several days later a series of bio-terror threats in the form of anthrax attacks were carried out causing severe illness and deaths.[669] The proximity between the World Trade Centre, the Pentagon attack and the bioterrorist attack led the United States to believe that the country might be under bioterrorist attack; this might resulted in an enormous public health emergency for North America.[670]

The Canadian government reacted rapidly by issuing a compulsory licence to a Canadian generic producer on 18 July 2001. This effectively eroded the German pharmaceutical company Bayer's patent for the antibiotics, Ciprofloxacin. The compulsory licence was for a million tablets of Ciprofloxacin, which was at the time the most effective drug in treating anthrax.[671] The United States followed suit, thus on 23 October by the Secretary of Health and Human Services (HHS) Tommy Thompson threatened Bayer with a compulsory license if it did not meet its demands for price

[667] Hoen, T.E (2002) TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha'. 3 Chicago Journal of International Law 27, at 47-48.
[668] .S. Department of State. Office of the Historian, Significant Terrorist Incidents, 1961-2001: A Brief Chronology, www.state.gov/r/pa/ho/pubs/fs/5902.htm.
[669] American Anthrax Outbreak 2001. http://www.ph.ucla.edu/epi/Bioter/detect/antdetect_intro.html
[670] Abbott. F.M. (2002) THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO. 5 J.Int'l Econ. L. 469
[671] See Harmon and Pear, 'Canada Overrides Patent for Cipro to Treat Anthrax', New York Times, 19 October 2001. The Canadian Government subsequently withdrew its decision after agreeing on the Monday to buy the tablets from Bayer.

reductions.[672] Unsurprisingly, Bayer subsequently reduced the price of the product by half the price at which it had offered to supply the drug in the first place, thereby supplying it at 45 cents per Cipro pill for purchases under a separate government program (twice the price for the Indian generic equivalent).[673]

Developing world was shocked at these developments. Whilst the US and its allies have threatened trade sanctions, withdrawal of economic benefits, and insisted on TRIPS plus standards in countries that attempt to grant compulsory license, here they were issuing compulsory licenses in a situation which they believed was a "national emergency". To many the moral standing of the USTR was brought into question.[674] Were the flexibilities within the TRIPS Agreement good for the US and Canada to use when they faced a public health emergency, but wrong when it came to developing countries using them? Were the lives of people in the developed world more important than the lives of people in the developing world? It seemed too many that there was in fact a double standard operating at the WTO.[675] Whilst the United States had in the past issued over 100 compulsory licensing in antitrust cases and settlements, including cases of antibiotics, synthetic steroids and several biotechnology patents, they sought to prevent developing countries from using the same instrument. Other questions that arose out of the incident were whether the use of the flexibilities within the TRIPS Agreement would ensure that more R&D would be done for neglected diseases? These were indeed the questions that the African group and indeed the rest of the world pondered upon during the Doha Ministerial Conference. Frederick Abbot held that the result of the

[672] Kristin Jensen, (23 October 2001.)*Thompson May Seek to Void Cipro Patent If Talks Fail'*, Bloomberg News Service (Bloomberg.com), dateline Washington, DC,
[673] Russell Mokhiber and Robert Weissman (2001) *MULTINATIONAL MONITOR 2001. The Ten Worst Corporations of 2001. Corporations Behaving Badly: The Ten worst Corporations of 2001*.
[674] Haochen Sun. *THE ROAD TO DOHA AND BEYOND: SOME REFLECTIONS ON THE TRIPS AGREEMENT AND PUBLIC HEALTH*. 2004. Eur.J.Int'L.123
[675] Marwaan Macan-Markar. *Bird Flu Brings Out Double Standards on Drug Patents.* Published on Saturday, October 22, 2005 by the Inter Press Service

anthrax-cipro situation demonstrated plainly the common sense underlying the heart of the developing country draft declaration. [676]He claimed that no responsible government with a choice would place the public health of its citizens below the interests of a few patent holders.[677]

Panagariya has suggested that the events that caused the US government to express a willingness to grant developing countries concessions that it had previously guarded jealously were more than meets the eye.[678] No sooner had the Declaration on TRIPS and public health been adopted that the cracks between the US position and the agenda of the developing country alliance (that patent protection should not hinder public access to affordable drugs) begin to show. The pharmaceutical industries began to seriously lobby the US government to reconsider its position and punish countries who failed to protect patented pharmaceutical products through its "Special 301" provisions of the US trade law. In 2002, under intense pressure from the pharmaceutical industry, the United States Trade Representative (USTR) added four new countries on its "priority Foreign Countries" with the possible threat of removing trade preferences and cutting development aid.[679] The actions of the US pharmaceutical industry have raised criticism amongst academics and NGO's.[680] Some have questioned whether the US government considers the interests of associations such as PhRMA to be more important to the

[676] Abbott. F.(2002) *THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: LIGHTING A DARK CORNER AT THE WTO*. 5 J.Int'l Econ. L. 469
[677] Ibid
[678] Panagariya, (2002*) Developing Countries at Doha: A Political Economy Analysis*', 25 World Economy. 1205.
[679] See Maria Bystorm & Peter Einarsson, (2001) *TRIPS – Consequences for Developing Countries: Implication for Swedish Development Cooperatio*n 36, 37 , at http://www.grain.org/docs/sida-trips-2001-en.pdf
[680] See Drahos, P (2002) Developing Countries and International Intellectual Property Standard- setting 14-18) at http://www.iprcommission.org/papers/pdfs/study_papaers/sp8_drahos_study.pdf

promotion and functioning of democratic institutions in developing countries.[681]

7.4 Compulsory Licenses

The issue of Member States capability to use compulsory licences has been a major cause of contention from the beginning of the TRIPS Agreement, nevertheless the availability of compulsory licenses as an option is not a new concept. Article 5A(2) of the Paris Convention states that 'Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent". Under Article 31k of the TRIPS a judicial or administrative ruling of anti-competitive practices also enables governments to issue a compulsory license without first seeking voluntary licenses, for domestic use or export.

At the Doha Rounds compulsory licenses was one of the main issues that developing countries wanted addressed. Thus compulsory licenses have been identified as one of the best ways for lowering the prices of drugs below the original manufacturers' price. It works in a variety of ways namely; it allows the government to issue a licence to produce patented pharmaceuticals without the consent of the patent holder. It also allows a country to import generic version of the patented drug under Article 31. [682]

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[681] Hernan L. Bentolila. Lessons from the United States Trade Policies to Convert A "Pirate": The Case of Pharmaceutical Patents in Argentina. Yale Journal of Law & Technology. 2002-2003. Available at http://www.yjolt.org/old/files/20022003Issue/Bentolila.pdf

[682] The text of the compulsory licensing provision reads, in relevant part:
Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made effort to obtain authorization from the right holder on reasonable commercial terms . . . . This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use ...
(f) any such use shall be authorized predominantly for the supply of the domestic market of the

The imported drug can be from a country in which the drug is not patented, or in a country where drugs are patented (in which case the exporting country has also to issue a compulsory license). Nevertheless the following conditions must be met: there has to have been adequate evidence that negotiations were made to obtain authorizations from the patent holder on reasonable commercial grounds (except in cases of public non-commercial use, situations of extreme urgency and national emergency) "within a reasonable amount of time"[683]which turned out to be unsuccessful.[684] Although the term "reasonable commercial grounds" is open to interpretation, it allows each particular negotiation to be taken into account. Similarly, some commentators have suggested that the flexibility of Article 31(b) allows the issue of compulsory licensing if the patent holder deliberately delays negotiation to prevent the grant of a compulsory licence.[685] Another key requirement of compulsory license is that the patent holder must be paid "adequate remunerations in the circumstance of each case, taking in to account the economic value of the authorization".[686] The provision that patent holders be paid adequate remuneration has been called into question by critics, on the basis that if the manufacturing pharmaceutical company that is being granted a compulsory licence has to pay a remuneration that is too high, it may defeat the entire purpose of the licence as compulsory licences are typically done to make the price of medication affordable. Some have also questioned what level of remuneration is 'adequate'?[687] To answer the question, some studies have

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

[683] Article 31(b) of the TRIPS Agreement

[684] Ibid. art 31(b) The requirement to put forth reasonable efforts to negotiate a license with the patent holder can be waived by the Member in circumstances of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

[685] Holger Hestermeyer. (2007) *Human Rights and the WTO. The Case of Patents and Access to Medicine*s. Oxford University Press.

[686] Ibid. art 31(h)

[687] J. Love, (2001) Compulsory License: Models For State Practice in Developing Countries, Access to Medicine and Compliance with WTO TRIPS Accord, Prepared for the United

suggested that between 2% and 15% of net sales is adequate remuneration. Ultimately member states have to provide the possibility of judicial review or other independent review of the legal weight of any decision relating to the authorization of use under Article 31 of the TRIPS Agreement.

Important to note is that fact that compulsory licences are limited by scope and duration.[688] If for example a compulsory licence was issued due to an epidemic, once the situation is over, the compulsory licence has to be terminated. The rationale for this is quite plain; the legitimate interest of the patent holder must be sufficiently protected. Secondly compulsory licences are non-exclusive and non-assignable; and thirdly and more controversial is the fact that compulsory licences are territorial. Article 31(f) of the TRIPS Agreement states that it must be "predominantly for the supply of the domestic market of the member states"[689] The word "predominantly" has been interpreted to mean: 50 percent of the use must be for use in the domestic market of the manufacturer and the domestic market has to be the most important market to benefit from the compulsory license. The important thing to note however is that since the coming into force of the TRIPS Agreement, the pharmaceutical industry in the developed world have questioned the use of compulsory licensing as a way of getting round the problem of high prices of medicines.

This problem has been compounded for developing countries that have no manufacturing capacity, who have in turn presented the argument that the strings attached to the requirements of issuing a compulsory licenses presents a major setback for providing access to medicines. [690]The controversy for countries without manufacturing capacities is centred on the fact that such

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Nations Development Programme at Para 2
http://www.cptech.org/ip/health/cl/recommendedstatepractice.html
[688] Article 31(c) of the TRIPS Agreement
[689] Article 31 (f0
[690] Ibid 31 (f)

countries would be unable to take advantage of the compulsory licensing provision under Article 31(h), [691] thus any attempt to import pharmaceuticals from other countries would have been interpreted as a violation of the WTO Agreement.[692] Attempts were made at the WTO Ministerial at Doha, Qatar in 2001 to overcome the problem when the TRIPS Council held a special discussion on intellectual property and access to medicines and came to the conclusion that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health. And that the Agreement shall be interpreted and implemented in a manner that is supportive of WTO members' right to protect public health by promoting access to medicines'. [693] At the request of the African group, the declaration emphasizes the importance of TRIPS' role in protecting and promoting human rights.[694] Specifically, Article 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health states that "Each member has the right to grant Compulsory licenses and the freedom to determine the grounds upon which such licenses are granted".[695] In what has been termed Paragraph 6 of the Doha Declaration, the WTO stated that "we recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."[696] The conflict was supposedly overcome on August 30, 2003 when a decision was reached permitting WTO member countries to waive its obligations under

[691] Haag, T.A (2002) TRIPS *Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?* 84 J. Pat. & Trademark Off. Soc'y 945
[692] Ibid at 951-952 and Haochen Sun (2003) *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. Int'l L.J. 101
[693] See Declaration on the TRIPS Agreement and Public Health, Para 4, WT/MIN(01)DEC/2(Nov.20, 2001) asserting that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to promote access to medicines for all") available at http://www.wto.org/english/thewto_e/minist_e/mindecl_trips_epdf [hereinafter Doha Declaration]
[694] Sun Haochen, (2004) *The Road to Doha and Beyond: Some reflection on the TRIPS Agreement and Public Health*, 15 Eur. J. Int'l L. 123
[695] This is the developing countries' negotiating target in the Doha Conference. See C. M. Correa, Implication of the Doha Declaration on the TRIPS Agreement and Public Health (2002).
[696] Para 6 of the Doha Declaration

article 31(f) of the TRIPS Agreement in particular scenarios.[697] The waiver allows countries to import generic[698] copies of patented pharmaceuticals made in other countries under article 31(f) of the Agreement,[699] however the provisions also puts the importing country at the mercy of the exporting countries. If a Member State with no manufacturing capacity wants to import generic medicines, it must find a Member who does not have patent on the medicines it wants to import.[700] Commentators have argued that there are exceptions to the rule, for example the rule does not apply if the medicines are solely for export, nevertheless the criterion has been criticised as being unduly cumbersome and untidy.[701] The difficulty of using compulsory licenses for developing countries which some have argued has never been resolved lies in the fact that the grant of a compulsory license solely to assist an importing Member is expressly prohibited under article 31(f) of the TRIPS Agreement. This has left developing countries with very few options on where to shop around when seeking to import from other countries using the option of compulsory licenses.

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[697] Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), at http://www.wto.org/english/news_e/pres03_e/ pr350_e.htm (hereinafter WTO Press Release).

[698] Generic drugs are Copies of brand name patented pharmaceuticals. See Black's Law Dictionary 513 (7th ed. 1999). Generic drugs contain the same active ingredient, but not necessarily the same recipient substances (such as binders or capsules) as the patented drug marketed under a brand name

[699] While all WTO members are eligible to import under this decision, twenty-three developed countries announced that they will not use the system to import. These countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, and the United States of America. WTO, The General Council Chairperson's Statement, at http://www.wto.org/english/news_e/news03_e/ trips_ stat_28aug03_e.htm (Aug. 30, 2003) (hereinafter Chairperson's Statement). Other countries have stated that they would only use the article 31(f) exemption in cases of national emergency or extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

[700] See Gopakumar, K.M (2004) The WTO Deal on Cheap Drugs. A Cri-. tique, in: The Journal of World Intellectual Property 7) No. 1, 99-113.

[701] See Holger Hestermeyer. *Human Rights and the WTO. The Case of Patents and Access to Medicines*. Oxford University Press. 2007

It follows that some developing countries who have attempted to issue compulsory licenses have been faced with a lot of difficulty when attempting to use the device to access medicines. A typical case of this is the Thai government which has constantly been on headline news for flaunting patent rules. For example in November 2006, the Thai government issued a compulsory license for efavirenz (Stocrin), a Merck & Co. drug. In February 2007, it announced that it would be issuing a compulsory licence for Kaletra and a number of other drugs used to treat cancer.[702] In June 2007, the Thai Ministry of Public health also announced that it would be issuing a compulsory licence for an updated version of Kaletra known as Aluvia. Subsequently in October 2007, Thailand's FDA completed the registration of the generic version of Aluvai manufactured by Matrix Laboratories in India.[703] The Office of the U.S. Trade Representative responded harshly to the Thai proposal in its annual "Special 301" report.[704] In the report Thailand was been placed on the Priority Watch List and accused of offering "weak protection against unfair commercial use of undisclosed test and other data" that were submitted by pharmaceutical companies seeking patent protection for their products.[705]

A background of the relationship between US and Thailand is essential in understanding how they have differed on public health matters and the treatment of patent laws. Although the two have retained a close relationship since the end of World War II, and cooperated in many areas, including defence and security, countering illegal narcotics trafficking, trade

[702] A LCORN, Keith (12 February 2007) *Abbott offers price cut to thwart Thai compulsory license on Kaletra*. Aidsmap.com
[703] Access to generic HIV/AID drugs increasing following Thailand's decision to issue compulsory licenses, ealth official says. Shttp://www.news-medical.net/?id=38261. Published: Sunday, 11-May-2008
[704] 2007 Special 301 Report. http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf (Accessed 7th June 2008)
[705] Kaiser Daily HIV/AIDS Report. http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44603. May 01, 2007.

liberalization, and fighting the war against international terrorism,[706] they seem to differ on the subject of how best to approach the subject of public health and the usage of the flexibilities within the TRIPS Agreement. Thailand has continually been seen as a threat to intellectual property by the US, and many have asserted that this has ultimately hampered the trade relations in the long run.[707]

Nimtri Tien-Udom, the director of Aids Access foundation in Thailand applauded the actions of the Public Health Minister Mongkol Na Songkhla for enforcing compulsory licensing for HIV medicines in the face of pressures not to do so from multinational corporations (MNC) in the US. Tien-Udom accused the United States for threatening access to medicines in Thailand.[708] Commentators have therefore argued that despite the fact that the option of compulsory license is available for the procurement of cheaper generic medicines as a substitute for expensive branded products, It t seems apparent that the option is not freely available as it was intended.

In 1997, the South African government passed the Medicines and Related Substances Control Amendment Act No 90 of 1997 (Medicines Act) to allow compulsory licensing of patented AIDS drugs so that local companies could make and sell cheaper generic versions. The US hit back by imposing trade sanctions on South Africa, including denying it tariff relief on certain exports.[709] Critics of a robust structure of intellectual property have argued that allowing compulsory license in developing countries like South Africa, Thailand and Nigeria where HIV/AIDS is a serious epidemic would not be a

[706] Wayne M. Morrison. (2003) CRS Report for Congress. Thailand-US. Economic Relations: An Overview. March 28
http://www.us-asean.org/Thailand/thailand-RS21478.pdf (Accessed 4th June 2008)
[707] TRIPS, AIDs and generic drugs. AVERT. http://www.avert.org/generic.htm
[708] Bangkok Post (4 May 2007) "AIDS activist lash out at US"
http://www.bangkokpost.net/topstories/topstories.php?id=118506 (23rd October 2007)
[709] Somershwar Singh. Compulsory Licensing Good for US Public, Not Others.
http://www.twnside.org.sg/title/public-cn.htm (Accessed 14 October 2007)

serious risk to the profits of the pharmaceutical industry and to research and development funding. Their argument is sometimes based on the fact that developing countries are not really a threat to the profits made by the multinational pharmaceutical industry as most of it comes from the developed countries.[710] Their cry has fallen on deaf ears as the pharmaceutical companies in the west have been adamant on maintaining stout limitations on the usage of the flexibilities within the TRIPS Agreement.

7.5 Parallel Importation

Whilst the difficulty of using compulsory licenses has been highlight above, the usage of using parallel importation as a way of getting round the high prices of medicines has also presented its own problems. Although some have argued that it is easier for developing countries to use parallel importation as a way of accessing cheaper medicines, the complexities of using it is more than some scholars have led one to believe. Parallel import occurs where a patented product is placed on the market by the patent holder, in such a situation the patent holder has by right exhausted his patent rights and the buyer of the product can sell the product as he wishes. Paradoxically whilst Article 28 of the TRIPS Agreement grants the patent holder the absolute right to import or export his products wherever he wishes, Article 6 allows member states to decide whether parallel imports are permissible in their jurisdiction or not,[711] it also allows member states to limit the patent holder's right under the exhaustion principle.[712] In order words whether a patent owner can block parallel imports is a matter of national discretion[713]. Whilst most countries have clearly distinguished between national and international exhaustion, the

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[710] Ibid

[711] See Carlos M Correa (2000) *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Option* 62

[712]) See Watal J (2001) *Intellectual Property Rights in the WTO and Developing Countries*. 317

[713] See World Health Organization, Globalization, TRIPS and Access to Pharmaceuticals 4 WHO Policy Perspective on Medicines No.3 (March 2001), available at http://www.who.int/mediciens/liberary/edm_ general/6pagers/PPM03%20ENG.pdf. [hereinafter TRIPS and Access to Pharmaceuticals]

issue of international exhaustion has sometimes raised some questions as different countries treat it differently. This has been made clear under Article 6 of the TRIPS Agreement which states that " For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". As such the WTO Dispute Settlement system makes it clear that it is not in the business of addressing exhaustion doctrine disputes[714].

The way in which a country treats territorial exhaustion in its national legislations is a significant component of how it can regulate and limit its use. There are basically three types of exhaustion of rights namely, national, regional and international exhaustion. Under the national exhaustion, the exclusive rights of the patent holder ends upon the first sale of the products within a country, however the patent owner may be able to exclude parallel imports from other countries.[715] Regional exhaustion operates by allowing the marketing of goods anywhere in a specific free trade zone or a customs union, such as the EC once the goods have been put on the market anywhere else in that region by or with the consent of the IP right holder.[716] The IP right holder can, nevertheless, prevent the importation of these goods from outside the specified region.[717] International exhaustion on the other takes place where a patent holder places his product in a foreign market and cannot prevent others from re-importing it into another country to be sold cheaper because he has

[714]) See World Health Organization, Globalization and Access to Drug, 24 (1999), available at htto://www.who.int/medicines/library/dap/who-dap-98-9-rev/who-dap-98-9rev.pdf. (visited Oct.7, 2002) [hereinafter Globalization and Access to Drug] (Mentioning that to improve the accessibility though parallel importation, members may establish that the exclusive rights of the patentee may not be claimed in cases where products marketed with that patentee's consent in any other countries are imported.)

[715] Maskus. K.E (2001) *Parallel Imports in Pharmaceuticals: Implications for Competition and prices in developing Countries.* Final Report to World Intellectual Property Organization. April. http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf

[716] Slotboom. M.M . (2005) *The Exhaustion of Intellectual Property Right. Different Approaches in EC and WTO Law.* The Journal of World Intellectual Property. Volume 6, Issue 3.

[717] Ibid

already been rewarded through the first sale of the product. This doctrine is very important especially with pharmaceutical products, because the same patent products are usually sold at different prices in different countries. For example a report by JAAIDS showed that Roche's rocephinea (branded version of Ceftriaxone was 58% cheaper in Colombia than in Nigeria, Glaxo's Combiviral (association of ART+Lamivudine for HIV) was 43% cheaper in Guatemala than in Nigeria. Although the doctrine of exhaustion within the same country has already been established, the doctrine has remained a "grey" area.[718]

Although the WTO tried to clarify the doctrine of international exhaustion in the Doha Rounds, there is no international consensus on what the rule should be. An extensive case study of the way different countries and trade blocks treat the doctrine will be undertaken below to help us discern the likely international direction that the future might go on the issue of parallel importation. The US clearly distinguishes between national and international exhaustion. [719] A good example is the US –Australia Free Trade Agreement (UAFTA) where an exhaustion provision is allowed but can be limited by contractual limitations.[720] Note that in most FTAs , there is a general tendency to be TRIPS-PLUS. Nevertheless It is still interesting to note that whilst the US are proponents of international exhaustion in its legal scheme for copyright and trademark[721], it is in earnest disagreement about the international exhaustion of patents.

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[718] See Erlikhman, D (2003) *Jazz Photo and the Doctrine of Patent Exhaustion: Implications to TRIPs and International Harmonization of Patent Protection*, 25 Hastings Comm.& Ent. L.J. 307, 323-31 where Erlikhman reviews the patent exhaustion rules of the U.S., Japan and EU and showed that all of them have a national or regional exhaustion policy.

