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**THE TRIPS AGREEMENT AND ITS
IMPLICATIONS FOR PUBLIC HEALTH IN
DEVELOPING COUNTRIES: A CRITIQUE**

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Dedication

TO MY DAUGHTER

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**AT A TENDER AGE OF THREE YOU ARE MY
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TO GO ON.**

I LOVE YOU SO MUCH!

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Abbreviations

ACP	African Caribbean Pacific Countries
EC	European Community
EU	European Union
GATT	General Agreement on Tariffs and Trade
IPRS	Intellectual Property Rights
IP	Intellectual Property
NGO	Non Governmental Organisation
R&D	Research and Development
TRIPS	Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organisation
WTO	World Trade Organisation
WIPO	World Intellectual Property Organisation
US/USA	United States of America
UK	United Kingdom

1 Introduction

Intellectual property rights have gone global with states around the world converging upon the same or presumably the same set of intellectual property standards in areas of law such as copyright, patents, trademarks and industrial designs.¹ The globalisation of intellectual property rights has seen access to information and products made more costly and difficult. This means that development based on access to public goods using strategies of free riding and diffusion has been circumscribed. The popular conception of patent systems that inventions change the world for the better is precisely the same conception held by many companies especially pharmaceutical companies and this they claim, is fundamental to the way the drugs of modern medicine are discovered and developed.² But questions are asked as to who benefits from the patent system and who pays the costs of such a system and further are these costs justifiable?

The adoption of the TRIPS Agreement in 1995 as an integral part of the Agreement Establishing of the World Trade Organisation has been described as a milestone in the history of intellectual property because the TRIPS Agreement is ‘the most comprehensive international legal instrument on intellectual property rights’.³ It embodies provisions of earlier instruments on intellectual property like the Berne Convention on the protection of Copyright and Related Rights and the Paris Convention on the protection of Industrial Property. It was thought that its successful adoption sorted out all the problems of intellectual property rights protection, but in reality, the situation is different. The TRIPS Agreement has been criticised by many scholars and activists championing the call for access to cheap medicines and have called it a barrier to access to life saving drugs.⁴ This criticism finds support in the fact that people in developing countries have problems in accessing drugs for the rampant HIV/AIDS pandemic and also for other communicable diseases like malaria and tuberculosis. Due to exclusive intellectual property rights, the drugs are rendered too expensive and well beyond the reach of most people in these countries. This is compounded by the ever-escalating poverty levels.

Although the TRIPS Agreement has made provision⁵ of how essential drugs could be accessed by