[719] A distinction may exist if the exporter is bound by express contract to sell outside the United States. In that case, U.S. rights would not be exhausted by the sale. See, e.g., Ariz. Cartridge Remanufactures Ass'n v. Lexmark Int'l Inc., 290 F. Supp. 2d 1034, 1043 (N.D. Cal. 2003)

[720] US- Australia Free Trade Agreement (UAFTA) http://www.livingstonintl.com/tradenewsarticle.cfm?id=2842 Last Visited 11:12:05

[721] Cahoy, D (2005) *Patent Fences and Constitutional Fence Post: Property Barriers to Pharmaceutical Importation.* 15 Fordham Intell. Prop. Media & Ent. L.J. 623

The issue of trademark for patented medicines is relevant because patent medicines are sold under trademarks; this makes it the more complicated. One of the most cited cases with regards to the international exhaustion in the US is Boesch v. Graff, which was decided by the Supreme Court as far back as 1890, even before the TRIPS Agreement[722] Although not a case to do with patented medicines the principle behind the reasoning of the case is interesting. In this case, the plaintiff owned parallel patents for lamp burners in the US and Germany; he subsequently sued to keep the lamp burners lawfully purchased in Germany from being sold in the US. With regards to the German law at that time, a third party could manufacture and sell patented products so long as that party had done so before with the patent owner's submission of the patent application.[723] The Supreme Court held that although the laws of Germany allow the selling of a product, this does not authorize the selling of "articles in the United States in defiance of the rights of patentees under a United State patent . . . . The sale of articles in the United States under a United States. patent cannot be controlled by foreign laws." [724]The effect of this was the plaintiff could not prevent a third party from selling his patented lamp burners in Germany but could prevent a third party from importing the lamps lawfully sold in Germany into the US.[725]

How far the Boesch rule extends, however, is debatable. A few years before the Boesch decision the District Court of New York in Holiday v. Mattheson held that parallel importation of patented goods first sold overseas under the authority of the patent owner did not infringe on the US patent.[726] In this case, the owner of the patent sold his patented goods in England;[727] the defendant

[722] Boesch v. Gr ff, 133 U.S. 697 (1890).
[723] Ibid
[724] Boesch v. Graff, 133 U.S. 697, 702 (1890).
[725] Ibid
[726] Holiday v. Mattheson, 24 F. 185 (C.C.S.D.N.Y 1885)
[727] Ibid

obtained the goods in England and imported them back into the US.[728] The defendant did not have the plaintiff's permission to import the patented product. Nevertheless, the court refused to grant the plaintiff an injunction.[729] The District Court reasoned that there was a presumption upon the sale of a good that the seller intended to give up his rights in the products sold; it would be therefore contradictory to allow the seller to restrict the buyer's use when no such restriction was made at the time of sale.[730] The court held that the plaintiff's patent rights at home were exhausted after the goods were sold abroad. [731] The discrepancies in the court's decision can also be seen in Curtiss Aeroplane v. United Aircraft.[732] In this case the Court of Appeal for the Second Circuit pronounced that the US operates a policy of international rights of exhaustion. A holder of US patents on aircraft components had licensed the British government to produce aircraft in Canada (for use in the First World War). After the war, the British government sold some of the aircraft it had produced to a third party that imported them into the US for resale. The Second Circuit held that the US patent holder, in consenting to the use of its patent for the manufacture of airplanes in Canada, had exhausted its right to control the importation of the resulting aircraft into the US

Interestingly other US courts have distinguished a patent owner granting an exclusive license to a third party to practice a patent in a foreign country from the patent owner selling her product in another country.[733] In Griffin v. Keystone Mushroom Farm, Inc., the District Court of Pennsylvania held that the Boesch doctrine against exhaustion applied even when the overseas first sale was authorized by the patent owner.[734] In Griffin, the plaintiff held parallel

[728] Ibid
[729] Ibid
[730] Ibid
[731] Ibid
[732] 266 F. 71 (2d. Cir. 1920
[733] Griffin v. Keystone Mushroom Farm, Inc., 453 F. Supp. 1283, 199 U.S.P.Q. (BNA) 428 (E.D. Pa. 1978);
[734] Ibid

patents on farm equipment in Italy and the US.[735] He licensed his Italian rights to a company he formed to produce the equipment.[736] The defendant purchased the equipment in Italy and imported it to the US.[737] The defendant argued that allowing the plaintiff to stop the importation of the equipment would amount to a double recovery since the plaintiff had already received a royalty for the equipment from the Italian licensing agreement.[738] The court disagreed, stating that the underlying principles governing patent law were to allow patent owners to exclude others from making, using and selling the patented invention.[739] One method of exclusion is to grant licenses to only those entities that the owner wants to practice the patent.[740] Allowing the defendant to import the equipment sold under the Italian license would thwart the patent owner's ability to exclude persons from practicing the patent in America.[741] Griffin restated the principle illustrated in Boesch, stating that the "sale of articles in the United States under a US patent cannot be controlled by foreign laws."[742] Ruling for the defendant would breach that principle by allowing rights confirmed under an Italian patent to control the rights of an American patent holder.

In Sanofi v. Med-Tech Veterinarian Products, Inc., the District Court of New Jersey clarified under what circumstances parallel imports infringe and who may bring an infringement action.[743] In this case a pharmaceutical company in France sold an exclusive license to American Home Products for its US patent on acepromazine maleate, a tranquilizer for the treatment of animals.[744] Sanofi continued to produce and market the drug in Europe. The defendant

[735]Ibid
[736] Ibid at 1284
[737] Ibid
[738] Ibid
[739] Ibid
[740] Ibid
[741] Ibid
[742] Ibid
[743] 75
[744] 76 Sanofi, S.A. v. Med-Tech Veterinarian Prod., Inc., 565 F. Supp. 931, 220 U.S.P.Q. (BNA) 416 (D.N.J. 1983

purchased the drug in Europe and then imported it to the US. [745] Both Sanofi and its exclusive licensee, American Home Products, sued for patent infringement citing Boesch and Griffin.[746] The court held that while American Home Products had a valid claim, its licensor, Sanofi did not.[747] Discussing Sanofi's claim, the court distinguished Boesch and Griffin on the ground that neither of the plaintiffs in those cases had sold the product overseas.[748] Sanofi sold the drug throughout Europe.[749] Consequently, the court analogized Sanofi's case to Mattheson where the US patent holder sold the patentable articles overseas. [750]

Like the court in Mattheson, the District Court of New Jersey found that allowing Sanofi to impose restrictions against the defendant's use would be inconsistent with the defendant's expectation of full ownership.[751] Moreover, the plaintiffs in Boesch and Griffin had authority to sell their product in the US.[752] Here, Sanofi granted an exclusive license to American Home Products for all US sales. [753] Therefore, the court determined that it could not enforce an injunction on behalf of Sanofi, because Sanofi had no rights to sell the drug in the US.[754] On the other hand, American Home had exclusive rights to practice the patent in the US. [755]Thus, the defendant's lawful purchase of the drug from Sanofi in Europe did not give the defendant the right to ship it to the U.S. because Sanofi had no right to sell the drug in the US. A purchaser, though acquiring the "whole right of the vendor in the thing sold," [756]still may only do with that product what the vendor could have lawfully done and acquires no

[745] Id. at 937.
[746] Ibid
[747] Ibid
[748] Ibid
[749] Ibid at 937-38.
[750] Ibid
[751] Sanofi, S.A. v. Med-Tech Veterinarian Prod., Inc., 565 F. Supp. 931, 938 (D.N.J. 1983)
[752] Ibid at 939.
[753] Ibid
[754] Ibid at 939.
[755] Ibid
[756] Ibid

right greater than that possessed by the owner.[757]Thus, American Home's infringement claim was valid. The court also addressed the differences between exclusive and non-exclusive licenses.[758] The court stated that a non-exclusive license confers only the privilege to sell the patented product without infringing the patent. [759] Because the owner of a non-exclusive license could not prevent the patent owner from granting other licenses, he could not bring a claim for patent infringement.[760] On the other hand, an exclusive license conveys the promise that others will be excluded from practicing the patent in the field of use for which the patent was granted.[761] Consequently, the owner of an exclusive license may bring a claim against those who infringe upon it.[762]

In sum, the courts have laid down the following rule: parallel imports are not infringing when the one authorized to practice the patent right domestically makes the first sale abroad. However, where the patent owner grants an exclusive license to practice the patent in the United States, the exclusive licensee's rights are not exhausted when another entity sells the product abroad. The important thing to note however is that while the Boesch decision may seem very odd in the context of modern intellectual property law as well as arguably discernible from many of the scenarios likely to occur with regards to pharmaceuticals imports, most courts in the US will address their case in accordance with Boesch or distinguish it basing its decision on technical grounds. The importance of Boesch cannot be understated as no other Supreme Court case has touched so specifically on the first sale doctrine.[763]

In 2001, the U.S. Court of Appeals for the Federal Circuit (CAFC)) court established to hear all patent appeals, which is also responsible for articulating national patent rules deliberated on a groundbreaking case that brought the

[757] Ibid
[758] Ibid at 939
[759] Ibid at 936
[760] Ibid
[761] Ibid 1t 937
[762] Ibid
[763] See Chisum, D.S (2001) *Patents: A Treatise on the Law of Patentability, Validity and Infringement* 16.03[2][a][iv] (2001) In the United States, the issue has arisen often with regard to trademark and copyright but relatively rarely with regard to patents.

subject of patent exhaustion back into the limelight.[764] In Jazz Photo v. International Trade Commission[765] Jazz Photo, Fuji Photo Film contended that its patented "lens-fitted film packages" were being violated by US buyers who were using the originally provided first roll of film and consigning the cameras to others who subsequently carried out the necessary steps imperative to replace the film roll and its container. Some US buyers were also replacing the batteries of cameras and replacing the film winding wheel and resetting the film exposure counter, resealing the outer case and adding new cardboard covers.[766] Fuji Photo had initially sold the cameras with instructions that the film roll should not be removed after use and the entire camera should be returned to it for photo processing. Fuji instructed buyers that the camera should not be opened by the consumer because of the danger of electrical shock and that the camera would not be returned after photo processing was completed.[767]

In a nut shell the case before the CAFC concerned the question of whether actions taken by third parties represented repair or reconstruction as a matter of US patent law. Under the applicable patent law in the US, a patent holder cannot prevent a third party from repairing a patented product that has been first sold, but may prevent the reconstruction of a product.[768] Reconstruction is seen in the same light as making a new product, and therefore to be within the acts the patent holder may prevent. The International Trade Commission (ITC) decided that the acts performed by third parties constituted reconstruction, and that importation of the used and reconstructed disposable cameras should be

[764] See Barfield C.E & Groombridge, M.A (1999) *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 Fordham Intell. Prop. Media & Ent. L.J. 185, 190 (1999).
[765] 264 F.3d 1094 (Fed. Cir. 2001), cert. denied, 536 U.S. 950 (2002).
[766] Mary Helen Sear: First Sale exhaustion clarified M.H Sears law Firm Washington D.C http://www.managingip.com/?Page=10&PUBID=34&ISS=12554&SID=471589&TYPE=20
[767] Ibid
[768] Ip-health] Fred Abbott on Jazz Photo case James Love james.love@cptech.org Tue, 4 Jun 2002 12:14:02 -0400 http://lists.essential.org/pipermail/ip-health/2002-June/003097.html

generally prohibited. The CAFC disagreed with the ITC's legal analysis, holding that the acts performed by third parties constituted repair, and therefore were permitted as to disposable cameras that had been first sold. That is, the rights of the patent holders to exercise control over repair of the cameras had been exhausted when they were first sold. The CAFC held that Fuji could not prevent importation of cameras that had first been sold in the United States, exported for repair, and then re-imported. However, since US patent rights as to cameras first sold outside the US were not exhausted, importation of cameras first sold and repaired outside the US could be blocked. Commentators have expressed disappointment with the analysis and result of the CAFC on this case. Lowe contends that the court did not adequately address existing US law on patents and parallel importation.[769] The CAFC had failed to take note of the contrary pre-existing case law, therefore the Jazz photo case was seen as producing a very disappointing decision. It purported to dispose of a critical issue in US patent law without addressing the potential implications in respect to patented medicines first sold outside the US.[770] The relevance of the above case law on parallel importation is very important in the access to medicine debate and on the flexibilities in the TRIPS Agreement for a variety of reasons. Firstly it show that even in the USA, the courts have struggled with the application and at times have had to reverse decisions made or like in the Jazz photo case clarify its position on parallel importation. Secondly, it also exposes the vulnerability that other developing countries or LDC who do not have the level of sophistication in which the courts have in the USA may be exposed to when it is called upon to interpret certain aspects of the TRIPS which they have little or no experience in dealing with.

Whilst the US position on parallel importation is interesting, the courts in two countries who were the principal driving forces behind the TRIPS Agreement- Britain and Japan, have confirmed the legality of parallel importation of

[769] Ibid
[770] Ibid

patented products in the absence of any indication to the contrary.[771] English common law on patent expressly states that a patentee may impose limited conditions on selling his goods; an ordinary vendor of goods may not. The authority for this position was the judge's reasoning in National Phonograph Company of Australia Ltd. v. Menck where it was stated that "it is open to the patentee, by virtue of his statutory monopoly, to make a sale sub modo, or accompanied by restrictive conditions which would not apply in the case of ordinary chattels; ... the imposition of these conditions in the case of sale is not presumed, but, on the contrary, a sale having occurred, the presumption is that the full right of ownership was meant to be vested in the purchaser while ... the owner's rights in a patented chattel would be limited, if there is brought home to him the knowledge of conditions imposed, by the patentee or those representing the patentee, upon him at the time of sale' .[772] The 1996 decision in Roussel Uclaf v Hockley [773] confirmed the English case law on exhaustion. In that case, a company received a licence to work a process patent in the People's Republic of China for the formulation of insecticide.[774] Roussel Uclaf SA ('Roussel'), the patent holder, supplied the Chinese company with the chemical resulting from the patented process. The Chinese company resold the chemical on the international market. When the defendant, Hockley International Ltd ('Hockley'), came into possession of a batch of that chemical in the United Kingdom, Roussel brought an infringement suit. It claimed that it had only given permission for the goods in question to be used in China and that it had expressly forbidden their re-export. In denying Roussel's motion, the English Patents Court held: "It is the law that where the patentee supplies his product and at the time of the supply informs the person supplied (normally via the contract) that there are limitations as to what may be done with the product supplied then, provided those terms are brought home first to the person originally supplied and, second, to subsequent dealers in the product, no

[771] Christopher Health. Parallel Imports and International Trade.
[772] National Phonograph Company of Australia Ltd. v. Menck , [1911] [28] R.P.C. 229, 248.
[773] Roussel Uclaf v. Hockley International, decision of 9 October 1995, [1996] R.P.C. 441
[774] [1996] RPC 441, 443

licence to carry out or do any act outside the terms of the licence runs with the goods".[775] The only exception to the rule would be in where there was a limited licence imposed at the initial sale of the goods and even if Roussel had only granted the Chinese a limited licence, the limitation was not communicated to subsequent purchasers such as Hockley.

By way of comparison, the Japanese Supreme Court stressed their position by emphasising the importance of international trade as its justification. In BBS Kraftfahrzeugtechnik AG v Racimex Japan KK; Jap Auto Products KK[776] the Supreme Court of Japan had the opportunity to decide an important question concerning the parallel importation of patent-protected goods, which it did in an interesting way.[777] It held that the rights of Japanese patent holders are not infringed by the importation into Japan of patent-protected goods placed on the international market by the holder of an equivalent patent in another country.[778] This is provided that the holders of the patents in the different markets concerned are the same legal entity or licensees of the same entity. The case is of significance as it directly addresses the conflict between an intellectual property owner's desire to maximise its profits by engineering variations in price for the same goods in different markets, and the desire of entrepreneurs to exploit those price differentials for their own gain.[779]

The exhaustion principle under the European Community [EC] also exposes one to the value of parallel importation in the EC market. The principle is

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[775] Ibid 443

[776] Case No H-7 (O) 1988, dated 1 July 1997. An English translation of this judgment has been published at (1998) 29 International Review of Industrial Property and Copyright Law 331 ('BBS v Racimex Translation').

[777] See Nanao Naoko, Koyama Takahiro and Sudo Hiromi, (1996) *Decisions of Parallel Imports of Patented Goods* 36 IDEA: The Journal of Law and Technology 567.

[778] http://www.austlii.edu.au/au/journals/MelbJIL/2001/7.html

[779] conflict causes recurring legal battles between intellectual property owners and arbitrageurs all over the world: see, e.g., Quality King Distributors, Inc v L'anza Research International, Inc, 523 US 135 (1998) ('L'anza'), Zino Davidoff SA v A & G Imports Ltd (2000) Ch 127 ('Davidoff') and W R Cornish, Intellectual Property: Patents, Copyright, Trademarks and Allied Rights (4th ed, 1999) 47–

based on Article 28 and 30 of the EC. Article 28 states that "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited.", whilst Article 30 states that "The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of . . . the protection of industrial and commercial property … A derogation from the principle of the free movement of goods is not . . . justified where the product has been put onto the market in a legal manner, by the patentee himself or with his consent, in the Member State from which it has been imported, in particular in the case of a proprietor of parallel patenes."[780] It follows that Article 28 has been interpreted to mean that governments of the EC Member States cannot hinder the importation of goods marketed in other EC Member States, even if these measures apply without distinction to domestic products and imported products from other EC Member States.[781] The combined effect of Articles 28 and 30 EC based on the ECJ rulings asserts the prohibition of national exhaustion of IP rights, thereby establishing the principle of regional exhaustion upon first-marketing by or with the consent of the IP right holder.[782]

According to this principle, the IP right holder cannot prevent trading between EC Member States in products that have been marketed in the EC by or with the consent of the IP right holder. The ECJ has justified its interpretation of Article 30 EC, prescribing regional exhaustion of IP rights instead of national exhaustion, by referring to the object and purpose of the EC Treaty: "If [an IP right] is relied upon to prevent the marketing in a Member State of products distributed by the holder of the right or with his consent on the territory of another Member State on the sole ground that such distribution did not take

[780] See Case 15/74, Centrajaam v. Sterling Drug [1974] ECR 1147, at § 10.
[781] See, for example, Case 8/74, Dussonviile, [1974] ECR 837; and Case 120178, Cusfis de Dijon, [1979] ECR 649.
[782] Consent is considered to exist when IP-protected products are marketed or sold by the IP right holder itself, by its subsidiary or affiliate, or, where the IP rights have been licensed, by a licensee: see Centmfuam, ibid, at 5% 18-21.

place on the national territory, such a prohibition, which would legitimize the isolation of national markets, would be repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market . . .''[783]

The case for regional exhaustion of patents has been validated by a 2000 EC Commission report called a Proposal for a Regulation on the Community Patent. Article 10 of that draft, titled "Community Exhaustion of the Rights Conferred by the Community Patent" provides that "The right conferred by the Community patent shall not extend to acts concerning the product covered by that patent which are carried out within the territories of the Member States after that product has been put on the market in the Community by the proprietor of the patent or with his consent, unless there are legitimate grounds for the proprietor to oppose further commercialization of the product."[784] Having established the fact that the EC operates a regional exhaustion principle, the ECJ has not yet clarified whether EC Member States have been cleared to operate a system of international exhaustion.[785] For an EC Member State to introduce the principle of international exhaustion, they must be trade agreement between the EC member state and a third country.[786] The ECJ ruling on international exhaustion on trade-mark clarifies this. In Silhouette[787] and Sebago[788] the ECJ confirmed the rule on regional exhaustion; however some have argued that it accepted the possibility of international exhaustion being extended to third countries.[789]

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[783] Case 78/70, Deutsche Grammophon, 119711 ECR 487
[784] See COM (2000) 412 Final, Proposal for a Council Regulation on the Community Patent, O.J. 2000, C 337E/278 and press release of the EC Council of 3 March 2003, 6874/03 (Prase 59), at p. 15
[785] Polydor v Harlequin Records Shops [1982] ECR 329.
[786] Ibid
[787] See Case C-355196, *Silhouette,* [1998] ECR 1-4799, at §§ 25-27.
[788] See Case C-173/98, *Sebago,* [1999] ECR 1-4103, at §§ 19 and 20
[789] See Article 7 of the Trade-Mark Directive. Available at http://europa.eu.int/comm/intern~_niarket/eu/indprap/tm/cxhaust.ht . For more discussion on this see Noor, M (1998) *ECJ leaves Key Questions Unanswered*. *Managing Intell. Property 13*

Having established the different options of parallel importation in developed countries, it is important to note that each developing country treats the issue of parallel importation of pharmaceuticals differently. Although Maskus notes that many developing countries disallow parallel importation[790], India allows parallel importation under section 107Ab of its amended Patent Act 1970 Act. Section 107Ab states that the "importation of patent products by any person from a person who is duly authorised under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights". In the case of Brazil, the law on the parallel importation of products can be found in art. 43, IV of Brazilian Federal Law 9.279/96 which states that exhaustion of rights is deemed to occur only with respect to products placed by the patentee or with his consent in the internal market, similarly under art. 68 § 4 if the patent owner imports his own products then third parties are entitled to carry out parallel importation. The case of American Home Products vs. Laboratório LDZ (subject to any higher Brazilian court judgment) is case law authority on parallel importation. In that case the defendant LDZ purchased Centrum vitamins in the internal market from an importer who was a trading company, the court held that the action should be brought against importer because the product had already entered into the local market.[791] That being said a number of developing countries including Argentina, Thailand, and South Africa, recently have enacted laws permitting parallel imports of pharmaceutical products.[792]

The importance of exploring the different approaches to parallel importation in different countries and economic blocs is important for developing countries

[790] Keith E. Maskus.(2001) *PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FORCOMPETITION AND PRICES IN DEVELOPING COUNTRIES. Final Report to World Intellectual Property Organization.*
[791] Daniel Advogados. (2002) *Brazil: Parallel Imports in Brazil*. 20 May 2002. http://www.mondaq.com/article.asp?articleid=16266
[792] Keith E. Maskus. *(2001) PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FORCOMPETITION AND PRICES IN DEVELOPING COUNTRIES*. Final Report to World Intellectual Property Organization. Draft.

that are yet to enact intellectual property legislation that will bring them in compliance with the TRIPS Agreement which gave developing countries like Nigeria a deadline of 1 January 2005 to comply. It shows the challenges that a country may have to face with gaining access to medicines through parallel importation depending on their health care crisis. In December 1997, the South African government amended its Medicines Act which gave the Minister of Health the right to legalize parallel importation of patented medicines in order to tackle the high prices of medicines. Even though this action was challenged in the South African Courts by the pharmaceutical companies, with much pressure from activist and NGOs, the case was dropped and today South Africa has the option to carry out parallel importation which some have suggested is an easier alternative to acquiring cheaper drugs than compulsory licensing.[793]

Regardless of the foregoing, some commentators have pointed out the disadvantages of parallel importation leading to a decreased incentive for R&D into pharmaceutical products and the development for global diseases that affect the third world. One of the main disadvantages is the establishment of international exhaustion could lead to the collapse of the objective of price regulation.[794] If patent-holder cannot confidently set prices near marginal cost in low-income markets where demand is highly price-elastic without the fear that these low prices could spill-over to other more potentially higher-priced markets, then the purpose of price discrimination could be defeated.[795] Pharmaceutical companies could therefore respond by attempting to set a uniform price throughout an economic bloc, Danzon and Wang points out that pharmaceutical have consistently attempted to set uniform prices in the EC to

[793] Keith E. Maskus.(2001) *PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FORCOMPETITION AND PRICES IN DEVELOPING COUNTRIES. Final Report to World Intellectual Property Organization*
[794] PATRICIA M. DANZON. (2003) *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents. International Journal of Health Care Finance and Economics*, 3, 183–205.
[795] Ibid

that effect.[796] The failure of market division and the patent holders' ability to maintain price differentials is a problem not only for re-importation into developing countries, but is equally a problem in developed countries like the US who have faced cross-border re-importation of prescription drugs from Canada.

The US healthcare system has been heavily criticized with democrats calling for a free national healthcare system during the 2008 presidential election, the fact remains that when compared with the healthcare systems in the developing world, the US has a smaller problem.[797] The US operates a health insurance scheme which enables people pay for medical expenses through privately purchased insurance, social insurance or a non-insurance social welfare program funded by the government,[798] however the prices of pharmaceuticals in the US has continued to soar. The most vulnerable victims of the high prices of medicines are senior citizens who despite the fact they qualify for Medicare[799] are unable to afford additional insurance for their prescription drugs.[800] States such as Michigan who are near the Canadian border have

[796] Danzon, P. M., Y. R. Wang and L. Wang. (2003). *The Impact of Price Regulation on the Launch Delay of New*
Drugs: Evidence from Twenty Five Countries in the 1990s. Working Paper, The Wharton School.

[797] By Andrea Santiago What's Right with America's Healthcare System Physicians and Patients from Around the World Come to US for Highest Quality

[798] According to the United States Census Bureau, approximately 85% of Americans have health insurance. See Income, Poverty, and Health Insurance Coverage in the United States: 2007." U.S. Census Bureau. Issued August 2008

[799] Medicare is a federal insurance program for people age 65 and older and certain disabled people. The Centres for Medicare & Medicaid Services (CMS) is the part of the United States Department of Health and Human Services that operates Medicare. The Medicare program consists of two parts, Medicare Part A (hospital insurance) and Medicare Part B (supplemental medical insurance). Part A covers hospital, skilled nursing facility, home health and hospice care. Part B covers doctors' services, outpatient hospital services, durable medical equipment and a number of other medical services and supplies. Medicare also provides limited coverage for preventive services. See http://hiicap.state.ny.us/medicare/medicare.htm (last visited Dec.27, 2005)

[800] Senior citizens are the older population in the U.S. i.e. people over 65 years or older. In 2002 there were about 35.6 million senior citizens. Senior citizens represent 12.3% of the U.S. population, about one in every eight Americans. The number of older Americans increased by 3.3 million or 10.2% since 1992, compared to an increase of 13.5% for the under-65 population. However, the number of Americans aged 45-64 who will reach 65 over the next

found consonance in gaining access to cheaper medicines through border-crossing and internet pharmacies. The most popular means of re-importation has been to travel over to Canada to purchase medications in individual quantities (note that practice is prohibited by the federal government if the individual is returning with a more than 90-day supply of prescription drugs).[801] Drug clubs have also been set up to sell drugs sold in America that are exported to Canada and are then re-importation back to the U.S.[802] In 2003, it was estimated that between one and two million US citizens purchase Canadian drugs over the internet, by phone, or through border-crossing.[803] Danzon has however asserted that trying to tackle the predicament faced by senior citizens in the US through parallel imports or external referencing to lower prices in other countries may not be the solution to gaining access to medicines in the long run because of the effects on R&D and the development of new chemical entities.[804] Her argument assets that such actions will indeed affect lower income countries who will be at loss if pharmaceutical companies become reluctant to grant lower prices on medicines in other countries for fear that these lower priced products will be re-imported into the US through referencing or parallel trade.[805]

One of the detrimental effects of parallel importation on access to medicines has been its potential to facilitate counterfeit medicines entering the

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two decades increased by 38% during this period. In 2002, there were 20.8 million older women and 14.8 million older men, or a sex ratio of 141 women for every 100 men. Since 1900, the percentage of Americans 65+ has tripled (from 4.1% in 1900 to 12.3% in 2002), and the number has increased eleven times (from 3.1 million to 35.6 million).

[801] See generally Paul Egan, Michigan may buy Canada drugs, DET. NEWS, Oct. 1, 2003, available at http://www.detnews.com/2003/politics/0310/01/b01- 285866.htm.

[802] Ibid

ju[803] Kim Norris, Medications crossing the border spurring concerns over safety, DET. FREE PRESS, Nov. 24, 2003, available at http:// www.freep.com/money/business/cdrug24_20031124.htm.

[804] DANZON. P.A (2003) Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents. International Journal of Health Care Finance and Economics, 3, 183–205

[805] Ibid

marketplace.[806] Although counterfeit drugs are discussed in the previous chapter, it will be slightly re-appraised here in light of its effect on exhaustion. However by far one of biggest counterfeit drug market in sub-Sahara is Nigeria; and most of the counterfeit drugs are imported from Asian countries such as china, India and Pakistan.[807]. As such a WHO report showed that 35% of counterfeit drugs in the world come from India.[808]The report also noted that the illegal business in counterfeit drugs makes up approximately 10 percent of the global medicines market and account for more than $32 billion in annual sales. [809] In 2001 Chinese authorities closed 1,300 factories and investigated 480,000 cases representing counterfeit drugs with a value of $57 million Likewise a report by WHO in 2001showed that more than one-third of products allegedly containing the anti-malarial drug artesunate in Cambodia, Laos, Burma, Thailand and Vietnam actually had no active ingredients.[810]

A follow-up study in 2004 showed that the situation had worsened, with 99 out of 188 artesunate samples found to be counterfeit.[811] The presence of counterfeit goods imported from other countries into Nigeria has a significant effect on parallel importation into neighbouring West African countries such as Benin, Chad, Niger and Cameroon as such West African countries buy their drugs from Nigeria.[812] The ill effects of parallel importation encouraging counterfeit medicines are felt not only in developing world, but in the developed world.

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[806] Combating Counterfeit Medicines and protecting patients through a Partnership Approach. European Federation of Pharmaceutical Industries and Association. http://212.3.246.100/Objects/2/Files/Q&Acounterfeit20052.pdf

[807] Prof. Dora Akunyili, Counterfeiting Drugs and Pharmacovigilance – The study of adverse Drug Reactions on 25th May 2005

[808] Fact sheet N°275 Revised 14 November 2006 Counterfeit medicines

[809] See NAFDAC, Safeguarding the Health of the Nation. http://www.nafdacnigeria.org/globaltrends.htm.

[810] China's Killer Headache: Fake Pharmaceuticals. e-drug@usa.healthnet.org. Fri, 30 Aug 2002 11:40:13 -0400 (EDT)

[811] Ibid

[812] Prof. Dora Akunyili, Counterfeiting Drugs and Pharmacovigilance – The study of adverse Drug Reactions on 25th May 2005

In September 2004, counterfeit Cialis, Eli Lilly's medicine for the treatment of erectile disorder was found as part of a parallel import stock in the UK. Shortly after that Abbott's Reductil counterfeit anti-obesity medicines were found in the legitimate parallel import supply chain.[813] Similarly in 2007, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) with assistance from Astra Zeneca Ltd had to recall parallel imports stock Lot 65520 of Bicalutamide tablets 50mg sold as Casodex and supplied from France after counterfeit tablets were discovered in the legitimate supply chain.[814] The fact that parallel trader have to repackage medicines before exporting them to other countries or regions makes the likelihood of counterfeit trade more serious. Most of the incidents of safety in the supply chain of parallel imports have been deemed to involve human errors of different proportions. As such Packaging Gateway has pointed out that sometimes a medicine has to go through as many as 20-30 pairs of hands before it eventually reaches the patient.[815] As such discriminatory and poor regulation of exports by exporting countries has been deemed to be one of the major reasons for counterfeit parallel imports into Nigeria.[816] NAFDAC has therefore responded by banning the imports of pharmaceutical products into Nigeria marked FOR EXPORT ONLY. Their rationale is based on the fact that any product that cannot be used in the country of manufacture should be unacceptable in Nigeria.

Despite the foregoing, the potential benefits of parallel importation in the access to medicines debate cannot be underestimated, people living in the developing world and even the developed world do benefit from parallel traders who purchase medicines at a lower price and sell them to patients at a lower price than the branded manufacturers would charge. Many observers

[813] Diminishing the Risks of Counterfeit Drugs. Packaging gateway.com. 05 March 2005. http://www.packaging-gateway.com/features/feature18/
[814] Drug Alert. Class 1 Medicine Recall. Action Now. EL (07) A/08. 1 June 2007. Ref MDR 40-05/07
[815] Fact sheet N°275 Revised 14 November 2006. Counterfeit medicines
[816] Prof. Dora Akunyili, Counterfeiting Drugs and Pharmacovigilance – The study of adverse Drug Reactions on 25th May 2005

have affirmed the positive consumer welfare effect of making pharmaceuticals available at lower prices. The advantages of parallel importation to the access to medicines dilemma is further demonstrated in the fact that it is the only "flexibility" in the TRIPS Agreement that has been left to the discretion of each member states to choose whichever policy best suits them. Although some have argued that the fact that Article 3 TRIPS states WTO Members should accord to the nationals of other WTO Members treatment no less favourable than it accords to its own nationals with regard to the protection of IP rights, subject to certain exceptions is defeated when countries operate a national or regional exhaustion practice. This argument is baseless, as discrimination on the bases of exhaustion policies do not amount to discrimination based on nationality.[817] Article 4 of the TRIPS Agreement also states that "any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members", however the Doha TRIPS Declaration states clearly that the TRIPS Agreement does not prescribe any kind of exhaustion of IP rights.

For many, including this author the way forward to maximize the usage of parallel importation would be to find ways to ensure that its potentials are maximized in fulfilling the role that it was intended for in the TRIPS Agreement. This can be done by making sure that parallel importation of authentic and genuine medicines are imported into the poorest developing countries and not re-imported into developed countries, whilst still ensuring that pharmaceutical companies are not deterred from investing into R&D for innovative medicines for all diseases including topical diseases. At present re-importation of patented and generic products from 76 countries including

[817]Slotboom, M. M. (2003.) *The Exhaustion of Intellectual Property Rights-Different Approaches in EC and WTO Law.* Journal of World Intellectual Property 6(3):421-440.

China, India and South Africa are banned from being imported into the EU.[818] However the fact that regional exhaustion of patented products is a legitimate trade puts EU members in a better position to explore their internal market and promote access to medicines between their member states. Malueg- Schwartz has recommended that countries should follow suit by implementing regional exhaustion as the key to achieving the optimal global policy on parallel importation.[819]

Although the idea may seem farfetched at first, the creation of a single market within Africa may be the key to promoting trade and the access to medicines. That being said, there are various regional and economic trading blocs within the continent which promote regional exhaustion in the same way that the EU does. The African Intellectual Property Organisation (AIPO) or OAPI is one of them. It consist of 16 French speaking member states including Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo. The AIPO have a shared structure to protection intellectual property rights which allows parallel imports from within any AIPO state. Parallel imports from other third countries are however prohibited. Nevertheless the AIPO has many shortcomings when it comes to promoting parallel importation between neighbouring countries in Africa. For example a parallel trader from Togo cannot import medicines from Ghana to sell to consumers in Togo even if the pharmaceutical products were cheaper in Ghana. Ghana on the other hand operates an international patent exhaustion policy; however its West African neighbour Nigeria operates a national patent

[818] PATRICIA M. DANZON. (2003) *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents. International Journal of Health Care Finance and Economics*, 3, 183–205

[819] Malueg, David A., and Marius Schwartz. (1994) *Parallel Imports, Demand Dispersion, and International Price Discrimination*. Journal of International Economics 37:167-196.

exhaustion policy with a ban on cheaper substances from India and China if domestically patented.[820]

A regional alliance which might have formed a formidable force in dealing with intellectual property rights in West Africa is the Economic Community of West African States (ECOWAS). It comprises of 15 countries of which Nigeria is one of. Established in 1975 with the Treaty of Lagos, ECOWAS had the fundamental goal of achieving collective self-sufficiency in all fields including economic, transport, telecommunications, energy, agriculture, natural resources, commerce, monetary and financial questions, social and cultural matters.[821] Interestingly, the Treaty of Lagos does not make any mention of intellectual property rights. The African Union (AU) however seems like a more likely organisation which may achieve the realization of a harmonised intellectual property regime within Africa. The AU consists of 53 states and is a successor of the OAU. It was established in September 1999 by the Heads of states and Governments of the African Union with the aim of promoting unity and solidarity as well intensifying co-operation on development.[822] In a paper released in November 2006 titled "Establishing a PAN African Intellectual Property Organisation" (PAIPO) 2006,[823] participants called for African leaders to establish an umbrella institution on intellectual property that would fit all members. The goals of the PAN African Organisation on Intellectual Property would be to provide a means for all Member States to co-ordinate specialised intellectual property knowledge and services with a goal to promote innovation, industrial competitiveness and

[820] The Use of TRIPS Flexibilities to Promote Pharmaceutical Production in Developing Countries24 October 2007"Pharmaceutical Production in West and Central Africa" BMZ-GTZ-UNIDO Regional Workshop Dakar, Senegal ChristophSpennemann, Legal Expert, IP Team Division on Investment, Technology and Enterprise Development, UNCTAD. http://www.gtz.de/en/dokumente/en-Spennemann-TRIPS-flexibilities-2007.pdf
[821] Ibid
[822] AFRICAN UNION IN A NUTSHELL http://www.africa-union.org/root/au/AboutAu/au_in_a_nutshell_en.htm
[823] Extraordinary Conference of the African Ministers of Council on Science and Technology (Amcost) 20-24 November 2006, Cairo, Egypt.

economic growth in Africa.[824] Although the institution is already facing opposition from other intellectual property regional bodies such as ARIPO, the future will tell if an African regional union on intellectual property matters is the solution to the problems of parallel importation and compulsory licensing at least between one Member State and the other.

7.6 Limitations of the Doha Declaration

Most commentators who have written on the values, triumphs and disasters of the Doha Declaration have one thing in common, and that is the fact that despite the success of the Doha declaration, many issues remained unresolved with regards to health. One of the key issues that remained unresolved at Doha was how to guarantee that countries with insufficient or no manufacturing capability in the pharmaceutical area could get medicines from countries who had obtained a compulsory licences for the purpose of exporting medicines to such countries with little or no manufacturing capabilities. This setback steams predominantly from Article 31(f) of the TRIPS Agreement which states that compulsory licensing should be limited to situations where the manufacture is "predominantly for the supply of the domestic market".[825] Whilst this kind of state of affairs would benefit developing countries such as India and Brazil who have laboratories and the man power to manufacture their own pharmaceuticals, it does not do poor countries that have a huge epidemic health crisis and no manufacturing capacity any favours.[826] Thus Article 31(f) of the TRIPS Agreement in requires that pharmaceutical products manufactured under compulsory licensing would be "predominately for the supply of the domestic market."[827] Although the African group pushed for this

[824] Ibid
[825] TRIPs, art. 31(f).
[826] Jean Bizet (France), The Trips Agreement and Public Health, Presented at Cancun Session of The Parliamentary Conference on The WTO (Sept. 9-12, 2003), at http://www.ipu.org/splz-e/cancun/5b.pdf (last visited March 8, 2008) [hereinafter Cancun Session]
[827] See Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports, at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited March 8, 2005) [hereinafter Patent Obstacle].

problem associated with Article 31 to be resolved at Doha, the difficulty could not overcome so easily. The Ministerial Council however promised through Paragraph 6 of the Doha declaration that they would endeavour to overcome the problem. Consequently Paragraph 6 states that "we recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" the General Council were subsequently instructed by the TRIPS Council to come up with "an expeditious solution to this problem ..." by the end of 2002.

Negotiations were held in Geneva throughout 2002 to no avail. Despite the paramount hard work of the Chairperson of the TRIPs Council and all the WTO Members to come up with a solution, a decision could not be reached as to how best to resolve the problem.[828] What became obvious however was some developed countries spear headed by the US had begun to backpedal on what had been promised at Doha. After harsh negotiations, the US Trade Representative was unyielding and this unequivocally led to the breakdown of discussions in the TRIPS Council on December 20, 2002. It must be noted however that even though all the 143 of the WTO trading partners had agreed to a compromise solution, the US alone refused to go along with the deal which doomed the Agreement to a deadlock situation. It was not until August 20, 2003 that members of the WTO broke this gridlock over Paragraph 6 by signing another WTO agreement,[829] titled "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".

[828] Declaration on The TRIPS Agreement and Public Health, Nov. 14, 2001 [hereinafter Doha Declaration], available at http:// www.wto.org/english/thewto_e/minist_e/min01_e/minde-cl_trips_e.htm.
[829] See Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports, at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited March 8, 2005) [hereinafter Patent Obstacle].

The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is instrumental. [830] It waived countries obligation under Article 31 of the TRIPS Agreement, thus allowing WTO member states that are facing a public health crisis to export pharmaceutical products under compulsory license until a final resolution to paragraph 6 of the Doha Declaration could be found.[831] A waiver was achieved using Article IX:3-4 of the WTO Agreement, which allowed the Ministerial Conference to waive a requirement imposed on a member state by the TRIPS Agreement in 'exceptional circumstances'.[832] For the second time the Doha Agreement was hailed as good news, the only conditions that were attached to it were that the Agreement be interpreted in good faith in order to deal with all diseases including HIV/AIDS, tuberculosis and malaria;[833] and secondly the importing member states had the obligation to prevent medicines that were intended to be imported into their country from being diverted to other countries. In order words parallel importation for medicines procured under Art 31 to other countries were prohibited from being re exported to other countries. General Council Chairperson Carlos Perez del Castillo, Uruguay's ambassador reassured the pharmaceutical industry who were exceptional worried about diversions that, "Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without

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[830] See Kelly A. Friedgen, (2002*). Comment, Rethinking The Struggle Between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather than Absolute, Patent Protection of Essential Medicines*, 16 EMORY INT'L L. REV. 689, 699 For a list of levels of Development in pharmaceuticals by country, see Phillip McCalma, The Doha Agenda and Intellectual property Rights. October 2002. http://www.adb.org/Economics/pdf/doha/McCalman.pdf

[831] Haag, T.A (2002) *'TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms of Compulsory Licensing?'*, 84(12) Journal of the Patent and Trademark Office Society 945, Jacques H.J. Bourgeois and Thaddeus J. Burns, (2002) *'Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution'*, 5(6) Journal of World Intellectual Property 835 , at 839.

[832] See also Bourgeois and Burns, *I*bid at 856.

[833] Correa, C.M (2003) *TRIPS and Access to Drugs: Toward a Solution for Developing Countries without Manufacturing Capacity,* 17 EMORY INT'L L. REV. 389, 390-391 at t 393

prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."[834]

Like the Doha Declaration 2001, commentators and the international community welcomed the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement as a step in the right direction for access to essential medicines; however they were still many criticisms levied against it. The US was accused of imposing burdensome conditions that would make the agreement unworkable.[835] As a matter of fact Professor Brook Baker describes them as "cumbersome" and an "procedural labyrinth"[836] One of the major encumbrances that have been pointed out by commentators is the procedural requirements that requires member states to alter and repackage the pill size and colours of the drugs. The catastrophic effect that these requirements have on access to essential medicines in developing countries is the financial burden that will accompany the adherence to the regulation.[837]
Other difficulties that come with adhering to the rules of the Agreement are the administrative hassles connected with the prerequisite of having to notifying the WTO of every decision made with regards to compulsory licenses. Furthermore the Council must also review periodically compulsory licenses issued, this it is suggested will result in prolonged delays and prove to be

[834] See WTO News, The General Council Chairperson's Statement, at http:// www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited March 8, 2005) [hereinafter Chairperson's Statement].
[835] See HIV Drugs for Africa Diverted to Europe, WASH. POST, Oct. 3, 2002 at A10; see also Naomi Klein, *Bush's AIDS Test*, The Nation, October 27, 2003, available at http://www.thenation.com/docprint.mhtml?i=20031027&s=klein (quoting Harvey Bale as saying that the Agreement weakens patents, will hurt corporate profits and will destroy the incentive for new research).
[836] Professor Brook Baker
[837] Godnick.. K (2007) *Profitability Versus The Public Interest: Is International Patent Law Hindering Third World Countries Access to HIV/AIDS Medication*? Richard Journal of Law and the Public Interest. Spring http://law.richmond.edu/rjolpi/Issues_Archived/2007_Spring/Godnick.pdf and Duncan Matthew. WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to essential Medicines Problem. 7 J. Int'l Econ. L. 73. 2004

exorbitantly expensive for the governments of developing countries.[838] The gifts and inadequacies of the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and its relationship with Article 31 of the TRIPS Agreement when it comes to access to medicines for developing countries are numerous. The WTO describes the resolution of the Paragraph 6 problem as removing the "final patent obstacle to cheap drug imports"[839], however Pascal Lamy, the European Trade Commissioner interestingly said that "We all have to be very modest. We have solved about 10% of the problem of access to medicines by developing countries." [840]

On December 6, 2005 the World Trade Organisation (WTO) members reached an agreement on the first ever amendment to the TRIPS Agreement. The agreement would make permanent the temporary waiver of Art.31(f) contained in the August 30, 2003 "WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".[841] The amendment was in fact the first ever amendment to the TRIPS Agreement to directly allow WTO members to issue compulsory licences to export generic versions of patented medicines to countries with insufficient or no manufacturing capacity in the pharmaceutical sector. Nigeria for example was extremely active role in this Agreement, thus on March 31 2005 she explained to the TRIPS Council on behalf of the African Group that Art 31 needed to be

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[838] Matthews, D. (2004) *WTO Decision on Implementation of Paragraph 6 of The Doha Declaration on the*
TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, 7 J. INT'L
ECON. L. 73 (citing World Health Organization Intellectual Property Rights, Innovation and Public Health: Report by the Secretariat (Geneva: WHO, 56th World Health Assembly Provisional Agenda
Item 14.9, A56/17, 12 May 2003)).

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

[840] See Scott Miller, *WTO Drug Pact Lifts Trade Talks - Landmark Deal Provides Medicines to Poor Nations*, available at http://www.usvtc.org/WTO/WTO% 20Drug%C20Pact%C20Lifts%C20Trade%Talks.htm; EU's Lamy Is Optimistic, WALL ST. J., Sept. 2, 2003, at A2.

[841] Duncan Matthew. (2006) *From the August 30, 2003 WTO decision to the December 6, 2005 agreement on an amendment to TRIPS: improving access to medicines in developing countries?* 2006. Intellectual Property Quarterly

modified and certain provisions eliminated.[842] The provisions that needed to be eliminated amongst others included para.6 (ii) on regional patent systems; para.8 on annual reviews and para.9 on prejudice to other right.[843]. In my opinion, the presence of Nigeria at the Council meetings is important because Nigeria is a potential world power that needs to play a more active in world matters especially on public health issues of the sub-Sahara. The Agreement was however circulated to WTO members for formal adoption and a deadline was set for December 1, 2007. In 2008, the deadline for accepting the TRIPS agreement amendment was extended to 31 December 2009 or "such later date as may be decided by the Ministerial Conference." [844] In a two-third of majority was however needed by members in order to accept a permanent amendment to the agreement and for it to be formally adopted. Regardless of the foregoing, one of the most decisive criticisms made against the successes of the Doha Rounds is the fact that it did not address the use of TRIPS plus measure used particularly by the US and EU to impose higher level of intellectual property protection than stipulated by the TRIPS Agreement. These TRIPS plus measures are usually in the form of bilateral and regional agreements, thus some have asserted that they have escalated the public health crisis in the developing world than the patent system.

7.7 TRIPS Plus

The United States has concluded a substantial amount of bilateral and regional free trade agreements with many developing countries. Each of these FTAs includes substantial obligations in the field of intellectual property rights that exceed those required by the TRIPS Agreement. Article 1 of the TRIPS

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[842] Ibid

[843] . Minutes of TRIPS Council Meeting held on March 8-9 and 31, 2005, IP/C/M/47, June 3, 2005.Art.7

[844] Amendment of the TRIPS Agreement – Extension of the Period for The Acceptance by members of the Protocol Amending the TRIPS Agreement. Decision of 18 December 2007. WTO WT/L/711. See also David Cronin, EU Acceptance Of TRIPS Health Amendment Adds 28 Members", Intellectual Property Watch (December 1, 2007), available at http://www.ip-watch.org/weblog/index.php?p=856

Agreement states that "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement". Most of the TRIPS plus measure have been aimed at increasing the level of protection for patent right holders beyond those given in the TRIPS Agreement, thereby reducing the scope or effective limitations on the rights and exceptions which establishes minimum substantive standards of protection and enforcement of IP rights for all WTO Members.[845] Before the conclusion of the Uruguay rounds in 1994, the US had already began to use its special 301 to pressurize Members states to implement TRIPS plus measures. In 1988 after a complaint by the Pharmaceutical Manufacturers' Association (PMA) about the absence of effective patent protection for pharmaceutical inventions in Brazil; tariffs were increased to 100 percent on exports of more than 20 pharmaceutical products from Brazil to the US. This affected Brazil's export trade by over $39 million.[846] In the face of such enormous financial loss, Brazil who was one of the chief opponents to some of the measures in the TRIPS Agreement during the negation at Uruguay backed down, and encouraged other developing countries to do the same.

Chile faced serious pressure from the United States to grant patent protection for its pharmaceutical products.[847] During the 1980s, PMA put pressure on the Chilean government to grant patent protection to pharmaceutical products for twenty-five years. Although initially the Chilean government resisted pressure from the US, however in 1990 it eventually succumbed to it and adopted a law

[845] Sisule F Musungu and Graham Dutfield. M*ultilateral Agreements and a TRIPS plus World: The World Intellectual Property Organisation (WIPO). T*RIPS Issues Papers 3. Published by: Quaker United Nations Office (QUNO), Geneva. Quaker International Affairs Programme (QIAP), Ottawa
Project undertaken with the financial support of the Government of Canada provided through the Canadian International Development Agency (CIDA
[846] Watal. J (2002) *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement.* The World Economy. Vol 23 , Issue 5
[847] Sell. K Susam (2003) *Private Power, Public Law. The Globalization of Intellectual Property Rights.* The George Washington University. Cambridge University Press. http://assets.cambridge.org/97805218/19145/sample/9780521819145ws.pdf

providing patent protection for pharmaceutical products for a 15 year period. [848] This action not only put the prices of essential medicines out of reach for the average Chilean citizens; it was also a forewarning of a global and internationally enforceable IP Agreement in the embodiment of the TRIPS agreement. The bilateral treaty between US-Chile FTA came into force on 1 January 2004. It required that Chile offer an extension to the 20-year term patent of patent holders by adding an additional five years to the length of protection. This puts access to affordable medicines such as HIV/AIDS drugs in jeopardy. In response to this a Chilean farmer Nicolas Garcia told the Washington Times (17/06/03) noted that it was indeed a "case of the biggest and strongest eating the smallest".[849]Mexico like Chile came under similar pressure. By 1990 it had already agreed to introduce product patent for pharmaceuticals products and was already at the initial discussion stage of NAFTA.[850] This resulted in it distancing itself from the camp of the resilient developing countries. Consequently by 1991 even before the TRIPS Agreement came into force, Mexico had already modernized its IP laws to the full approval of the US Trade Representatives (USTR).[851]

By threatening bilateral trade sanctions against resilient countries, one by one, the US and its partners successfully undermined the developing countries resistance to the TRIPS Agreement. Other developing countries like China and Korea were placed on the priority watch list because of inadequate patent protection for pharmaceutical products.[852] Other factor that made it impossible for developing countries to withstand pressure from the US was the fact that many developing countries were dependent on the US market. This coupled with political and economic pressure forced them to accept terms that did not

[848] Ibid
[849] US –Chile. http://www.bilaterals.org/rubrique.php3?id_rubrique=20
[850] Ibid
[851] Ibid
[852] Blakeney, M (1996) *Trade Related Aspects of Intellectual Property Rights: A Concise guide to the TRIPS Agreement,* London : Sweet and Maxwell

adequately take into consideration their best interest.[853] Although commentators have argued that developing countries gained access to the markets of industrialized states for their agricultural product and textile goods (which was part of the bargain of agreeing to the TRIPS Agreement), [854] it seemed that they remained opposed to the idea in principle.[855]

The US president has been able to sign many FTA with other governments based on the 2002 Bipartisan Trade Promotion Authority Act[856] which gives the him the power to conclude agreements with trading partners. The agreements are in turn presented to congress who then votes on the trade negotiations made by the president but in the real sense are not expected to amend or make any changes to the proposed agreement.[857] Commentators have suggested that the Bipartisan Act legislation has been used to encourage TRIPS-plus agreements, and in so doing preventing access to medicines. The main section which the US has used to raise the level of intellectual property standard is Article 21012(b) (4) (A)(9i)(II) which explicitly states that "the provisions of any multilateral or bilateral trade agreements governing intellectual property rights that are entered into by the United States reflect a standard of protection similar to that found in the U.S law.[858]

The Genetic Resources Action International (GRAIN) has identified at least 23 negotiated bilateral and regional treaties between developed and developing world, in which the US required other member states to provide IPR protection that were greater than the minimum standard outlined by the TRIPS

[853] See Kennedy .D and Southwick . J (2001),*Trips in the political economy of international trade law: essays in honour of Robert Hudec* , Cambridge, Cambridge University Press.
[854] Ibid
[855] Gervais, D (1998) *The TRIPS Agreement: Drafting history and analysis*. London: Sweet and Maxwell. Pg:18
[856] Bipartisan Trade Promotion Authority Act, Pub. L.No.107-210(2002)
[857] Abbot. F.M (2006) Intellectual *Property Provision of Bilateral and Regional Trade Agreements in Light of US Federal Law February* UNCTAD - ICTSD Project on IPRs and Sustainable Development. Issue Paper No 12
[858] Ibid

Agreement.[859] The same report admitted that such agreements were affecting more than 150 developing countries at the time. Developed countries such as the US have continuously sought to fulfil the inadequacies of a lesser intellectual property protection at the multilateral level through bilateral and regional negotiations.[860] For example the TRIPS Agreement clearly allows member states to exclude plants and animals from patent protection; however many of the negotiated bilateral agreements do not include such exclusions and require patents on biological inventions.[861] The UN Convention on Biological Diversity (CBD) which states that countries own and should controls its genetic resources and that other countries cannot basically exploit such resources without prior consent from the owners. Whilst the US government have threatened and punished countries who do not adhere to intellectual property rights which violate the rights of the patent holder, it does not seem to mind that the use of genetic resources are being misused by the same people it seeks to protect.[862]

The irregularity of the multilateral system has seen MNC mainly in the US and the EU manufacturing pharmaceutical and agricultural products from genetically modified ingredients. These genetically modified ingredients include medicinal plants, soil microorganisms, animals and genes which belong to indigenous people in third world communities and have been used by MNC to make profits without the permission or remuneration to the owners.[863] Consequently in March 2006 in a case, "Out of Brazil: A Peanut Worth

[859] Genetic Resources Action International (GRAIN), *TRIPS plus" Through the Back Door* 4 (2001), available at http://www.grain.org/trips-plus-en.pdf (last visited February 2008)
[860] See David Vivas- Eugui. Regional and bilateral agreements and a TRIPS-plus world: the Free Trade Area of the Americas (FTAA) TRIPS Issue papers. Quaker United Nations Office (QUNO), Geneva. Quaker International Affairs Programme (QIAP), Ottawa International Centre for Trade and Sustainable Development (ICTSD), Geneva
[861] Ibid
[862] Tove Iren S. Gerhardsen. *Brazil Fights to Make Case for International Biodiversity Protection*. Intellectual Property Watch. See http://www.ip-watch.org/weblog/index.php?p=322
[863] Martin Khor. A Worldwide fight against bio piracy and patents on life. Third World Network. See http://www.twnside.org.sg/title/pat-ch.htm Accessed 23 August 2008

Billions,"[864] the US was exposed for using groundnut which originated from Brazil to treat disease-resistant tomato spotted wilt virus found in US peanut varieties since 1987.[865] The genetic product is now being used in innovative peanut multiplicity in the United States and is projected to add at least $200 million every year to the US market.

The USA has since concluded free trade agreements with Israel[866], Australia,[867] Morocco[868], and with Central American countries (CAFTA), including Costa Rica, El Salvador, and Guatemala, Honduras and Nicaragua.[869]. The Dominican Republic recently joined CAFTA. In all of them, specific provisions on IPRs are included. The USA has also signed FTA with the five nations of the African Southern Customs Union (SACU)[870], including Botswana, Lesotho, Namibia, South Africa and Swaziland. A number of Middle-East countries including Bahrain[871] have also signed FTA with the US. Panama, Colombia, Peru, Bolivia and Ecuador are also in FTA with the US,[872] and negotiating several other FTAs with countries such as Thailand and Malaysia.[873] Joseph Stigliz advised developing countries to be

[864] Tove Iren S. Gerhardsen (2006) *Brazil Fights To Make Case For International Biodiversity Protect.* Intellectual Property Watch. .
[865] Out of Brazil: A Peanut Worth Billions (to the US) " (available at http://www.edmonds-institute.org
[866] The agreement was signed on April 22, 1985, but the final phase of the agreement was fully implemented on January 1, 1995. See text at: http://www.us-israel.org/jsourcae/USIsrael/FTA_Text.htm
[867] The agreement was concluded on February 2004 and signed in May 2004. See: http://www.ustr.gov/new/fta/Australia/text/
[868] Negotiations were concluded on March 2, 2004 and the FTA was signed on June 15, 2004. See the US–Morocco FTA at http://www.ustr.gov/new/fta/Morocco/text/index.htm
[869] CAFTA was signed in May 2004. See, http://www.ustr.gov/new/fta/cafta/text/index.htm
[870] The USA and the SACU launched negotiations for a Free Trade Agreement in Pretoria, South Africa, on June 2, 2003. It will be the first free trade agreement for the USA in Sub-Saharan Africa and the first time that SACU nations would jointly negotiate such kind of agreement. This will be done under the framework of the African Growth and Opportunity Act
[871] Negotiations with Bahrain for a free trade agreement were launched on January 2004 and concluded on May 28, of the same year. See "Trade Facts" of March 2, 2004, available at the Office of the United States Trade Representative web site: http://www.ustr.gov
[872]Negotiations with Colombia, Ecuador and Peru were launched on May 18 - 19, 2004
[873] IPR violations high on Bush visit agenda. Inter Press Service. 29 July 2008. http://www.bilaterals.org/article.php3?id_article=12808

cautious when entering into FTA and claimed that "bilateral agreements have been a disaster, for the developing countries and for the global trading system".[874]

Another FTA agreement worth mentioning is the US- SACU (Southern African Customs Union). The SACU compromises of five countries namely South African, Namibia, and Botswana. Lesotho and Swaziland, of which one (Lesotho) is recognized by the WTO as a Least Developed Country (LDC), meaning it has no obligations with respect to patents for pharmaceutical products until 1 January 2016. Mr Zoelick, former United States Trade Representatives who wrote the briefing paper for the US-SACU FTA claimed that the paper would set out minimum standards of patent protection, similarly the Office of the USTR stated that the agreement will "bring new hope and prosperity to southern Africa and the United States [and] further drive regional growth and development, and provide for a common economic future",[875] these assertions are doubtful as the US-SACU FTA demands standards that reflect IP protection that are similar to those found in US law be established.[876] The SACU countries would have to significantly strengthen their domestic enforcement procedures, strengthen measures in SACU countries that provide for compensation of right holders for infringements of intellectual property rights. They would also have to provide for criminal penalties under the laws of SACU countries that are sufficient to have a deterrent effect on piracy and counterfeiting. The irony of the US-SACU FTA lies in fact that the South African region already suffers tremendously from the HIV/AIDS epidemic and the high prices of the medicines for antiretroviral medicines has not made the situation any better. Nevertheless the important thing to note is that the U.S.-

[874] Stiglitz: (30-08-2007) *FTAs advantageous to US*. The Edge Daily (Malaysia) |by Maryann Tan & Yong Yen Nie. http://www.bilaterals.org/article.php3?id_article=9510
[875]http://www.ustr.gov/Trade_Agreements/Bilateral/Southern_Africa_FTA/Background_Information_on_the_US-SACU_FTA.html
[876] Jonathan Berger and Achal Prabhala. (17 February 2005*) Assessing the Impact of the TRIPS PLUS Patent Rules in the Proposed US-SACU Free Trade agreement.* Johannesburg, South Africa Draft http://www.who.int/hiv/amds/capacity/tza2_oxfamreport_pricing_financing.pdf

SACU FTA bilateral negotiations that was initiated in June 2003 came to a deadlock after a number of official meetings where the bilateral FTA negotiations were replaced by an effort to negotiate a framework agreement covering trade and investment with the hope that a bilateral FTA will be agreed upon in the future. [877]

The EFTA also attempted to sign a FTA with the SACU in November 2004; however the SACU rejected the European Free Trade Association's (EFTA; which comprises Switzerland, Norway, Iceland, and Liechtenstein) proposal. South Africa-based public health group as well as the South African Minister of Trade Minister Mandisi Mpahlwa were aware that the EFTA's proposed IPR provisions went beyond the requirements of the TRIPS Agreement.[878] The TRIPS plus measures in the FTA sought to introduce a five- to ten-year data protection period for clinical test data, as well as a provision to potentially allow five-year patent extensions to brand-name drugs. This of course would "block and delay generic competition," thus hindering access to medicine.

7.8 Is There TRIPS Plus in the ECP? If so is this the way Forward for Nigeria?

Although slow but major IP reforms are underway, the EU has been seeking rapid changes to the IP laws in Nigeria through regional treaties with ECOWAS. [879] One of the reasons for this is to push for reforms that they have previously not been able to get through multilateral agreements at WTO and

[877] The Congressional notification letters were available online at http://wwww.ustr.gov/Trade Agreements/Bilateral/Southern Africa FTA/Section Index.html.
[878] Southern African Countries Reject "TRIPS PLUS" FTA Negotiation. ICTSD. 2004 See http://ictsd.net/i/publications/7481/
[879] The Economic Community of West African States (ECOWAS) is a regional group of fifteen West African countries, founded on May 28, 1975 with the signing of the Treaty of Lagos. Its mission is to promote economic integration. Member states of ECOWAS are Benin, Burkina Faso, Cape Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

WIPO.[880] For example in 2006 and 2007, the EU through the European Commission attempted to complete what it called the comprehensive Economic Partnership Agreements (EPAs) with the 79 member African, Caribbean and Pacific (ACP) group of countries.[881] The major thrust of this change was its Global Europe strategy, which states that, "[t]he EU should seek to strengthen IPR [Intellectual Property Right] provisions in future bilateral agreements and the enforcement of existing commitments ...,"[882] . The target was to conclude comprehensive agreements to meet the 2007 goal for bringing the EU's preferential trade arrangements for goods with ACP countries into conformity with the World Trade Organization's (WTO) General Agreement on Tariffs and Trade (GATT).[883]

Although Teddy Sseezi Cheeye argues that by signing the EPA, Europe would be "pressurizing its former colonies [into] signing an enslaving trade agreement",[884] the agreement is a goods-only interim agreement; hence some commentators state that it presents a chance for ACP countries to organize themselves if and when it decides to negotiate on IPRs in future EPAs. The objective of this is so that they can ensure that they do not compromise their

[880] Dalindyebo Shabalala with contributions from Marcos Orellana, Nathalie Bernasconi-Osterwalder and Sofia Plagakis (April 2008). Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries: What way Forward after the Cariforum EPA and the interim EPAs?. Centre for International Environmental Law

[881] Update: Interim economic Partnership Agreements. 19 December 2007. http://trade.ec.europa.eu/doclib/docs/2007/november/tradoc_136959.pdf

[882] European Commission "Global Europe: competing in the world" EU Policy Review, October 4, 2006 (available at http://EU.europa.eu/trade/issues/sectoral/competitiveness/global_europe_en.htm), Section v.

[883] 2 The deadline came about because of a 2001 waiver from the WTO that was obtained by the EU and ACP regarding
the Cotonou Agreement, allowing for the continuation of the preference regime but only until the end of 2007. The preference regime largely excluded Latin American countries who objected to what they argued was unfair discrimination between similarly situated developing countries. Beyond that date, the EU would not have been allowed to continue the preference regime without establishing a regional trade agreement under Article XXIV of the GATT. The waiver is "European Communities — the ACP-EC Partnership Agreement, Decision of November 14" WTO Document Number WT/MIN(01)/15, available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_acp_ec_agre_e.htm.

[884] There is No Need for the Continent to Sign EPA. The Monitor (Kampala) Column 26 November 2007

position in multilateral forums and that any IPR provisions in EPAs actually reflect their interest. Oxfam argues that the signing of the interim EPAs has inevitably increased the complications of future intellectual property negotiations.[885] The CARIFORUM – EC EPA (the EPA text) acknowledges that access to medicines is imperative. This is reiterated in Article 139.2 of the IPRs section, which emphasis the right to take measures to protect public health and nutrition in Art 8 of the TRIPS Agreement.

In 2007, Nigeria refused to sign a separate interim agreement with the EU through ECOWAS.[886] The European Commissioner for Trade, Mr Peter Mandelson responded by saying that Nigeria is "sitting like an elephant in the middle of the road". Although this was said to denounce Nigeria's position, some observers have chosen to see this as a positive sign that a developing country has refuses to be bullied into signing an EPA that will pose a serious major challenge to their ability to gain access to cheap medicines.[887] OPINION analysis of Mandelson's comments that Nigeria is sitting like an elephant in the middle of the road when she refused to sign EPA is interesting in signalling the angle that the country hopes to play in future multilateral agreements. OPINION states that the "elephant indeed is a prestigious animal at least, for its size and gait, but more importantly for the ornamental value of the tusk. Whether it is walking, standing, or sitting, one fact is clear - it cannot be moved easily from one position to another against its will. This indeed is Nigeria's position as far as the EPA is concerned. Nigeria appears to be the only country within the ACP bloc that can sit and stand tall before any other (colonial headmasters inclusive) or even withstand any form of ferocious

[885] Ibid
[886] For full text (in French) see http://www.acp-eu-trade.org/library/files/Cote-d-Ivoire-CE_FR_071207_bilaterals.org_APE-d-etape.pdf.
[887] Chibuzo Nwoke. (Posted 21-05-2008.) Nigeria: Country to lose $478.4 million revenue to EPA.. Institute of International Affairs. http://www.bilaterals.org/article.php3?id_article=12164&var_recherche=nigeria

pressure from any kind of oppressor in the face of negotiations".[888] Article 46.1 of the text states that "Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognize the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS…in line with the international standards with a view to reducing distortions and impediments to bilateral trade". This signifies that countries are well within their rights to refuse to negotiate on certain parts of Intellectual property rights.

In responses to pressure to sign TRIPS plus agreements in bilateral and regional agreements, the Centre for International Environmental Law argues that ACP countries need to refrain from further negotiating on intellectual property in EPAs. The rationale for this is that the addition of any TRIPS-Plus intellectual property provisions in the EPAs will dramatically alter the whole scene of international intellectual property negotiations for a country like Nigeria. It has been suggested that during the interim Nigeria will be better of concentrating its resources on carrying out a full national policy impact assessment that would involve retrospective, concurrent or prospective health impact assessment of any intellectual property agreements.[889]. The imperative of the urgent need to amend Nigeria's IP Laws to take full advantage of the TRIPS Agreement and flexibilities in the form compulsory licensing and parallel importation is understandable, however Nigeria must factor into their national legislations their level and pace of development, whilst enacting legislations that are public health friendly. Nevertheless Article 44 of the EPA text in relation to what is next for ECOWAS urges the parties to conclude a global EPA between the West Africa region and the EU before the end of 2008, whether the agreement will be concluded remains to be seen

[888] Nigeria: EPA - Reasons Why Nigeria is a Sitting 'Elephant' Leadership (Abuja) OPINION 18 November 2007. http://allafrica.com/stories/200711190348.html. Accessed 12 June 2008
[889] Health Impact Assessment in Development Policy and Planning. Report of an Informal WHO Consultative Meeting. Cartagena, Colombia. 28 May 2001. WHO/HDE/HID/02.4. See http://www.who.int/mediacentre/events/HSD_Plaq_02.4_def1.pdf Accessed 28 June 2008

7.9 Summary

The search for access to medicines after the TRIPS Agreement was signed in 1994 has led to different alliance. While one camp praised it for ensuring that MNC companies would continue to invest in R&D for NCES, the other camp saw it as an end to public health. So when the Doha Declaration came about in 2001 bringing with it clarifications that developing countries could use the flexibilities within the TRIPS Agreement to gain more access to medicines, many developing countries welcomed it as a breakthrough in the fight to ensure that the Agreement did not affect public health in a negative way. Nevertheless some issues remained unresolved. Firstly the issue of lack of manufacturing capability was not resolved by the TRIPS Agreement or the Doha declaration, indeed many developing countries do not have the manufacturing capacity to take advantage of compulsory licences as stipulated in the agreement because their pharmaceutical industries are not advanced enough. They must therefore rely on other countries that have manufacturing capacity in order to reap the benefits of compulsory licenses.

The issue of Trip-plus has also been left unresolved by the TRIPS Agreement. Developing countries therefore have to contend with pressures from countries in the EU and the US to raise IP standards beyond a level that is helpful for the development of their economies. Although Nigeria has withstood the pressure to become TRIPS-plus, it is also equally important that it amends its laws to become TRIPS –compliant. As such it is the responsibility of the Nigerian government to ensure that it enacts legislations that are public health friendly, which also fosters an environment where local pharmaceutical industries can thrive and begin to manufacture their own medicines as well as using parallel importation and compulsory licences where necessary.

8 THE PHARMACEUTICAL INDUSTRY AND ESSENTIAL MEDICINES

8.1 Introduction

Without drugs, a health service has no substance and no credibility. Every effort to ensure that the right drugs are available where they are most needed in the primary health care system, at prices that are realistic, demands an alliance between a sovereign government and the pharmaceutical manufacturer.
Dr Hiroshi Nakajima, WHO's Director-General 1989

A love for tradition has never weakened a nation; indeed it has strengthened nations in their hour of peril.
Winston Churchill

There is no medicine like hope, no incentive so great, and no tonic so powerful as expectation of something better tomorrow.
Orison Swett Marden

When the World Health Assembly convened in 1975, it introduced the concept of essential medicines and national drug policies. By October 1977, the World Health Organization (WHO) had produced the first Model List of Essential Drugs. The vision that WHO had was to ensure that people all over the world have access to the essential medicines that they need; that the medicines are safe, effective, of good quality, prescribed and used rationally.[890] The report of the UK Working Group on Increasing Access to Essential Medicines in the Developing World recommended that pharmaceutical companies provide medicines at near to production cost for HIV/AIDS, TB and malaria to countries who cannot afford to purchase them. Since the realization that access

[890] Essential Medicines and Pharmaceutical Policies (EMP) http://www.who.int/medicines/en/ Accessed 19 May 2007

to medicines is a fundamental human right that many people in poorer countries lack because of the high prices of medicines, the pharmaceutical industry has been consistently blamed for this status quo. This position has been further reinforced by the TRIPS Agreement which makes it difficult for people to obtain cheap generic versions of patented drugs and allows patent holders to set prices which are prohibitively expensive.

The purpose of this chapter is therefore to show that pharmaceutical MNC and their emphasis to maintain a strong patent system are not the only reasons to blame for the lack of access to essential medicines. There are other factors that have contributed to the situation. Some of these factors include a lack of commitment by governments in developing countries to invest in pharmaceutical local companies that will enable them to become self sufficient; a lack of investment in primary health care systems; inappropriate use of medicines; corruption, lack of education and failed government national policies. In order to achieve the above stated goal, this chapter will also carry out an evaluation of the pharmaceutical industry with major emphasis on two developing countries namely Nigeria and India.

The reasons for choosing these two countries are that both countries have a similar history; they are both former colonies of Britain; they both have a rich tradition of traditional medicines, they are both facing a health care crisis with relation to HIV/AIDS, they both have the right to health as a provision in their constitution. Both countries have a huge population; in 1970 both countries passed the Patent Act. Most antiretroviral medicines that are used in Nigeria come from India. Most pharmaceuticals set up in Nigeria have affiliations with India e.g. Ranbaxy, most counterfeit medicines come from India, both countries have a high level of poverty but more importantly Nigeria has a lot it can learn from India in how to make their pharmaceutical industry self-sufficient.

Whilst India has been successful in developing its pharmaceutical industry and providing medicines for majority of its population and a large proportion of the population of the developing world, Nigeria is still struggling to for its pharmaceutical industry to become self-sufficient and provide medicines for its population A case study of the Indian pharmaceutical companies is therefore important for a variety of reasons: it is important to show the reader that it is possible to take advantage of a country's traditional medicines to provide more access to medicines; it is important to show the reader that Nigeria can learn from India key resolutions that will enable the Nigerian pharmaceutical industry to become self-reliant and prosperous. The purpose of this chapter is not to transport the Indian analysis to the Nigerian situation, but to learn important elements of how a government that is determined to strengthen its primary healthcare can succeed with the right national policies.

8.2 Proximity between India and Nigeria

India has the highest population of people living with HIV/AIDS in the world. Presently there are over 5.7 million people who are infected with the HIV/AIDS in India.[891] The National Commission on Macroeconomics and Health (NCMH) has warned that India's noncommunicable disease burden is set to rise from 1804.34 cases per 0.1 million in 2005 to 2636.31 cases per 0.1 million in 2015.[892] Likewise Nigeria also has a high population of people living with HIV/AIDS with statistics showing that Nigeria has third highest number of people living with the disease. In 2007, estimates showed that 2.4 million people were infected with HIV/AIDS.[893] Nigeria and India both have

[891] HIV Policy Fact Sheet. http://www.kff.org/hivaids/upload/7312-03.pdf 2006. Accessed 18 November 2007
[892] See One-day National Consultation o Access to Medicines in India, CENTRE for Trade and Development. http://www.centad.org/events_32.asp and UNAIDS, 2006 Report on the global AIDS epidemic
[893] Globalhealthreporting.org
http://www.globalhealthreporting.org/countries/nigeria.asp?collID=11&id=953&malID=956&

the right to health enshrined in their constitution; nevertheless both countries have been identified by the National Intelligence Council as two of the five countries most likely to bear the heaviest burden of HIV infection by 2010.[894] Interestingly while India has managed to develop its pharmaceutical industry, Nigeria on the other hand has not been so successful and is still lacking behind in the developing its pharmaceutical industry. Indian has a thriving generic industry which produces half of the generic medicines used in many developing countries. When the deadline for India to adhere fully to the TRIPS Agreement came in 2005, many feared that this would be the end to cheaper generic medicines, but this has not been the case. The Indian pharmaceutical industry continues to grow and provide access for medicines for many developing countries that do not have manufacturing capacities.

India and Nigeria have had a close relationship for some time now. Apart from its similar colonial past, India has also been instrumental in providing cheaper genetic ARV's to the Nigeria government to enable them meet their obligation in providing access to medicines to its populace. For example in 2002, the Nigerian government entered into an ambitious programme to supply 10,000 adults and 5000 children with ARVs within a year. An initial $3.5 million worth of ARVs were imported from India and delivered at a subsidized cost of $7 per person. Although the programme suffered a setback in 2004, when it encountered a shortage of drugs, where some people did not receive treatment for a period of three months, the programme was later resumed when another $3.8 million worth of drugs were ordered. India has also set up pharmaceutical manufacturing facilities in Nigeria, indeed Ranbaxy one of the biggest manufacturing companies in India has a manufacturing facility in Nigeria.

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tbID=955&hivIC=954&malIC=960&tbIC=959&map=958&con=Nigeria&p=1 Accessed 15 June 2007

[894] Journalists Against AIDS in Nigeria: www, Nigeria-aids.org - In 2002, the National Intelligence Council identified five countries expected to bear the heaviest burden of HIV infection as India, China, Nigeria, Ethiopia and Russia.

A comparative analysis of the evolution of government policies and legislations regarding the growth of the pharmaceutical industry in India and Nigeria may therefore be useful in identifying clues as to why Nigeria is still struggling to develop its pharmaceutical industry despite being one of the richest countries in Africa and at one point the 5th largest oil producer in the world.

8.3 Evolution of the Modern Pharmaceutical Industry: A History of the Pharmaceutical Industry

The pharmaceutical industry is one of the largest and most firmly established manufacturing industries in the world.[895] One of the chief roles of the pharmaceutical industry is providing medicines. Indeed medicines are considered to be extremely important because they are the most important determinants of the health of every nation. The innovation, progress and successful use of medicines has enhanced many people's quality of life, and in many cases reduced the need for surgical operations, reduced the amount of time spent in hospital and saved many peoples' lives.[896]

Looking back at how far medicines have come in changing the landscape of what qualifies for good health requires an analysis of the evolution of pharmaceutical Multinational corporations (MNC). Merck is one of the oldest pharmaceutical MNC in the world. It was first established in 1668 by Friedrich Jacob Merck. However it did not begin large scale production until 1827 when Merck began intense industrial production. It went further to establish its roots in the United States in 1891 and from there emerged some of the most

895 Facts and Statistics from the Pharmaceutical Industry. The Association of British Pharmaceutical Industry. http://www.abpi.org.uk/statistics/section.asp?sect=1
896 House of Commons Health Committee - The Influence of the Pharmaceutical Industry. Fourth Report of Session 2004-2005. Vol 1. HC 42-I [Incorporating HC 1030-i-iii] Published on 5 April 2005 by authority of the House of Commons. London: The Stationery Office Limited

successful and innovative medicine used throughout the world today.[897] Only recently on 12 October 2007 - Merck announced that the U.S. Food and Drug Administration approved ISENTRESS the first medicine which in a new class of antiretroviral drugs.[898] The significance of such discoveries by the pharmaceutical industry to the access to medicines debate can therefore not be ignored. Indeed it shows the strong links in which patents have to the western world and why it is only natural that most of the developed world has successfully transformed into not only accepting the TRIPS Agreement but also applying it to their national laws. This has in turn ensured that firstly the pharmaceutical industries in developed countries thrive and that access to medicines is made more readily available to the population.

The roots of the modern pharmaceutical (MNC) can also be traced back to Felix Hoffman who invented aspirin in 1897. Hoffman had worked for a German Chemist known as Bayer, and was later issued a U.S. patent for the drug (No. 644,077) in 1900.[899] The need to invest in continuous innovative medicines can also be traced back to the advent of WWI where the huge R&D demands of the war required that the scientific community invest in rapid technology.[900] WWII brought with it even further advances in health methods, but the most dramatic single medical advance was probably the successful production of penicillin by Florey and Chain in 1948. Penicillin was considered a breakthrough in medical industry because for the first time there was a pharmaceutical product that had the twofold effect of killing bacteria and inhibiting their growth. Penicillin worked against a wide range of pathogenic micro-organisms, including pneumococcal, streptococci, gonococci,

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897 AGGRASTAT® (tirofiban HCI) Used to decrease chances of clots after certain cardiac events. CANCIDAS® (caspofungin acetate) used to treat Aspergillus fungal infection and RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] used to treat Hepatitis-B. See http://www.cogforlife.org/merckproducts.htm

898 FDA Approves ISENTRESS™ (raltegravir) Tablets, First-in-Class Oral HIV-1 Integrase Inhibitor
http://www.merck.com/newsroom/press_releases/product/2007_1012.html

899 This made Bayer the first known pharmaceutical MNC

900 Calder. R (1962) *The Life Savers*, London: Hutchinson & Co. p. 20

meningococcal, the clostridium of tetanus, and the syphilis spirochete. It was also been used to effectively treat fatal diseases such as subacute bacterial endocarditic, septicaemia, gas gangrene, gonorrhoea, and scarlet fever.

Other innovative medicines were also developed during the 1950s, however by the 1960s these medicines began to be mass produced and marketed in many parts of the world. Some of these medicines included high blood pressure drugs, and tranquilizers (Haloperido and chlorpromazine) for psychiatric medication.[901] By the 1970's cancer drugs became the highlight of innovative discovery in the medical world. The continuous demands for such groundbreaking medicines meant that by the mid-1980s, small biotechnology companies were struggling for survival. The formations of mutually beneficial partnerships with larger pharmaceutical companies were therefore necessary and this led to a host of corporate buyouts of the smaller companies. The growth of MNC was further accelerated when pharmaceutical manufacturing became concentrated, with a few large companies holding dominant positions throughout the world and few companies producing medicines within each country.[902] Interestingly when HIV/AIDS was discovered in the 1980's the pharmaceutical industry was already on the path to becoming regulated and transformed, a process which was enhanced by the discovery of new DNA chemistries and technologies for analysis and computation.

In the case of HIV/AIDS which has become a priority area of R&D for the many pharmaceutical companies, the discovery of antiretroviral drugs has turned HIV/AIDS from a deadly and fatal disease into a controllable and manageable one.[903] Although HIV/AIDS was discovered in 1983, it took four years before GlaxoSmithKline discovered the first antiretroviral drug

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902 Chaudhuri. S (2005) *The WTO and India's Pharmaceutical Industry. Patent Protection, TRIPS and Developing Countries.* Oxford university Press

903http://216.239.51.104/search?q=cache:gmX3iJH0YgAJ:www.ifpma.org/documents/NR543/GPF_HIV_leaflet_final.doc+evolution%2Bpharmaceutical+industry%2Bantiretroviral%2Baids&hl=en&ct=clnk&cd=2&gl=uk

(zidovudine or AZT), which was approved by the FDA in 1987. From that time until now significant progress by the pharmaceutical industry to ensure that people gain access to medicine can be measured by the number of companies manufacturing antiretroviral medicines. Thus by 2000, six major MNC namely Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, and Roche were producing antiretroviral medicines.[904] Although there are many pharmaceutical companies spread out all over the world. The top pharmaceutical MNCs are based in developed countries, particularly in the United States, European Union and Japan. The importance of discussing the evolution of the pharmaceutical MNC is to show that the practice as the world knows it today has evolved mainly from Europe and the US, their role in determining the future direction of R&D can therefore not be ignored. For medicines to be invented and cures found for diseases, the industry must collaborate and share information.

8.4 Leading Pharmaceutical Companies in the World ($ Billions)

2005Rank	2004Rank	Company/Country	2005 Global Pharma Sales ($ B)	%Growth
1	1	Pfizer (U.S.)	$44.3	<4%>
2	2	GlaxoSmithKline (U.K.)	$34.0	+8%
3	3	Sanofi-Aventis (France)	$32.3	<5%>
4	7	Novartis (Swiss)	$25.0	+16%
5	6	Astra-Zeneca (U.K.)	$24.0	+12%
6	4	Johnson & Johnson	$22.3	+1%

904http://216.239.51.104/search?q=cache:gmX3iJH0YgAJ:www.ifpma.org/documents/NR543/GPF_HIV_leaflet_final.doc+evolution%2Bpharmaceutical+industry%2Bantiretroviral%2Baids&hl=en&ct=clnk&cd=2&gl=uk

		(U.S.)		
7	5	Merck (U.S.)	$22.0	+2%
8	N/A	Roche* (Swiss + Chugai)	$15.7	N/A
9	9	Wyeth (U.S.)	$15.3	+10%
10	8	Bristol-Myers Squibb	$15.3	<1%>
11	11	Eli Lilly (U.S.)	$14.7	+12%
12	10	Abbott Labs (U.S.)	$14.0	+16%
13	13	Amgen (U.S.)	$12.0	+13%
14	14	Boehringer Ingelheim	$10.8	+2%
15	15	Takeda (Japan)	$8.5	+3%
16	N/A	Astellas (Japan)**	$8.0	N/A
17	16	Schering-Plough (U.S.)	$7.6	+18%
18	18	Bayer (Germany)***	$7.6	+18%
19	N/A	Daiichi Sankyo****	$7.3	N/A
20	17	Schering AG (Germany)	$6.3	+3%
21	22	Genentech (U.S.)	$5.5	+46%
22	25	Novo Nordisk (Denmark)	$5.4	+1%
23	19	Eisai (Japan)	$4.8	<5%>
24	20	Teva (Israel)	$4.7	+10%
25	21	Merck KGaA (Germany)	$4.6	+21%
26	24	Otsuka (Japan)	$3.3	<11%>
27	29	Forest Labs (U.S.)	$3.2	+19%
28	26	Baxter International	$3.0	+11%

		(U.S.)		
29	31	Akzo Nobel (Netherlands)	$2.9	+21%
30	32	Altana (Germany)	$2.8	+27%

Source: Pharmaceutical Executive, May 2006

These pharmaceutical companies carry out intense production and marketing of pharmaceuticals products at a level which has never been seen before in the world.[905] Statistics show that since the 1970s, a small amount of approximately 50 pharmaceutical companies accounted for more than two-third of the world production and export.[906] Between 1997 and 2003 pharmaceutical sales increased by over 12 percent annually. Likewise global production in pharmaceutical products grew from $70 billion in 1975 to $300 billion in 2000. [907] In 2004, the total global sales for pharmaceutical product were estimated to be in the region of $550 billion, this represented a 7 % increase from 2003.[908] The evolution of the pharmaceutical industry has brought with it a dominance of the industry by a small number of MNCs who exert extraordinary financial power. Statistics show that the total worth of Pfizer, GlaxoSmithKline, Merck, AstraZeneca and Aventis[909] are worth more than the entire income of Mexico or India and twice that of the entire income of sub-

905 Silverman, Milton and Philip R. Lee (1974) *Pills, Profits and Politics,* Berkeley and Los Angeles: University of California Press. pp. 1-6

906 Mossialos, E., P. Kanavos and B Abel-Smith (1994*), The Pharmaceutical sector in the European Union –an overview*', in E Mossialos, C. Ranos and B. Able-Smith (eds, Cost Containment, Pricing and Financing of Pharmaceuticals in the European Community – The Policy Makers' View, London: LSE Health and Pharmetrica SA, pp 18-87

907 Ballance, R., J. Pogany and H. Forstner (1992) *United Nations Industrial Development and Organisation (UNIDO)* (eds) The World's Pharmaceutical Industrial, Aldershot, U (1992: 22-23, 29)

908 Bill Trombetta (2005). For the fourth year in a row, Pharmaceutical Executive slices and dices the numbers to learn who's really on top see http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=177964

909 The leading Pharmaceutical companies in the world in order of ranking (2003) are Pfizer, GlaxoSmithKline, Merck, Johnson & Johnson, Aventis, AstraZeneca, Novartis and Bristol-Meyers Squibb

Saharan Africa.[910] Similarly a single product of Pfizer - Lipitor sold twice the total drug sales in India for all the products and companies in 2003;[911] thus statistics also show that the top 50 pharmaceutical MNCs accounted for 74.6 per cent of the world market in 2003.[912]

Some of the factors that have enabled pharmaceutical MNCs to acquire such financial powers are Mergers and Acquisitions (M&A) in the EU and the US[913] which began an intense wave in the 1980s and 1990s. Most of the top pharmaceutical companies in 2003 are the result or one or more horizontal mergers.[914] For example Glaxo-SmithKline's antecedents consist of Glaxo, Welcome, SmithKline French and Beecham, similarly Aventis is a consolidation of Hoechst (German), Rhone-Poulenc (French), Rorer, Marion, Merrill, Dow (US); Pfizer on the other hand is the combination of Pfizer, Warner-Lambert, and Pharmacia and Upjohn.[915]

Consequently between 1988 and 1992, there were 760 M&As in the pharmaceutical and biotech industries world-wide of which the total value exceeded $47 billion.[916] The pharmaceutical-biotechnology industry has become progressively more united over the past 15 years and sales have grown considerably. By 1985 the 10 largest pharmaceutical companies accounted for approximately 20 percent of worldwide sales, however by 2002 the total

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910 Julian Borger, Industry that stalks the US corridors of power, the Guardian, February 13 2001. Oxfam 2001a, p.11 citing UNDP, Human development Report, 2000
911 IMS World Review, 2002 and Pharmaceutical Executive, May 2003
912 Pharmaceutical Executives, May 2004
913 Pugtach
914
915 Patricia M. Danzon, Andrew Epstein and Sean Nicholson (2004) . *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries.* The Wharton School University of Pennsylvania http://hc.wharton.upenn.edu/danzon/PDF%20Files/Mergers&AquisitionsInPharma&Biotech.Danzon&Epstein&Nicholson_May04.pdf and Hall, Bronwyn H.(1999) *Mergers and R&D Revisited*, mimeo.
Hall, Bronwyn H., (1988) *The Effect of Takeover Activity on Corporate Research and Development.* In Auerbach, Alan J., ed., Corporate Takeovers: Causes and Consequences. Chicago: University of Chicago Press.
916 PhRMA (2003: 81, Table 9)

amount of worldwide sales had risen to 48%.[917] The significance of mergers lay in that for pharmaceutical companies who have to face patent expirations and cracks in its follow-on products, merging with another company that has a channel but lacks adequate marketing and sales capacity to adequately launch its own drugs may create value.[918] Other benefits of merger are that they offer the potential for cost cut in administration, consolidation of R&D expenditure, greater market access in the sense of increased specialized treatment, offsetting the negative effect of declining revenues on net profits and generating the economies of scale in the longer run.

Interestingly enough whilst a lot of people talk about M&A, there are actually two separate concepts. Mergers take place when there is a combination of two companies; acquisitions on the other hand take place when there is a takeover of one company by another. An acquisition may either be affable or aggressive. In the former case, the pharmaceutical company may cooperate in negotiations; in the latter case, the takeover target may be unwilling to be bought or the target's board will have no prior knowledge of the offer. One of the largest pharmaceutical acquisitions to take place in modern times has been Glaxo's hostile acquisition of Burroughs Wellcome in 1995. Glaxo's financial strength at the time was measured by the amount of sales it was making at the time. Thus between 1980 and 1994 Glaxo's sales had increased from £618 million to £5,656 million. This growth was led by the best selling prescription drug in history, Zantac (a peptic ulcer treatment that was launched in 1981). For much of this period, Zantac accounted for over 40 percent of Glaxo's sales. Wellcome's sales also showed that between 1986 and 1994, its market increased from £l,005 million to £2,662million. Its leading product, Zovirax (a

[917] Danzon, P.M , Andrew Epstein and Sean Nicholson. *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries.* May 2004. The Wharton School University of Pennsylvania http://hc.wharton.upenn.edu/danzon/PDF%20Files/Mergers&AquisitionsInPharma&Biotech.Danzon&Epstein&Nicholson_May04.pdf

[918] Ibid

treatment for genital herpes and shingles first sold in 1982) accounted for over 40 percent of its sales and was the fourth best-selling drug in the industry for much of the 1990s. During the bidding Glaxo discouraged any competing bids by offering cash and stock that were 49% higher than the closing price of Wellcome's shares, this put other bidders off and led to a somewhat undisputed acquisition.[919] Even so by 1997, the US patents on both Zantac and Zovirax had expired, and Glaxo and Wellcome were faced with the challenges of a changing industry environment and the decline of their major sources of growth. By combining two firms with similar financial powers and targets GlaxoWellcome created over $2 billion in stock market

As has been discussed above, M&As have been a key factor in the expansion and corporate strategy of pharmaceutical companies in the 20th century.[920] Statistics show that between 1990 and 2000, more than $250 billion worth of assets had been acquired in over four hundred deals involving a pharmaceutical or biotech company.[921] These mergers and acquisitions have considerably augmented the company sizes of many pharmaceutical companies, putting the total value of business carried out by pharmaceutical companies during that time at approximately $1 billion.

With regards to patented products however, pharmaceutical MNC face serious competition from generic based companies. The Generic Competition 2007-2011 report predicts that between 2007 and 2011, there will be expiration of patent protection on at least 52 major drugs in the US. This it is asserted will have a clear impact of the loss of revenue and the growth for the patent orientated pharmaceutical companies and threaten over $100 billion worth of revenues generated by patent orientated companies in the US and Europe.[922]

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[919]. Hilzenrath. D.S (1995) *Glaxo Bids $14 Billion for Rival Wellcome; British Firm Would be Biggest in Drug industry*. Article from: The Washington Post.
[920] Rozens, A. (2006). *Wall Street Expects Merger Recor*. Associated Press Online..
[921] David J Ravenscraft and William F. Long. (2000*) Paths to Creating Value in Pharmaceutical Mergers. In Mergers and Productivity* (National Bureau of Economic Research Conference Reports) (Hardcover) by SN Kaplan. Chicago University Press
[922] Generic Competition 2007-2011. URCH February 2007

Statistics show that the most affected will be the loss of patent on Lipitor between 2010 to 2012.[923]

8.5 Generic Pharmaceutical Industry

Generic companies have the advantage of not incurring the significant risks and costs associated with R&D for innovative medicines. Generic companies are smaller in terms of capital, funding, asserts, scope of operations, diversity and specialization when compared to pharmaceutical MNC.[924] One of the advantages that they have is that they are flexible and this allows them to specialize in specific market areas, such as gene or cell therapy as well as working with MNC at various stages of R&D.[925]

The rise of the generic industry can be traced back to The Drug Price Competition and Patent Term Restoration Act of 1984, which is commonly known as the Hatch-Waxman Act.[926] The Act was a milestone in the hub of generic trade in the US and effectively promoted generics while leaving untouched the financial incentive for R&D.

Whilst there are many supporters of the rise of the generic industry, there are opponents to the rise of the generic industry. Most of these opponents base their arguments on the fact that the rise of the generic industry will hurt innovation by preventing adequate patent protection is the lifeblood of biomedical research.[927] The Hatch-Waxman Act is therefore significant in that it allows generic companies to gain FDA marketing approval by discarding the

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[923] Ibid
[924] Ballance, R., J Pogany and H Forstner (1992), United Nations Industrial Development and Organization (UNIDO) (eds) The World's Pharmaceutical Industries, Aldershot UK and Brookfield, US: Edward Elgar
[925] Commission on the European Communities, Economic Advisory Group (1985), The Community's Pharmaceutical Industry, Brussels
[926] Grabowski, H., and J. Vernon.(1992*) Brand loyalty, entry and price competition in pharmaceuticals after the 1984* Act. Journal of Law and Economics 36:331-50.
[927] Eli Lilly's challenge of generic provision stirs debate
Drug Store News, Sept 22, 2003 by Michael Johnsen

requirement of carrying out clinical trials and allows the generic companies to simply submit bioequivalence.[928] The Hatch-Waxman Act has all the same been criticised for granting a 30-month stay to firms that file suit against generic manufactures that challenge their patents. The controversy of this provision steams from the fact that pharmaceutical companies have used the provision to keep generics off the market by protecting their drugs with extra patents of poor quality, filing lawsuits to protect the patents even when the lawsuit will be lost, but getting the extra market exclusivity anyway.

The importance of the generic pharmaceutical industry has continued to grow and it has continued to provide access to cheaper medicines. MSF reports it relies on affordable generic antiretroviral drugs (ARVs) from India to treat over 80% of the more than 100,000 people receiving treatment in MSF projects.[929] Between 1989 and 1992 generic market share increased from 47% to 72%.[930] The US generics Market in 2004 was also reported to be worth over $18bn.[931] The importance of the generic industry towards meeting the healthcare needs of the global populace is evident in that in Britain for example, more than 66% of all prescription drugs are generics.[932] Some GP surgeries prescribe more than 90% of generic medicines to their patients.[933] Globally, In 2006, generic medicines were prescribed to patients in approximately 50% of cases globally and represented a total of 10% of sales of the entire pharmaceutical market.[934] Statistics has also shown that between 2004 and 2006 the sale and popularity of generics drugs grew faster than

[928]Donald O Beers. (2004) *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*. Aspen Pub.,. 6th Edition

[929] Promoting Generic Competition. http://www.accessmed-msf.org/main/hiv-aids/introduction-to-hivaids/promoting-generic-competition/

[930] Grabowski, H., and J. Vernon. (1996*). Longer patents for increased generic competition in the U.S*. PharmacoEconomics 1O:llO-23.

[931] The World's Top Ten Generic Companies

[932] Pharmaceutical Industry Issues. http://www.abpi.org.uk/publications/publication_details/pharidustryissues-bk040113/pii8.asp

[933] Ibid

[934] Booming US Generic Drug Market

branded[935] patented drugs. As result In 2006 the US government saved an estimated $10.2 Billion.

The usefulness of generics as an alternative to patented medicines was also established when in 2001, the Greater Access to Affordable Pharmaceuticals Act (GAAP), bipartisan legislation was introduced. The Act was intended to provide Americans with more choices when buying their medicine by ensuring that all safe and effective pharmaceuticals are made available to them in a timely manner and not kept off the market because of reasons that were unjustifiable. The author of the Act Senator McCain stated that by easing the entry of generic alternatives to the marketplace, the legislation could save consumers $71 billion over ten years.[936] With such optimism it is no wonder the report "Booming US Generics" has reported that unbranded generics will account for approximately 19% of the US pharmaceutical market by 2011,[937] further pointing to the development of the US generic pharmaceutical industry.[938] What this proves is that the prices of medicine do affect availability not just in third world countries, but also in the industrialised world. If a country like the US, which is one of the most advanced countries in the world need more access to generic medicines, it is fair to argue that developing countries need such access as well.

The generic pharmaceutical companies have continued to grow at an alarming rate and are now major competitors of patented MNC. Indeed some of the top pharmaceutical companies in the world are generic orientated. An evaluation of the financial might of some generic companies below will give the reader an

[935] The brand name is chosen by the manufacturer, usually on the basis that it can be recognised, pronounced and remembered by health professionals and members of the public
[936] Grabowski, H., and J. Vernon. (1996*). Longer patents for increased generic competition in the U.S.* PharmacoEconomics 1O:llO-23.
[937] Booming US Generic Drug Market
[938] To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy. By United States Federal Trade Commission, Federal Trade Commission, United States. DIANE. 2003

insight into the level of competition that generic companies bring to the pharmaceutical industry. For example, Teva is a generic orientated pharmaceutical company based in Israel, its consumer base is mostly in the US and EU, thus over 80 percent of its sales are carried out in the West[939]

As of 2008, Teva was estimated to be worth over $38 billion and had an annual sale of more than $9 billion.[940] Teva specializes in developing, manufacturing and marketing generic and pioneering human and active pharmaceuticals ingredients, it also concentrates its R&D on animal health pharmaceutical products. In September 2008, Teva announced that it had signed an agreement to set up a primary generic pharmaceutical company with Kowa Pharma Co., Ltd in Japan.[941] Teva-Kowa Pharma Co., Ltd has pledged to pull the marketing, R&D, manufacturing and distribution capabilities of each company to become a broad based supplier of high quality generic pharmaceutical products for the Japanese market and reach sales of $1 billion by 2015.[942]

The Brazilian generic industry is another market which has been crucial in the fight towards access to medicines. In 1997, Brazil embarked on an on an ambitious program to locally manufacture expensive affordable versions of expensive patented medicines. The competition from generic medicines brought prices down by over 90% in some cases.[943] By 1999, the Brazilian government introduced new generics laws which legitimized pharmaceuticals

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[939] Script Magazine 1993, 40-41; Aizenberg 2000
[940] Lewis Krauskopf. Reuters. *Makers of generic drugs likely to keep jumping the gun on patents*. Accessed 16 January, 2008
[941] Kowa is responsible for sales and marketing of innovative drugs and focuses on promoting cardiovascular drugs, such as treatment drug for hypercholesterolemia "Livalo tablet" and hypertension drug "Olmetec tablet" through its wholly owned subsidiary, Kowa Pharmaceutical Co. Ltd. In addition, Kowa has focused on lifestyle diseases (arteriosclerosis, kidney disorder and diabetes) as main strategic therapeutic area for research and development.
[942] Calisha Myers. Teva and Kowa Announce Strategic Partnership to Create a Leading Generic Pharmaceutical Company in Japan. http://www.fiercebiotech.com/press-releases/teva-and-kowa-announce-strategic-partnership-create-leading-generic-pharmaceutical-co
[943] Paul Davies. (2001) *New Trade Agreement for the Americas Jeopardizes Brazil's Acclaimed Generic AIDS Drug Program*. FOR IMMEDIATE RELEASE. ACT-UP . 215.731.1844

companies to legally produce generic drugs that were copies of patented drugs.[944] The legislation made many MNCs uncomfortable about the emergence another stronger generic industry, however many NGO's were pleased with the fact that consumers in Brazil would be better off in manufacture or purchasing generic versions of expensive patented drugs. The influence of the Brazilian generic manufacturer continues to grow, by 2004 it was producing 11.6% of all drugs in Brazil. The Brazilian generic industry is expected to take over 20% of the entire drug market by 2009.[945] Faced with such huge competition Patented oriented MNCs have responded by seeking to secure their position in the generic markets through setting up coalitions with generic companies, by so doing regulating the level of competition that they face. Many MNC have also set up their own generic units,[946] for example Merck's generic-drug division has nearly 5,000 employees.[947] Pfizer was also been reported to be moving into generics.[948]

Although an in-depth study of the Indian generic pharmaceutical industry will be carried on later in this chapter, it is important to note that another key generic industry which has the threatened the patent based pharmaceutical industry with competition is the Indian generic pharmaceutical industry. Most Indian generic companies have the added advantage over their counterparts in developed countries of producing bulk and formulation medicine at approximately 10-20% of the cost of production in the west. [949] The report

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[944] Generic Drugs in Brazil Are a Hard Pill for Big Pharma to Swallow. Section Especial. (Jan 16, 2006) http://wharton.universia.net/index.cfm?fa=viewArticle&id=1086&language=english&specialId=

[945] Ibid

[946] Faigen, N. (1993), *The multinational threat in the generic marke*t, Scrip Magazine, April, pp. 13-14

[947] The German drugmaker Merck to sell generic-drug unit to Mylan. Published May 13, 2007. http://www.iht.com/articles/2007/05/13/business/merck.php

[948] Jacob Goldstein. Pfizer. October 16, 2008. http://blogs.wsj.com/health/2008/10/16/pfizer-goes-generic and Lewis Krauskopf. Reuters. *Makers of generic drugs likely to keep jumping the gun on patents*. Published January 16, 2008

[949] India – An Emerging Pharmaceutical Export Hub, Says RNCOS. *PRLog (Press Release) – Aug 25, 2008*

called “Booming Pharma Sector in India” predicts that exports from India pharmaceutical companies will grow at 18.5% between 2007 and 2011[950]. According to the report, one of the key reasons for the predicted growth will be the expirations of many product patents.[951] The growth of the generic industry can therefore not be underestimated in their role of providing more access to medicines and its potential to dominate the pharmaceutical industry in the near future after the expiration of certain patents, it is with this background in mind that the next section seeks to explore the Nigerian pharmaceutical industry and the pharmaceutical practice in Nigeria.

8.6 The Origins of the Nigerian Pharmaceutical Industry and Practice

The origins of pharmaceutical laws and practice in Nigeria can be traced back to the Lagos Pilotage and Harbour Ordinance which was enacted in 1878. This Ordinance established the control and supervision of medicines and medical treatment on ships when the ships docked in the Lagos harbour.[952] However it was not until 1887 that Dr R Zacchaeus opened the first pharmacy store for Europeans in Lagos.[953] During that time people who trained to handle drugs were called “dispensers”. Such dispensers functioned as dispensers of medicines, sanitary officers, medical aids and anaesthetics in operating theatres.[954] Subsequently, the Hospital Ordinance 1881, and the Ereko Dispensary Rules of 1889 were further enacted in support of the early laws controlling pharmacy and pharmaceuticals. Indeed, some sceptics have argue that the practice of pharmacy in Nigeria did not begin as a well defined health care area of specialization, this suggest that whatever pharmaceutical training there was existed from the necessity to provide assistance to expatriate medical

[950] RNCOS. Booming Pharma Sector in India, Aug, 2008
[951] RNCOS. Booming Pharma Sector in India, Aug, 2008
[952] *HISTORY OF PHARMAVY REGULATION IN INGERIA*. Pharmacists Council of Nigeria. 2001. Lindoz Products Limited, Lagos, Nigeria.
[953] Adenika FB.(1998) *Pharmacy in Nigeria*. Panpharm Ltd, Lagos, Nigeria
[954] Daily Times (Nigeria), 8 Jan 1975.

officers who were at the time their colonial masters.[955] What this also indicates is that because the industry was more centred on providing the healthcare needs of its colonial masters as opposed to its local indigenes, it would later struggle with the future responsibility of enacting a new philosophy where the health care needs of own populace would be cared for.

As the colonial masters settled into Nigeria, the number of dispensers and medical stores increased and this brought about a need to regulate the pharmaceutical industry and practice. Early legislation was therefore enacted in the form of the Pharmacy Ordinance No8 of 1902. The Ordinance sought to control the sale and distribution of drugs and poisons and was restricted to Lagos, Calabar, Opodo, Warri, Forcados and other areas that were declared by the Governor in Council.[956] In 1923, the Poison & Pharmacy Ordinance was enacted to control the sale and distribution of drugs and poisons in Nigeria. Under the Ordinance the Board of Medical Examiners was established and had the sole responsibility of controlling the training of medical assistants and the supervision of training dispensers and chemists. However it was not until 1925 that a Medical College was set up in Yaba, Lagos. The College consisted of the School of Medicine and the School of Pharmacy. In 1936 another Poison and Pharmacy Ordinance was enacted which made major improvements on the 1927 Ordinance which had already been passed. This Ordinance increased the membership of the board, standardised the syllabus, and curriculum of Chemist and Druggists Diploma and the issuance of Dispensers Certificate. The Ordinance also established the Pharmacy Board of Nigeria. The Pharmacy Board of Nigeria was crucial in the sense that it consisted of representatives from the Nigerian Union of Pharmacist (NUP) and the Association of Dispensers which were to later form the Pharmaceutical Society of Nigeria (PSN).

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[955] https://tspace.library.utoronto.ca/bitstream/1807/3173/1/pr03010.pdf Accessed 25 November 2008

[956] *HISTORY OF PHARMAVY REGULATION IN INGERIA*. Pharmacists Council of Nigeria. 2001. Lindoz Products Limited, Lagos, Nigeria.

Note that today the PSN is one of the most important bodies in the directing pharmaceutical practice and research in Nigeria. The relevance of the origins of the pharmaceutical practice in Nigeria in relation to India cannot be lost on the reader. Indeed as will become evident below like Nigeria, India began to practice orthopaedic medicine in the 19th century and passed its first Indian Patent act in 1856. Like India, Nigerian's pharmaceutical industry and pharmacy practice was based on providing medicines for its colonial masters. The comparison is therefore important in discerning why the problems of the pharmaceutical industry in Nigeria failed to become self sufficient and why the Indian pharmaceutical industry has thrived.

The PSN was also in charge of granting licences to sellers of patent and propriety medicines and making sure that facilities were drugs and poisons was sold were inspected.[957] Subsequently, in 1947 the School of Pharmacy Zaria was established in the North of Nigeria, which is also affiliated with the Ahmadu Bello Teaching Hospital, one of the most renowned teaching hospitals in Nigeria today. In 1958, another Ordinance known as the Poison and Pharmacy Act 152 was enacted and this gave the Pharmacy Board of Nigeria additional powers to regulate the examinations for certificates and to keep a register of pharmaceutical chemists and pharmaceutical premises. The consecutive evolution of legislation was a clear indication that pharmacy laws and the pharmaceutical industry were constantly evolving. The Nigeria government was desperately seeking to consolidated the regulation of drugs and revolutionize the healthcare delivery system, but this proved not to be an easy task.

After Nigeria gained its independence in 1960, the Pharmacist Act No 26 was passed in 1964. The 1964 Act was crucial because it amalgamated the

[957] Ibid

regulation and control of all pharmacist affairs including the profession. Further development led to the Food and Drugs (Lagos) Act 1965 and the Foods and Drugs Act (Commencement) Order was enacted in 1967 to control the importation of drugs and other products into Nigeria. By 1969, the first national pharmaceutical inspectors' workshop was organised by the PBN in Lagos, it continued to operate so that by 2001 zonal pharmaceutical inspectors' workshops were set up in Kaduna, Jos and Enugu. Consequently after that, the control of industrial chemicals was taken over by NAFDAC which has been discussed in an earlier chapter.

8.6.1 Problems of the Pharmaceutical Industry

The Nigerian pharmaceutical industry as far back as its history goes has been saddled with serious problems such as limited local input in production in terms of raw materials, machinery and technical manpower. The industry has also faced the problems such as lack of infrastructure, lack of electricity, water, roads, communication and information technology. Another major setback for the Nigerian pharmaceutical industry has been the lack of (R&D) by its local industry into the discovery and development of medicines which are peculiar to diseases that affect the country. The development and role of the pharmaceutical industry has followed the pattern of other British colonies and has historically been in line with the developments in Britain,[958] however the industry has seriously fallen short of its expectation to produce critical input in agricultural raw materials, intermediate chemicals from the nations' petrochemicals and engineering infrastructure for the pharmaceutical industry.[959]

A study carried out in 1971 revealed that there were ten local manufacturing companies in Nigeria, and that most of the drugs used were imported from

[958] Daily Times (Nigeria), 8 Jan 1975.
[959] Fredrick Adenika. Paper on "*Nigeria's pharmaceutical industry -an agenda for survival in the 1990s and beyond"*

abroad. The development of the pharmaceutical industry was lunched with the Food, Drug and Cosmetic Decree No. 35 of zd1974.[960] The Decree took effect in 1976 and formed the basis for setting up the nation's Food and Drug Administration (FDA) department of the Ministry of Health. The Decree sought to regulate manufacturing practices, quality control, advertising of drugs to protect consumers' from fake and counterfeit products, and gave the FDA wider powers to inspect and control the industry. Findings showed that by 1976, the number of indigenous companies producing drugs had risen to 15, and were providing only 5% of the total drugs consumed in Nigeria, although by 1984, the number of pharmaceutical companies manufacturing medicines for the local population had further risen to 26, they were only producing 20% of the total amount of medicines consumed.

8.6.2 Nigeria's National Health Plan

Nigeria came up with its first National Health Policy in 1986. The policy stated that its aim was to achieve a level of health which would allow all Nigerians to achieve socially and economically productive lives by 2000. Obviously, this objective did not materialize because the World Health Report 2000 showed that Nigeria had a disability adjusted life expectancy (DALE) of 38.3 years and its health system was ranked at 187, one of the worst in sub-Saharan Africa.[961] The National Health Policy also stated that the Nigerian government had the an overall obligation of establishing a comprehensive health care system, based on a primary health care that is promotive, protective, preventive, restorative and rehabilitative. This they stated should be available to every Nigeria to enable them have a level of productivity that would ensure a degree of social well-being that would be suitable for an enjoyment of living. This goal could not be achieved because the basic health service delivery is run by the states and local government which are not adequately quipped with enough revenue

[960] *Ibid*
[961] WHO Country Cooperation Strategy: Federal Republic of Nigeria 2002-2007. World Health Organization Regional Office for Africa Brazzaville

and resources to fulfil such obligations as the bulk of government revenues is retained by the federal government.[962]

In the same way that the Nigerian Primary health care is based on a three tier government system namely the federal, state, and the local government authorities (LGAs); the Nigeria Healthcare system is divided into three main sectors. The first sector is the primary healthcare which is the local government responsibility and oversees the healthcare clinics, health centres and community health workers. The second sector which is the secondary healthcare system which is run by the state and oversees the general hospitals in the 774 local government areas and other secondary health care providers and thirdly the tertiary healthcare system which is the Federal government responsibility. The tertiary healthcare system consists of teaching and specialist hospitals and there is at least one in all 36 states including the Federal Capital territory. Some private hospitals with specialist services are also included in the Tertiary health care system of Nigeria. The Nigerian Constitution of Nigerian gives state governments and LGAs the principle responsibility for providing basic services including primary health care. This primary health care is based on the Bamako initiative of 1987 and stipulates the following obligations: namely that primary health care must seek to encourage community participation in primary healthcare services; and aim to increase the availability of essential medicines and other health care services.
Regardless of the Bamako initiative, evidence suggest that the initiative has not been very successful due to a variety of reasons: there has been a lack of community participation in setting charges for drug; funding for essential medicines is limited because the bulk of LGA health funds are allocated to staff salaries, thus a survey done in Kogi state in 2000 showed that LGA spent approximately 78% of health care expenditure on salaries. Similarly in Lagos,

[962] Monica Das Gupta, Varun Gauri and Stuti Khemani. (September 24, 2003) *African Region Human Development Working Paper Series. Decentralized Delivery of Primary Health Services in Niger. Survey Evidence from the States of Lagos and Kogi*.. Development Research Groups. The World Bank

65% of health expenditure was used to pay staff salaries.[963] The same study showed that whilst malarial drugs were available in more than 60% of the facilities surveyed, they was no equipment for testing for malaria in more than 90% of the facilities. This suggests that medicines are simply administered if malaria was suspected, further pointing towards the irrational use of medicines.[964] Thus for there to be rational usage of drug, patient must receive medications that are appropriate to their clinical and medical needs in doses that treat specific medical problem, for an adequate time and at the lowest possible cost to them and their communities.[965]

In a study carried out by the Nigerian Ministry of Health, it was revealed that the average number of medicines per prescription was only 4.7.[966] In another survey carried out on the rational use of ARV in Nigeria, it was revealed that the labelling of ARV which should include the name of the ARV, name or code of patient, frequency and duration of administration was unsatisfactory in 86% of cases.[967] As some cases the suitability of medicines administered was as low as 2% in diarrhoea prescriptions, and 10% in cases of acute respiratory tract infection. Similarly in cases of mild to moderate pneumonia only 21% of medicines were correctly prescribed. Because of the foregoing, the irrational use of drugs has been identified by WHO as one of the major cause of lack of access to medicines.[968] Indeed whilst the rational usage of medicines is very important in the access to medicines debate because although drugs have the power to heal, it also has a potential to cause harm and prolong illness if administered in the wrong way for the wrong illness.

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[963] Adeniyi, J., O. Oladepo, and A. Soyibo (2003) *Survey of Primary Health Care Service Delivery in Lagos and Kogi: A Field Report."*Mimeo, African Regional Health Education Center, University of Ibadan
[964] Ibid
[965] Ibid
[966] *Baseline Assessment of the Nigerian Pharmaceutical Sector* (2002) Federal Ministry of Health in collaboration with the World Health Organization.
[967] *Situation of ARV DRUG USE IN NIGERIA*. (November 2003). The Federal Ministry of Health.
[968] *How to develop and implement a national drug Policy*. (1988) World Health Organization. 2nd Edition,

8.6.3 Nigeria's National Drugs Policy

National Drugs Policy and is a guide line for developed and developing countries alike. The objectives of a national drug policy for the purpose of this chapter are threefold: firstly to ensure the availability and adequate supply of most useful drugs at reasonable prices to the general populations; secondly to provide adequate governmental control in ensuring drug quality and ensure the safety in use and handling by all and thirdly to stimulate the growth of local pharmaceutical manufacturing industry which will provide medicines for the general population as well as compete in local and international markets thereby resulting in the balancing of trade.[969]

The Nigerian National Drug Policy was enacted in 1990 and sought to make the Nigerian pharmaceutical industry self reliant. The main aim of the Nigerian National Drugs Policy was to reduce the high level of dependence on foreign sources for finished drug products. In the 1970s and 80's, Nigeria begun on a path to lessen the level of dependence on imported pharmaceuticals and provide medicines for its general population through their local manufacturing industries, these gains have however been short-lived. Although it is important to note that the most superb year when Nigeria recorded that its pharmaceutical local industries was providing 25% of the medicines needed was in 1984,. By 1987, that amount had dropped to a low of 20%. Thus Fred Adenika commented that "It is obvious that after 1984, the gains made since the mid-seventies in increased local production are being eroded by a wave of increased importation".[970] In another paper delivered in March 1984 titled "Developing appropriate strategies for local manufacturer", Frednika noted that 'Faced with mounting opposition to our self-reliance programmes, it is clear that our nations in West Africa will, above all, need strong political will,

969 Fred B. Adenika. *Principles of Essential Drugs Management*. 1992. Published by Shaneson C.I.

970 Adenika FB.(1998) *Pharmacy in Nigeria*. Panpharm Ltd, Lagos, Nigeria

at the national level, we must develop and enforce these policies despite local professional and commercial opposition. At the international level, we need the political will to co-operate among ourselves and end today's 'drug colonialism'. We require astute, effective and loyal leadership which can match those of the developed countries, and indeed surpass them in single – minded dedication to our cause".

Bearing the above stance in mind the Nigerian National Drug policy 1990 sought to:

1. To ensure that - drug research and development is an essential component of health research which is itself an important feature of most of the strategies for achieving the goals of a national health policy.
2. To produce more high-level research scientists and technicians in the area of drug research and development so that by 2000 shortage of people with such skills and expertise would no longer constitute a handicap to the national effort on local production.
3. To achieve the objective of full local capacity in drug manufacture, exploratory and development research into local raw materials as sources of new drugs ...[shall] be pursued as a major drug research objective.
4.

The National Drug policy's objectives in reaching the above goals are outlined in Article 1(I) and it states that its aim is to "make available at all times in all sectors of the health care system adequate supplies of drugs which are effective, affordable and safe, are of good quality". Despite the above goals, Nigeria is still struggling to meet its National Drugs Policy objectives and has remained heavily reliant on imported medicines. Thus the 2007 BMI estimates showed that imported pharmaceuticals accounted for 54% of the Nigerian market.[971]

[971] BMI – Pharmaceuticals in Nigeria (BMI 2008),

Pharmaceutical R&D are the backbone of any the self-reliant nation, many commentators have therefore suggested that the prospect for R&D in Nigeria is enormous . Thus despite the setbacks that the Nigeria pharmaceutical industry has faced in becoming self-reliant, in 1987 it managed to set up a National Institution for Pharmaceutical Research and Development (NIPRD) in Abuja. The Institution is one of the most advanced organizations in Nigeria that engages in extensive R&D. NIPRD has sought to work with traditional medicines, receipts and formulas in a bid to advance R&D in the country. Accordingly in 1986, Professor Bona A Obiorah stated that "the Key to Nigeria's Pharmaceutical industrialization lies in the bush".[972] This statement was made because of the rich pharmacopoedie collection that Nigeria has collected over the years. The advantages of this in propelling the Nigerian pharmaceutical industry forward in becoming a major competitor in creating NCE cannot be overstated, thus according to WHO, 80% of the world's population uses medicinal plants for the treatment of diseases.[973] A survey carried out by UNCTAD showed that 33 % of drugs produced by the industrialised countries are plant derived and that if microbes are added 60% of medicinal products are of natural origin.[974] Whilst approximately 400 compounds derived from plants are currently being used in the preparation of medicines, higher plants (higher plants are plants in the kingdom Plantae that have specialized tissues for conducting water, minerals, and photosynthetic products through the plant) have been identified as the future of drug development.[975] Statistics also show that the total global sales of plant derived drugs in 2002 were estimated at $13.7billion. Evidence also suggests that plant derived drugs accounts for 50% of the global drug market.[976] Indeed

[972] Adenika FB.(1998) Pharmacy in Nigeria. Panpharm Ltd, Lagos, Nigeria
[973] Frances O. A. Ajose, Some Nigerian plants of dermatological importance. International Journal of Dermatology. Vol 46 Issue s1, pg 48-55
[974] UNCTAD
[975] Farnsworth and Morris (1976)
[976] BCC Research Report ID:BIO022C, Published: February 2003, Analyst: Andrew McWilliams

Obafemi Awolowo once stated that the prospects are great for finding new drugs from plant; the chances are even greater in developing countries where a lot of plants used in traditional medicines are yet to be checked. A survey carried out in Dermatology Clinic, Lagos State University Teaching Hospital (LASUTH), Ikeja in Lagos suggested that 65% of patients had applied herbal medicines before going for consultation.[977]

The objectives of the national drugs policy are imperative in pushing forward the Nigerian pharmaceutical industry agenda, however the wealth of herbs and plants in Nigeria will also play an important role in the successful implementation of the national drugs policy if the healthcare delivery system is to be refurbished. It is with this background that the Indian National Drug policy will be explored in the next section to discern any similarities that may enable one to discern what direction Nigeria should take if it is revamp its goal of making the pharmaceutical industry independent and ensuring that it gains access to medicines.

8.6.4 Essential Drug List (EDL)/ Nigeria's Essential Drugs List (NEDL)

The WHO essential drug list was conceived in 1975 by the World Health organisation but was complied and promulgated in 1977. Since then it has been consistently updated every two years and the current version was updated in March 2007.[978] Also note that the NEDL which consisted of 205 essential drugs when it was published in 1986 was updated in 1996 to 484 drugs.[979] It was last reviewed in 2003. The list of essential medicines has been very important in the access to medicines debate and has doubled from 186 in 1977 to 320 in 2002. With regards to HIV/AIDS, WHO's EDL contains medicines in three classes of antiretroviral for the treatment and prevention of HIV

[977] Frances O. A. Ajose, Some Nigerian plants of dermatological importance. International Journal of Dermatology. Vol 46 Issue s1, pg 48-55
978 Ibid
[979] Baseline Assessment of the Nigerian Pharmaceutical Sector, (2002) Federal Ministry of Health in collaboration with the World Health Organization

(including treatment for the prevention of mother-to-child transmission and post exposure prophylaxis).[980]

An EDL must reflect the pattern of diseases a country faces by taking into consideration the health care facilities available; the training and experience of the health care personnel; financial resources available and the genetic, demographic and environmental factors.[981] The first Nigerian essential drug list (Fed.Government's NEDL 1986) contained 204 drugs, the drugs were listed by generic names, dosage, forms and strength.[982] Some of the drugs listed were probably obtained from WHO Model lists at the time, however the Minister of Health Ransome Kuti stated in an interview that "we developed our own essential drugs list. We know our patterns of diseases, and we have listed the drugs we need for each diseases and we produced our national essential drugs list".[983]

The NEDL has outlined four main guideline as the foundation of its strategy namely: to develop and affordable and sustainable supply of safe drugs; improve the skills of health workers in providing drugs; change the harmful practices of patients; and strengthen institutional capacities to undertake essential drugs programs.[984] The background of the NEDL reveals some important factors that has formed the basis of the national drug policy. Thus at the time that the essential drug list was compiled, Nigeria was facing major problems within its health care delivery services. There were acute shortages of both preventive and curative drugs especially in the public health sector. This was further aggravated by the rapid increase in population and the rapid

980 WHO list of Essential Medicines 15 List March 2007 http://www.who.int/medicines/publications/EssMedList15.pdf. The three antiretroviral medicines on the EDL are *Nucleoside/Nucleotide reverse transcriptase inhibitors, Non-nucleoside reverse transcriptase inhibitors and Protease inhibitors*

981 HOW TO DEVELOP AND IMPLEMENT A NATIONAL DRUG POLICY. WHO. 2ND EDITION. 2001

982 See Nigerian National Drug Formulary and Essential Drugs List, 1986.

983 Kuti. O Ransome . *National Drug Policy in Nigeria*.

984 Ibid

decline of economic resources. The Federal Ministry of Health was therefore given the task to set up an Essential Drugs working Group that would organize workshops for all states and selected LGA's to make sure that this policy was implemented from the local grass root level.

The Federal Ministry of health was able to engage the commitment of WHO and the World Bank financial aid and by doing this set up an assistance program through WHO that would manage the preparatory process of NEDL.[985] Subsequently the preparatory process was done in collaboration with the Essential Drugs Unit in the Department of Primary Health Care (DPHC) who began a series of studies on logistics, training, quality assurance, local production and public education for establishing the NEDL.[986] The Ministerial Committee on the Reorientation of curricula in Medicines and the Dentistry and Pharmacy on the Essential Drugs Concept was also set up to assist the federal government come up with ways to ensure a "total implementation" of a comprehensive curriculum on the Essential Drugs Concept in all relevant institutions of health training.[987] Through the long history of the evolution of the Nigeria's essential drugs policy and programmes, there has been a precedents of several attempts made to improve and rectify failed policies that have handicapped the advancement of the healthcare delivery system. It is therefore important to note that the advantages of the EDL in promoting the access to medicines is to ensure that: "essential drugs … are available at all levels of the health care system" and guarantee that access to health care is a human right. Hestermeyer states that "by their very nature, human rights have the potential to reach all human behaviour' and thus governments and international agencies have an obligation to see that this right is progressively

[985] WHO Technical Reports, Series , No. 615.
[986] Adenika. Fredrick B (1992) *Principles of Essential Drugs Management.* Shaneson C.I. Limited
[987] The Committee concluded their work in 1989. The Committee was headed by Prof. B.D Musa and Prof H. O Obianwu had several other university teachers in medicine and pharmacy, practicing doctors and pharmacists including Dr. F.B. Adenika as its members

realized. Having a list of essential drugs is therefore an essential step in ensuring that people have access to it.

The EDL is also useful to developing countries in their search for access to medicines and in ensuring that drugs are specified by their international non-proprietary name or generic equivalent without reference to the brand name. The importance of this lies in that it makes it easier for accurate and comprehensive information to be given on all drugs in the essential drugs lists. Hence the NEDL has also been instrumental in ensuring access to medicines and making it easier for pharmacist, dispensers, or prescribers to familiarize themselves with the pharmacological properties of the drugs; and enabling them to make more accurate judgment on the type of prescription to use on patients thereby improving rational use. The NEDL has also made it easier for NAFDAC to formulate strategies to evaluate the quality of medicines as well as ensuring the regular inspection of factories to ensure that they are complying with the guidelines for good manufacturing practices (GMP).[988] Indeed another major advantage of the NEDL has been its reduction in the number of drugs in circulation in the health care system which has ensured easier organization of the procurement, storage, and distribution of drugs. For example in Nigeria, procurement in public health facilities and the National Health Insurance Scheme is limited to medicines listed in the EDL.[989]

8.6.5 Supply Systems

The availability of a proper drug supply system has been identified as a vital factor in the quest for access to essential medicines in Nigeria. WHO states that "a good supply system requires an interaction between the public and private sector that will guarantee that public funds available for drug purchases are used effectively to maximize access, to obtain value for money, avoid

988 Ibid
[989] Ibid -Baseline Assessment of the Nigerian Pharmaceutical Sector, 2002

waste and ensure an economy of scales".[990] A good supply system also requires good pharmaceutical procurement practices[991]; publication of price information on raw materials and finished products as well as prevention of waste, theft and the disposal of unwanted or expired drugs.[992]

A good supply system is particularly relevant in the case of Nigeria as some of the major deterrents of access to medicines are expired medicines, counterfeit medicines, poor procurement that is centred on state central medical stores and the irrational use of medicines. A survey carried out in 2006 by the Ministry of Health on six state medical stores revealed that only three of the stores were functional. The survey also revealed that public CMS procurement was 500% higher than NGO procurement.

For developing countries to have a good supply system, WHO has outlined four basic principles for good pharmaceutical procurement,[993] which are listed below: the most cost-effective drugs must be procured in the right quantity; reliable suppliers of high-quality products must be selected to ensure timely delivery; procurement and distribution systems must achieve the lowest possible total cost. The procurement and distribution should take four main components into consideration: (1) the actual purchase price of drugs, (2) the hidden costs of the product due to poor product quality (3) poor supplier performance or short shelf-life, (4) inventory holding costs at various levels of the supply system (5) operating costs and capital loss by management (6) administration of the procurement and distribution system.[994]

With regards to providing medicines for HIV/AIDS, most of the goals of the ARV programs in Nigeria have been to provide a constant supply of drugs to

[990] How to develop and implement a national drug policy(2002) WHO. 2nd edition
[991] Operational Principle for Good pharmaceutical Procurement. World Health Organization. WHO/EDM/PAR/99.5. http://www.who.int/3by5/en/who-edm-par-99-5.pd
[992] How to develop and implement a national drug policy. 2002. WHO. 2nd edition
[993] Ibid
[994] Ibid

patients in a timely and cost effective manner while minimizing drug expiration of drugs; however the drug supply system has not been ineffective.[995] A survey by the Ministry of Health revealed several problems with regards to the supply system of ARV in Nigeria. The survey listed the following as major distractions to the supply chain: lack of communication between the central supply system and the local centres;[996] centres stocking expired ARVs, centres running out of ARVs. Thus expired drugs were also found to be a major problem in the supply system of ARV in Nigeria. The three ARVs on the NEDL most suitable to the health needs of people living with HIV/AIDS in Nigeria - Nevripine, Stavudine and Lamivudine have problems with supply coordination. In the baseline assessment by the Ministry of Health (2003), 64% of the health facilities surveyed had expired drugs. 7,188 packets of Nevirapine were found to be expired in 50% of health facilities, 2,934 packets of Stavudine were found to be expired in 27% of facilities, while 6,553 of Lamiviudine were found to be expired in 31% of facilities.[997] The total amount of wasted funds for these ARV was $146,717 and 19,953,510 in naira.

Affordability also poses a serious problem with patients gaining access to the supply chain of medicines. Affordability is usually measured by comparing the cost of medicines with daily wages of the lowest paid government worker.[998] Presently, the minimum wage of a Nigerian is set at 5,500 (naira) per month, which is an equivalent of $11.3 per week.[999] A person earning the minimum wage in Nigeria has to work for 0-6 days to procure one month's supply of drugs from the government health facilities. He would have to work for 30-90 days for an equivalent supply of ARVs from the private sector.

[995] *Situation of ARV Drug Use in Nigeria*. November 2003. Published by The Federal Ministry of Health in collaboration with the World Health Organisation.
[996] Ibid
[997] Ibid
[998] Ibid
[999] Ibid

Naturally, brand medicines for all medicines in the NEDL are higher than their generic equivalent (see table below).[1000] However evidence suggests that generic medicines were up to 825% more expensive in Nigeria than in other countries.[1001]

Additional problems included the fact that some centres stocked first line triple therapy despite the fact that second line therapies were available at the central medical stores.[1002] Data Recording in many health facilities were also found to be inadequate. ARVs were being dispensed to patients without keeping detailed record of prescriptions, stock cards and patient data. Funds for procurement were also being delayed, especially when it came to subsequent purchase of medicines, the situation was made more dire because success of many ARVs are based on follow up medication. All these were evidence of a failed drug supply system

Another major problem which has blocked the supply system of medicines in Nigeria has been the lack of a National Health Act to back up the National Health Policy. This problem has meant that there is no health legislation describing the national health system, defining the roles and responsibilities of the three tiers of government and the stakeholders in the system. This has led to confusion, duplication of functions and sometimes lapses in the performance of essential public health functions. On a positive note however, a long awaited National Health Bill was passed in May 2008, which improved the coordination of the healthcare system. According to the bill, a primary healthcare development fund is to be established to ensure that basic healthcare facilities are provided under the NHIS. The bill organised healthcare funding in order to prioritise goals more efficiently. Meanwhile, problems of corruption

[1000] Ibid
[1001] Medicines Prices in Nigeria. Prices People Pay for Medicines. Published by the Federal Ministry of Health in collaboration with World Health Organisation, DFID, EU and the Health Action International March 2006.
[1002] Ibid

in the healthcare system are still crippling the healthcare system with various allegations of corruption being levied. In April 2008, the Health Minister Grange Adenike Grange and the Minister of State for Health Gabriel Aduku were sacked after an investigation by the Economic and Financial Crimes Commission (EFCC) revealed that 300million naira had been misallocated and embezzled.

8.6.6 The Present Status of the Nigerian Pharmaceutical Industry and Practice

In October 1977, at the 50th Anniversary Conference of the PSN held in Lagos, Fred Adenika urged more pharmaceutical companies to engage in the local manufacture of drugs. "No nation can truly control what it does not make; if Nigeria wishes to have real control over the drug needs of its populace, it must organise and produce the drugs" Remarkably, the drug industry in Nigeria experienced some growth in local drug manufacture (from 5 companies supplying 5% of national requirement in 1979 to nearly 70 companies supplying about 50 % of national requirement in 1995). Many indigenous pharmaceutical industries such as: Berewa Pharmaceutical Limited, Biode Pharmaceutical Industries Ltd, Bond Chemical Industries Ltd, Continental Pharmaceutical Limited, Emceea Limited, Emzor Chemist, Kafal Industrial Enterprise Ltd, Leady Pharmacy Ltd, Leo Melos, Link World Nigeria Ltd, Mopson Pharmaceutical Industries Ltd, Oily Chemists Ltd, Rajrab Limited, Tisco Industries Ltd, Toki Dabur Production Ltd, Vofmed Nigeria Limited sprung up and are manufacturing and producing medicines for some percentage of the population.

In the 1980s, the need to ensure the availability of the much needed drugs in Nigerian hospitals at affordable prices led to hospital pharmacists becoming more interested in the manufacture of drugs within the hospital system. The introduction and acceptance of clinical pharmacy into the practice of pharmacy

in Nigeria in the 1980s led some hospital pharmacists to be involved in clinical activities including drug information service and unit dose dispensing. However, unlike many developed countries, the involvement of pharmacists in Nigeria in the application of the emerging roles has not been impressive. In a survey conducted in 2002, only 18.2% of 119 pharmacists practicing in Nigeria stated that they applied most of the 52 suggested practice standards obtained from round one discussion by the Delphi panel of pharmaceutical care experts in their settings. Although pharmaceutical care has become a preferred mode of practice, most pharmacists in Nigeria still hardly offer significant patient-oriented services.

The Nigerian pharmaceutical industry has prospects, but its R&D efforts have been limited to isolated endeavours of individual scientists in universities, with little cross-pollution and without central guidance.[1003] Some of these pharmaceutical scientists are outstanding and internationally recognised but the nation as a whole has achieved very little that is concrete in this field.[1004] The international pharmaceutical companies in Nigeria had therefore shunned local medicinal research. This has impacted negatively on the Nigerian pharmaceutical industry because research is the springboard for growth of any modern pharmaceutical industry. Because it is a costly low-yield process, each nation must first clearly define its research goals and then purse them systematically. The first generation of Japanese scientists were educated mainly abroad, and then returned home to produce the next generation of pharmacist who formed the nuclei of important research centres in Japan (this is why they were a strong force at the Uruguay round) subsequently generations developed into a formidable scientific community. The process took 50 years and today Japan produces virtually all the drugs it consumes and is a world leader in drug discovery. Nigeria when compared to countries that have succeeded in developing their manufacturing industries do not have clear

[1003] Adenika FB.(1998) *Pharmacy in Nigeria*. Panpharm Ltd, Lagos, Nigeria
[1004] Ibid

cut goals (this will become clearer below when the development of Indian pharmaceutical industry is examined). Nigeria has fallen behind in the prospect of it being able to produce critical input in agriculture raw materials, intermediate chemicals from the nation's petrochemicals, machine tools and engineering infrastructure for the pharmaceutical industry. These problems have not only retarded the industry's technical advancement but have also threaten its sources of supply and its survival. Despite government efforts to promote domestic manufacturing, Nigeria remains heavily reliant on imported pharmaceuticals.

The National Drug Policy sets a target for 70% of the country's demand for drugs to be met by local industry. However, in 2007 BMI estimated that imports supplied 54% of the market. On the whole, domestic players do not appear ready to manufacture high tech products so Nigeria can expect imports to remain dominant. Indeed, domestic drugmakers seem to be increasingly looking to diversify into consumer health products, most likely in response to the difficult operating environment in their core market. In January 2008, both Fidson Healthcare and Neimeth Pharmaceuticals announced they were to launch consumer health lines. Neimeth revealed it would do this through two newly created subsidiaries - one concentrating on food and pharmaceuticals, the other on herbal remedies. The Nigeria Pharmaceuticals and Healthcare Report provides independent forecasts and competitive intelligence on Nigeria's pharmaceuticals and healthcare industry. The market was estimated to be worth US$278mn in 2007 and it should grow at around 5% year-on-year, reaching US$369mn by 2012.[1005] These forecast are indeed optimistic, but how far reaching this prediction will be remains to be seen.

[1005] Nigeria Pharmaceutical Market Should Grow at around 5% Year-on-Year Reaching Us$369Mn by 2012. 2008-04-23 10:07:21 – http://www.pr-inside.com/nigeria-pharmaceutical-market-should-grow-r552361.htm

8.7 Background of the Indian Pharmaceutical Industry

India has one of the most powerful pharmaceutical generic industries in the world. As a matter of fact, it is one of the few countries where western MNCs do not control its pharmaceutical industries.[1006] India has a $7 billion drug market and is the fourth biggest drug market (in terms of volume) in the world;[1007] it has 24,000 drug manufacturers, approximately 500,000 chemists, and provides medicines to at least a million people in 200 countries.[1008] Before the British colonial rule in India which lasted from 1858 to 1947, only local indigenous medicines were used in India;[1009] however the East Indian Company brought with it new modern bulk medicines and introduced new patent laws in India.[1010] The British rule brought with it the first Indian patent Act of 1856 which was enacted based on the recommendations of Lord Macaulay Law Commission.[1011] In 1859 another amendment was enacted introducing exclusive privileges for the making, selling, licensing and using inventions. These initial legislations gave patent holders a 14 years exclusive privilege period.[1012] For a young India pharmaceutical industry, the tenure was too long and allowed no opportunity for the indigenous firms to grow.[1013] Many indigenes were concerned about the high prices of medicines and the

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1006 Ibid -Chaudhuri. S.

1007 Saritha Rai, (24 Mar 2005) *India Adopts Patent Law Covering Pharmaceuticals*, N.Y. TIMES, Mar. 24, 2005, available at http://www.nytimes.com/ (search "NYT Since 1981" for "India patent law pharmaceuticals"; then follow "INTER Interview with Ranjit Shahani, President, Organization of Pharmaceutical Producers of India (Mar. 2, 2005), available at http:// www.pharmabiz.com/article/print.asp?articleid=26475NATIONAL BUSINESS; India Adopts Patent Law Covering Pharmaceuticals" hyperlink and

1008 Indrajit Basu (Jan. 11, 2005)*A Brave New World Indian Drug Industry*, WASH. TIMES. available at http://www.washtimes.com/upi-breaking/20050111- 114414-9131r.htm

1009 Raj in Hindi/Urdu means Rule. This refers to the British rule between 1757–1947 of the Indian Subcontinent, or present-day India, Bangladesh, Pakistan, and Myanmar, during which period these lands were under the colonial control of Britain as part of the British Empire.

1010 The first patent law in India, enacted in 1856, was assented to by the Governor General on February 28, 1856. First Indian Patent Law, Intellectual Property Rights (Tech. Info., Forecasting & Assessment Council (TIFAC)), Jan.-Feb. 2002, at 1, available at http:// www.tifac.org.in/do/pfc/pub/jan02.pdf.

1011 Ibid

1012 Srividhya Ragavan,(Accessed Jan. 28, 2003). *Patent Amendments in India in the Wake of TRIPS*, CASRIP Newsletter (Univ. of Wash. Sch. of Law), Winter 2001, available at http://www.law.washington.edu/casrip/newsletter/newsv8i1Ragavan.pdf This Act was "modelled on the same lines as the British Patent Act of 1852." Id.

1013 Ibid

renowned Indian Chemist, Prafulla Chandra Ray set up the Bengal Chemical and Pharmaceutical Works (BCPW) in 1892 and began the manufacturing of the British Pharmacopoeia which was previously imported. This was indeed the origins of what was to later become one of the most vibrant third world pharmaceutical industries in the world. Ray went further to revitalize the use of robust indigenous drugs, which were traditionally prescribed by "medicine men"; and like in the case of Nigeria, a system for collecting the formulas, prescription and putting them into circulation in the market. And for the first time there was an ordered system of marketing indigenous medicines in modern day India.

However in 1911 the very famous Patent and Design Act was passed repealing earlier enactments and entrenching the patent system into the Indian structure. Although the Patent and Design Act was seen by critics as suiting only the needs of the British colonial masters. The 1911 legislation coupled with the establishment of several medical schools by the British brought about a culture of producing modern drugs and subsequently paved the way for a thriving pharmaceutical culture that exists in India today. What became apparent at this point was the fact that like in the case of Nigeria, the colonial masters were paving the way for what direction the future pharmaceutical industry would take. Thus Ray observed with unease that the local raw materials were being exported to foreign countries and imported back to India as finished products at extremely high prices.[1014]

Like many Asian countries with long civilization histories, India has always had a reasonably well-organized system of medicine, known as ayurveda, which is several centuries old, thus the direction for the restructuring of indigenous medicine foreseeable and projectable.[1015] Indeed the need to

1014 Ray, Prafulla Chandra (1932), *Life and Experiences of a Bengali Chemist*, Calcutta: Chuckerverthy Chatterjee & Co.
1015 Ibid

organise a pharmaceutical industry which was self reliant was at the forefront of government agenda. Consequently in 1919, the Bengal Community was established; it consisted of a group of leading physicians and scientists who came together with the aim of attaining medical self sufficiency in India. By 1939 when WWII began, indigenous firms produced approximately 13 percent of the medical requirement of India.[1016] By a remarkable turn of events by the end of the war in 1945 indigenous firms were producing 70 percent of the country's pharmaceutical needs.[1017] The reason for this was remarkable; the war had diverted the attention of MNC from importing medicines into India, [1018] The India pharmaceutical industry was therefore given a chance to set up its own local firms to respond to their own medical needs and this enabled them to become self-sufficient. New indigenous pharmaceutical companies such as the Indian Process Chemical Laboratory, Unichem and IndoPharma were established.[1019] Also worth noting is the fact that indigenous firms also revived the use of ayurvedic drugs which, in effect, enlarged the range of drugs available to modern doctors. Many of these drugs such as Kalmegh and sarpaganadha (used to suppress high blood pressure) are still used today.[1020]

By 1947 when India gained its independence it had to a large extent become self-sufficient, indeed it sought to take full control of it drug expenditure and set about this setting up several law commissions. These law commissions has the task of proposing legal reforms to realize national objectives. High on the list of legal reforms were efforts to improve "the standard of living of the people by efficient exploitation of the resources of the country", which

1016 Pharmaceutical Enquiry Committee (1954), Report of the Pharmaceutical Enquiry Committee, New Delhi: Government of India, Ministry of Commerce and Industry. S.L. Bhatia was the chairman of the Committee
1017 Ibid
1018 Ibid
1019 Ibid -Chaudhuri pg 24
1020 Ibid

included the traditional systems of medicines.[1021] Between 1948 and 1950, the Tek Chand Committee also known as the (Patent Enquiry Committee) was set up. The committee was quick in noting that MNCs had been given wide powers under the old patent systems. The system allowed all inventions made by any "manner of manufacture" to be patentable,[1022] and this enabled owners of vague patent provisions being granted patent rights beyond the scope of their invention.[1023] The Tek Chand Committee was also instrumental in recommending the incorporation of compulsory licensing into India Patent laws. Note that by 1950, the law was amended but it made no substantial changes in the realm of providing access to medicines for the Indian population.[1024]

8.7.1 India's National Drug Policy

The first Indian national drug policy 1978 emerged from the Hathi Committee recommendations which was set up in 1975 to investigate the connection between MNCs and indigenous pharmaceutical companies.[1025] The main objectives of the Hathi report were to strengthen R&D activities in the country, issue licenses for the formulation of only 117 essential drugs that were essential for the treatment of diseases which were prevalent in India. The Hathi report also suggested the dissemination of drug information to both prescribers and consumers, the development of self-reliance in drug technology, reduction in the level of importation so as to encourage the development of the domestic sector. Finally the report asserted that in order to ensure that drugs are easily available and accessible at a reasonable price, the State Trading Corporation

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1021 The Planning Commission was set up in March 1950 by a resolution of the Government of India. Planning Comm'n, 1st Five Year Plan intro., available at http://planningcommission.nic.in/plans/planrel/fiveyr/default.html (last visited Jan. 8, 2006) [hereinafter 1st Five Year Plan].

1022 Banerji, S. (2000) *The Indian Intellectual Property Rights Regime and the TRIPs Agreement, in Intellectual Property Rights in Emerging Markets* 47, 57 Clarisa Long ed

1023 Ibid at 66

1024 Ibid

1025 Ministry of Petroleum and chemicals, Report of the Committee on Drugs and Pharmaceutical Industry (Hathi Committee Report), Delhi, 1975

(STC) government must begin a process of importing raw materials, pooling them together and re-distributed them to manufacturers.[1026]

Since then the 1978 Indian National Drug Policy has been revised three times in 1986, 1994 and 2002. What was striking in the Hathi report was that like the Nigerian National drugs policy, the Indian drug policy sought to: ensure the availability of essential life-saving medicines at reasonable prices; strengthen quality control and promote the rational use of drugs; encourage investment in new technologies and cost-effective production; and strengthen the indigenous capacity for production of drugs and most importantly ensure self-reliance. Whilst the characteristics of both national drug policies are similar to many other countries, the fact that Nigeria and India have an almost identical policy makes the case for Nigeria to follow in the footsteps of India if it is become self sufficient and conquer the access to medicine problem.

Self reliance for the Indian pharmaceutical industry was the cornerstone of India's national policy. Thus the government planning commission Third Plan states that "special emphasis has to be placed on industries such as steel, coal, oil, electric power, machine building and chemicals...(as) the development of these industries is an essential condition of self-reliant and self-sustained growth"[1027] The Hathi Committee noted that MNCs "activities (such as finished drugs being imported, marketed and formulation drugs[1028] being imported in bulk[1029]and repackaged locally) were carried on without investing

[1026]P K Sarkar.(Accessed 12 June 2007) *A Rational Drug Policy.* Indian Journal of Medical Ethics. http://www.issuesinmedicalethics.org/121di011.html

[1027] Third Five Year Plan, New Delhi, Planning Commission, Government of India, 1961, p 24

[1028] "formulation" means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include - any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.; any medicine included in the Homeopathic system of medicine; and any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

[1029]" Bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards

in factories or employing technical personnel'.[1030] By pointing out specific concerns that the Indian pharmaceutical industry was facing in becoming self-reliant was crucial and made the difference in whether concrete actions would be taken in the future to ensure that the national drug policy was implemented or not.

One of the most significant points that the Hathi Committee recommended was that foreign drug companies should not be given any preferential treatment under the Foreign Exchange Regulation Act 1973 (FERA) and Industrial Licensing Policy Committee of February 1973 (ILPIC). Under FERA, all corporate bodies with 40% or less of foreign holdings were considered indigenous bodies. The Hathi Committee believed that reducing foreign equity in companies in India to 26% foreign equity would be reduced. One of the examples that the Haiti Committee cited in support of its recommendation was, where if a company owns 10% or more in foreign equity, they are considered foreign. Likewise in Canada if a foreign company owns more than 5% in foreign equity it is considered foreign.[1031]

India was clever enough in discerning that foreign MNC were only interested in marketing formulations under brand names in order to maximise profits as opposed to the production of the less profitable bulk drugs.[1032] Thus before India become self reliant, 80% of total formulations drugs such as antibiotics, vitamins, antirheumatics, analgesics and cough syrups were being sold by MNCs and hardly any bulk medicines including Tetracycline and Aspirin were being sold by foreign MNC was evidence of this

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specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;

[1030] Ministry of Petroleum and chemicals, Report of the Committee on Drugs and Pharmaceutical Industry (Hathi Committee Report), Delhi, 1975. P87.

[1031] Benjamin Cohen, Multinationals and Asian Exports, New Haven, 1975, p 9

[1032] Ibid

India's experience with MNCs is useful in establishing why Nigeria has never been able to attain self sufficiency in the pharmaceutical industry. India introduced industrial policy restrictions which required MNCs to accelerate their activities. The policy required that unless bulk drugs are produced in specified quantity, MNC could not expand their activities in formulations. What later appeared evident was that MNC were willing to undertake production in India when they found it profitable to take advantage of India's low costs and outsourcing their global requirement of off patent drugs.[1033] Nigeria on the other hand has never sought to take the kind of drastic actions that the Indian has taken, the fact that the Indian pharmaceutical industry is the 4th largest producer of medicines in the world in terms of volume is testament of the hard work and dedication that successive governments have placed in ensuring that medicines is a priority for its population of 1 billion people.[1034]

8.7.2 Disadvantages of the Indian Indigenous Firms pre-1970 and How they were Overcome

The pharmaceutical indigenous firms in the India had initially operated at a disadvantage in the sense that the advent of colonialism brought about the denigration of traditional systems of medicines in India. A Drugs Enquiry Committee had been set up in 1931 and the report noted that because the British controlled trade, they could obtain a superior variety of medical plants at cheaper prices to be exported back to Europe, whilst the indigenous firms were left with the inferior ones for local production.[1035] Restrictions were placed on the movement of domestically produced spirituous preparations between one province to another, however imported spirituous preparations

[1033] Chaudhuri. S (2006) *THE WTO and India's Pharmaceutical Industry. Patent Protection, TRIPS, and Developing Countries.* Oxford University Press
[1034] Srividhya Ragavan. *The In equals of Uruguay.* University of Oklahoma College of Law. http://jay.law.ou.edu/faculty/sragavan/Docs/PPT%20Folders/Inequals%20of%20Uruguay.ppt m
1035 Drugs Enquiry Committee (1931), Report of the Drugs Enquiry Committee, 1930-1931 Calcutta: Government of India.

could be distributed anywhere in India once the custom duty was paid at the point of entry.[1036]

The Indian government took the important step of setting up the Ayyanger Committee which was named after Justice Rajagopala Ayyangar, head the committee in 1957. Between 1957and 1959, the Ayyangar Committee also known as the Committee on the Revision of the Patents Law was set up. The findings and reports of the committee were useful in laying down the foundations of the Indian Patent Act 1970. The Committee proposed that India should diverge away from incompatible patent policies of industrialized nations.[1037] The Committee also affirmed that a patent regime is an unconditional requirement to facilitate and advance industrialization, as long as it is designed "with special reference to the economic conditions of the country, the state of its scientific and technological advance, its future needs and other relevant factors." [1038] The report is significant for the following reasons: firstly the report led to the improvement and growth of the pharmaceutical industry in India and set the stage for making India's pharmaceutical industry one of the strongest generic providers today

Secondly the Ayyangar report resounded one of the core national goals of the Indian Constitution which can be found in Article 21 which guarantees the right to life including the right to good health,[1039] and social and economic rights.[1040] Thirdly the Ayyangar report was revolutionary because it recognized that public health concerns need to be balanced with business interests. Fourthly the Ayyangar Committee specifically examined issues that are were later discussed during the TRIPS negotiation such as whether patenting food,

1036 See Indian Bare Acts: THE SPIRITUOUS PREPARATIONS (INTER-STATE TRADE AND COMMERCE) CONTROL ACT, 1955.
1037 N. Rajagopala Ayyangar, Report on the Revision of the Patents Law P 8 (1959)
1038 Ibid
1039 Indian Constitution, art 21
1040 Indian Constitution Pmbl.

chemical, and pharmaceutical inventions will affect developing countries ability to gain access to such products; and whether compulsory licensing can enable accessibility while at the same time promoting innovation.[1041] The Ayyanger report not only made significant recommendations but was a premonition of the many the challenges that the Indian indigenous pharmaceutical industry would have to overcome in order to become self sufficient.

The Ayyangar Report argued that a patent policy giving absolute monopoly power to MNC would deny majority of the Indian population access to medicines.[1042] What made the Ayyangar Report innovative was that it advocated the adoption of a patent regime with an intense logic of accomplishing national goals.[1043] The report concluded that giving unregulated monopoly rights went against the right to good health guaranteed under the Indian Constitution;[1044] and concluded that the development of a local pharmaceutical industry in India was the only way that India could compete with MNC whilst meeting their local needs.[1045]

8.7.3 Product Patents and not Process Patents

The Ayyanger Committee favoured a ban on process patent because it believed that granting product patents to food and pharmaceuticals would prevent majority of the population access to the vital products and contravene the constitutional right that Indians have to life and good health. [1046] In order to support their logic the committee examined the historic evolution of patents

1041 N. Rajagopala Ayyangar, Report on the Revision of the Patents Law P 8 (1959) [hereinafter Ayyangar Report].
1042 Banerji, S (2000) *The Indian Intellectual Property Rights Regime and the TRIPs Agreement, in Intellectual Property Rights in Emerging Market*s 47, 57 .Clarisa Long Ed at 69
1043 Ayyangar Report
1044 Krishna, V. R (2002) *Patent Law-Patently Unfair*?, The Hindu, at Opinion Section
1045 Ibid
1046 Banerji,. S (2000) *The Indian Intellectual Property Regime and the TRIPs Agreement, in Intellectual Property Rights in Emerging Markets* 63 Clarissa Long ed.

on chemicals and foods in other developed countries. The Ayyanger committee recommended that India draw on examples of how other industrialised countries has developed their own pharmaceutical industries, citing the example of the German patent Law of 1877. The German patent law of 1877 prohibited product patent for chemicals in other to develop its pharmaceutical industry and stimulate research, and in less than 30 years the chemical industry had grown to be self-sufficient.[1047] Similarly the French Law of 1844 prohibited the patenting of products for food and medicine, although other chemical products could be patented. The Belgium Patent Law of 1854 employed the French style and as a matter of fact Italy, Spain, Sweden and Japan excluded patent on medical products and were all able to develop its pharmaceutical industry.[1048]

The Ayyangar Committee noted that "such important articles of daily use such as medicine or food which are vital to the health of the country should be made available to everyone at reasonable prices."[1049] The Ayyangar Committee therefore suggested that product patents should not be granted in critical areas like food and medicines. It recommended that exclusive rights to the process of production would accelerate research in developing alternative processes. Thus the committee also asserted that process protection could lead to increased diversity of products at competitive price.[1050]

Subsequently, the Ayyangar Committee sought to redress the problem of foreigners not working their inventions locally with Compulsory license.[1051] It recommended that the government should maintain the right to revoke

1047 Ayyangar Report
1048 Ibid
1049 The Ayyangar Committee discusses the Sargant Report and § 38A of England's Patents and Designs Amendment Act of 1919, which marked an introduction to restrictions on patent protection for food and to process patenting. Section 38B(2) introduced compulsory licensing of patents relating to food substances
1050 Ibid
1051 Ibid pt. V.

patents whenever they are not worked locally and issue compulsorily license for patents when the patent owners decline to license them. [1052] The committee based its assessment on the works of Sir Walterscheid, who stated that Queen Elizabeth I made an effort "to stimulate domestic production of both raw materials and a wide variety of manufactured goods previously imported from abroad" by granting patents.[1053] The history and development of British patents and the model of compulsory licensing was important in the recommendations of the Ayyangar Committee.[1054]

In the case of Britain, the Ayyangar Committee was able to observe that compulsory licensing has been an important concept in the development of intellectual property rights in England. India should therefore follow the same direction if it wanted to observe the same progress in its development. Ayyanger therefore pointed out that “though the U.K. has been one of the major industrial countries of the post-war world, she clings with tenacity to the provisions regarding compulsory working." [1055] The Committee noted that, compared to the policies of the United Kingdom between 1907 and 1919, India remained underdeveloped even in 1947, thus justifying the need to include compulsory licensing provisions.[1056] Thus compulsory licenses have been historically seen as an option in promoting industrialization in many developed countries. The Ayyangar report was relevant in the way that it sought to replicate how developed countries had succeeded in developing their pharmaceutical industry

1052 Ibid p.125. Impartial arbitrators will decide what royalties are payable for such licenses.
1053 Ibid at 1261 (quoting Edward C. Walterscheid, The Early Evolution of the United States Patent Law: Antecedents (Part 2), 76 J. Pat. & Trademark Off. Soc'y 849, 855 (1994)).
[1054] See Chapter 3 for a more detailed analysis of this
1055 Ibid P. 133
1056 Ibid P 135

8.7.4 Indian Patent Act 1970

The Indian Patent Act, 1970 is crucial for a variety of reasons; firstly it abolished product patents on drugs and in so doing removed the monopoly power of MNCs in India; secondly it allowed indigenous pharmaceutical companies to produce patented drugs, thirdly it granted patents to inventor for a limited period of time, giving them monopoly rights and allowing them to exclude of others from using their invention, and fourthly it served as an imperative tool in developing and preserving the generic competence of the country. Interestingly the initiative of the process regime that was epitomised in the 1970 Patent Act was borne back in 1959. The key objectives of the Act were to boost the domestic development of pharmaceuticals at the expense of foreign corporations which enabled the pharmaceutical industry to become self-reliant. The 1970 Patent Act also sought to put in place a variety of protectionist measures: to assist the development of an independent Indian pharmaceutical industry; to make new pharmaceuticals cheaply available to the Indian public; to encourage local process development followed by bulk pharmaceutical production; to reverse the negative pharmaceutical balance of payments by stimulating exports; and to encourage original pharmaceutical R&D in India.[1057]

The creation of a process patent pharmaceutical regime in the Patent Act 1970 excluded patent protection of the final product. This was an important development because it meant that a MNC inventing a new drug could only patent the process of manufacturing the new drug and not the final product[1058] [1059] In order words only one method or process best known to the patentee

1057 Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450 (1979) India is not a signatory to the Paris Convention. However, under § 135 of the Patents Act, India recognizes the priority date of the matter disclosed in the application prosecuted originally in a convention country. Section 135 also requires that the patentee file an application in India within twelve months of a PCT application.

[1058] For the provisions, see The Patents Act, 1970 (New Delhi, Ministry of Law and Justice and Company Affairs, Government of India) See section 5 & 8 of the Act.

1059 The Patents Act of 1970 reads as follows:

could be patented.[1060] Another important feature of the 1970 Act that came into effect in 1972 was its special provision on drugs and foods manufactured under chemical processes. The life of the drug and food patents was reduced from 16 years to five years from the date of sealing OR reduced to 7 years from the date of filling complete specification, whichever one came first.[1061] For all other patents the limit was set for a period of 16 year.

The significance of the 1970 Act was that it ensured that indigenous manufacturers were able to manufacture new drugs immediately if they could use an old process of manufacture or new process that was not mentioned by the Patentee. The ingenious companies were thereby free to reverse-engineer medicines. This resulted in sometimes the same products being produced by several manufacturers who could each hold a patent for different processes of a patent. [1062] [1063]

Section 87 of the Patent Act 1970 was significant in the sense that it liberated the Indian pharmaceutical industry and drove it into becoming more self-reliant. Section 87 of the Act stated that process patents for the manufacture of food, medicine, drug, and chemical had to be endorsed with the "license of

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(1) In the case of inventions-
a. claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
b. relating to substances prepared or produced by chemical processes
(including alloys, optical glass, semi-conductors and inter-metallic compounds),
no patent shall be granted in respect of claims for the substance themselves,
but claims for the methods or processes of manufacture shall be patentable.
Patents Act of 1970 § 5.

[1060] Borkar S.K (1974) *Patent Act 1970 and its Effect on the Drug Industry in the Country'*, IDMA Annual Publication, Bombay: Indian Drug Manufacturers Association.

[1061] Chaudhuri. S (2006)The *WTO and India's Pharmaceutical Industry. Patent Protection, TRIPS, and Developing Countries*. Oxford University Press

1062 Ragavan, S (2006) *Of the Inequals of the Uruguay Round*. Marquette Intellectual Property Law Re view, Vol. 10. No 2

1063 The process patent provisions contravene the product patent regime envisioned under TRIPs, which stipulates that Members shall ensure patent protection "for any inventions, whether product or processes, in all fields of technology." Article 27 of TRIPs requires member countries to establish a product patent regime. Hence, the process patent provisions contravene Article 27.

right" after three years from the grant of a patent.[1064] What this meant was that even before the three year from the date of sealing expires, the Controller of Patent had the power to grant a compulsory license and fix the rate of royalty if he thought it was "necessary or expedient in the public interest", see section 86 of the Patent Act 1970.[1065] These "licenses of right" were issued on the same terms as a compulsory license. The only difference is that it was the government responsibility to request the licenses of right as opposed to third parties. Compulsory licenses and licenses of right were significant in the way that they enabled other parties to gain a manufacturing license without the patentee's consent.[1066] The Indian government found the usage of these licenses efficient in enabling them intervene if the patents were not worked to the benefit of the indigenous people.[1067] This had very far reaching implications, because after the Patent Act 1970 was passed anyone could ask for a compulsory license and be granted one.

The 1970 Patent law also imposed artificially low royalty ceiling on compulsory licenses. Under section 88, the maximum payment of royalties for license under the Act was set at 4 percent of the ex-factory sales; this was much lower than those of other countries. For example the United Kingdom fixed a maximum limit of 40 percent, whilst the US does not even have a maximum limit.[1068] The Patent Act also required tests on innovative drugs to be carried out in the public domain. Local indigenous companies could then use the information to produce their own medicines thereby avoiding costly expensive clinical trials. All the indigenous companies had to prove to the Director General of Health Services was that the medicines in question were the bioequivalent; this automatically entitled him to register the pharmaceutical

1064 Section 87(1)
1065 Section 97 of the Patent Act 1970
1066 Section 88 of the PATENT ACT 1970
1067 Article 27(1) of TRIPS stipulates that patent rights shall be enjoyed "without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced."
1068 Redwood. H (1994) *NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEUTICAL PATENT PROTECTION* 17

as generic.[1069] Of course many indigenous companies took advantage of the liberal environment and explored various processes for manufacturing drugs to the great disappointment of many MNC.

The Indian Patent Act began the revolution of developing the Indian pharmaceutical industry which has enabled the country provide medicines for over 70% of its population. Despite this extraordinary achievement, some critics have argued that the policies initiated in the 1970s and 1980s to regulate MNC have been withdrawn since the 1990's. Industrial licensing has now been abolished for all bulk and formulation medicines. Other reversal of polices include the fact that all production of drugs are now open to the public and private sector, and more importantly MNC are permitted to have 100% foreign equity.[1070] Indeed critics have consequently argued that the gains of the Patent Act has been further reversed by the advent of the TRIPS Agreement in 1995 and the coming into force of the Agreement in developing countries in 2005 which forced India to provide patents for both process and products if it is was to comply with the TRIPS Agreement.[1071]

8.8 Nigeria's Patent and Design Act 1970

Ironically the same year that India passed its revolutionary Patent Act, Nigeria enacted its Patent and Design Act into law and published as chapter 344 of the Laws of the Federation of Nigeria 1990. Unlike the Indian Patent Act 1970, the Patent and Design Act made no significant progress to the pharmaceutical landscape in Nigeria, neither did it alleviate the public health crisis facing the country.[1072]

Under the Act, a patent could be granted for a product or process for a period of 20 years on condition that the annual renewal fees is paid for the duration of

1069 Ibid
[1070] Working Group of Drugs and Pharmaceuticals 2001, p. 60
1071 The Patents (Amendment) Act, § 5, Acts of Parliament, 2005 (India).
[1072] Cap 334 Law of the Federation of Nigeria, 1990. Hereinafter called "the Act".

the patent. The important thing to note about the act is that it does not exclude from patentability innovative pharmaceutical products or processes. Indeed Chapter 344 (2) (c) "states that an invention is capable of industrial application if it can be manufactured or used in any kind of industry, including agriculture", and can therefore be patented'. Interestingly the Patent and Design Act does not guarantee that a patent granted to a patent holder is valid, thus Section 4(4) of the Act provides that "Patents are granted at the risk of the patentee and without guarantee of their validity". In my opinion this provision went a long way in revealing the uncertainty of the times with regards to the validity of national policies and legislations. The Patent and Designs Act was therefore not aimed at promoting R&D, nor was it aimed at making the pharmaceutical industry self-reliant. Some commentators have blamed the uncertainty of the time on the presence of military regimes in Nigeria.

Nigeria has had a very troubled history of military regimes since it gained its independence from Britain in 1960. Beginning in 1966, Nigeria has had eight military regimes succeeded, which was interspersed between the fourth and fifth military regime by a return to civilian rule with the Second Republic between October 1979 and December, 1983. The final military regime left power on May 29, 1999. Critics have also argued that some of the provisions in the Patent and Design Act 1970 were lifted from the English patent law and applied to the Patent and Design Act without judging whether it would promote the Nigerian industrial climate or not.

Another provision in the Patent and Designs Act 1970 that is disturbing is the fact that section 1(1)(b) of the Patent and designs Act 1970 states that an invention will still be patentable if it is an improvement on an already patented invention. This section clearly does not leave any scope for boost the domestic development of pharmaceuticals. Indeed the Patent and Design Act had no protectionist policies that would have assist the development of an independent

Nigerian pharmaceutical industry, encouraged local process development or encouraged original pharmaceutical R&D in the country.[1073]

Schedule 1 of the Patent and Design Act deals with compulsory licenses, and makes provisions for the non-working of patents. It gives statutory rights to the Nigerian government to authorise the use of patents for the service of government agencies.[1074] The provisions state that four years after the filling of a patent application or at the least three years after a patent is granted, an application for compulsory licence can be made to the High Court of Lagos State and granted.[1075] The provision stipulates that the court can issue a compulsory licence if the following criteria are met. Firstly the applicant must prove that the patented invention though capable of being worked in Nigeria has not been worked, secondly the applicant must prove that the working of the patented invention in Nigeria is insufficient to meet the local demand for the patented product; thirdly the applicant must prove that the importation of the patented product is preventing the local working of the patent and fourthly the applicant will have to prove that the patentee has refused to grant licences on reasonable grounds and this has adversely affected the development of commerce in Nigeria. When compared to the Indian Patent Act 1970, the criteria that had to be proved before a compulsory license can be granted appear to be very cumbersome, if not near impossible for individuals or small business to prove. Nevertheless it is important to note that no compulsory license was ever issued under the Patent and Design Act.

Although the Patent and Design Act 1970 is still the authority on patents in Nigeria today, Nigeria was supposed to have amended its intellectual property

1073 Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450 (1979) India is not a signatory to the Paris Convention. However, under § 135 of the Patents Act, India recognizes the priority date of the matter disclosed in the application prosecuted originally in a convention country. Section 135 also requires that the patentee file an application in India within twelve months of a PCT application.

1074 S.K date-Bah. (1981) Transfer of technology to Nigeria and the Patent and Designs Act 1970. Journal of African Law, vol. 25, No. 2.

1075 See s.1 of Schedule 1.

laws by 1 January 2005 to conform to the TRIPS Agreement in the same way that India has done, but January 2005 passed with no legislation emerging from the National Assembly.[1076]

In 1991, the Nigerian Law Reform Commission took on the task of amending the Patent and Design Act. It recommended extensive amendments to the existing patent law and modifications to the administration of the IP laws in general. On the strength of those recommendations, a draft decree on Industrial Property (including patents) known as the Industrial Property Decree[1077] was drafted. Incidentally, this draft was never enacted into law.

The Nigerian Law Reform Commission draft is nevertheless important for a variety of reasons, it reveals the direction that the law makers intend on taking in their bid to promote intellectual properties as well as whether they intend to create a climate which will encourage innovation and R&D. With regards to the access to medicines debate both the 1970 Act and 1991 Draft can be said to be inadequate for three reasons, firstly they both failed to lay strong emphasis on enacting laws that would promote public health in the face of the HIV/AIDS epidemic and other opportunistic diseases, secondly both laws do not take advantage of the flexibilities available within the TRIPS Agreement, namely compulsory license and parallel importation; and thirdly are not aimed at fostering the growth of the pharmaceutical industry.

In 2002, the Minister of Commerce inaugurated the Intellectual Property Commission to establish a legal framework to harmonise and amend Nigerian's Intellectual Property rights laws and bring it up to date with the TRIPS Agreement, however by January 2009 no new intellectual property laws has been enacted. Indeed many lawyers I spoke to in Nigeria said they did not know of any intellectual property Commission and if it existed it did not

[1076] Cap 334 Law of the Federation of Nigeria, 1990. Hereinafter called "the Act".
[1077] Industrial Property Decree No. 10 of 1991.

have an office. Regardless of the foregoing the bottom-line remains that The Patent and Design Act 1970 is out-dated and should be considered obsolete. It does not promote R&D in the country, it practically offers no protection to the patent holder, the compulsory licenses and parallel importation clauses in the Act are impracticable and unfavourable to the Nigerian government, it does not encourage the pharmaceutical industry to grow and does not comply with the TRIPS Agreement

9 CONCLUSION AND RECOMMENDATIONS: WAY FORWARD FOR NIGERIA

The Federal Government of Nigeria has a lot of grounds to cover in the quest for access to medicine for its citizens; nevertheless one of the factors that become clear in this research is that the TRIPS Agreement cannot be blamed entirely for the lack of access to medicines in many developing countries. Indeed Nigeria can take advantage of the flexibilities of compulsory licenses and parallel importation in the TRIPS Agreement to ensure that it gains access to medicines in the short and long term.

Whilst the high prices of medicines which is one of the effects of the TRIPS Agreement contributes to the exorbitant prices of some medicines, other factors remain equally important to rectify before the problem of access to medicines can be resolved. Nigeria should seek to put in place infrastructure, electricity, good transportation systems, technical assistance to existing laboratories and guidance on setting up new laboratories for improved medical/ scientific research and diagnosis and ensure that the most vulnerable people in society such as women, children and PLWHA are protected by the law. One of the ways of ensuring that that such people are protected is by equipping these people with education and ensuring that these people know their rights as citizens of the Federal Republic of Nigeria.

Nigeria should therefore initiate and reaffirm policies and national laws that will protect the fundamental human rights of its citizens and in so doing ensure that ordinary people have access to the most basic primary health care.

Another key issue that became clear in this thesis was the fact that access to medicine cannot be achieved substantially by over-dependence on expensive foreign pharmaceutical drugs that are out of reach for most people

suffering from diseases like HIV/AIDS. Indeed what became obvious was that access to medicine for Nigerians can be enhanced when local pharmaceutical industry, traditional medicine, healthcare, and national infrastructure are developed and improved.

Nigeria should therefore seek to gain access to medicines by acknowledging that the TRIPS Agreement has an important part to play in the social fabric of the nation and that due process of law can be followed to achieve the quest. It is with the foregoing that the following legal frameworks and policies are r recommended as the way forward for Nigeria to improve access medicine for the people:

Nigeria should seek to become TRIPS compliant as soon as is possible by amending its outdated patent laws.

The new patent legislation should contain a clause that protects pharmaceutical products as well as limiting patent protection to new chemical entities. The legislation should also limit the scope of patentable products to avoid frivolous or ambiguous claims and evergreening.

The new patent legislation should ensure that it permits generic manufacturers who are already producing generic new drugs can continue to do so uninterruptedly. The legislation should also ensure that it does not put in place unnecessary legal requirements that will end up deterring local companies that may be interested in producing generic medicines.

The new patent legislature should ensure that it incorporates the flexibilities available in the TRIPS Agreement into the new law. Flexibilities such as compulsory licences and parallel importation can facilitate local production of generic drugs and promote FDI.

The Nigerian government should also ensure that it sets up a patent office for the registration of patent applications apart from the Nigerian Industrial Property Offices which presently does not have a website or an office.

The government should seek to make the pharmaceutical industry more self-reliant. The Nigerian government should adopt national policies that promote R&D into NCEs. This will include tax cuts, custom duty exemptions and other government incentives for bringing new drugs and medicines unto the market.

The pharmaceutical industry should also be encouraged to develop its manufacturing capacity in generic medicines and ensure that it perfects the act to reverse engineering of medicines when the patent on them expires.

The Nigeria government should tackle the problem of lack of electricity, telephone, water, and transport as a matter of urgency in order to encourage FDI and ensure that indigenous companies are able to operate their factories and engage in R&D.

The fight against counterfeit trade through NAFDAC should be continued and sustained with the enactment a new law criminalising trading in counterfeit drugs in Nigeria in order to deter criminals from selling fake drugs.

Indeed the quest for access to medicines is a complex issue that requires a multi-sectotal approach. Nevertheless I have attempted to show that whilst the TRIPS Agreement can always be put at the forefront of the access to medicines debate, the Nigerian government will be more successful in tackling the problem and saving lives if it focuses on enacting laws that will enable the country to have a focus on intellectual property laws which will go a long way in ensuring that the search for access to medicines is attained.

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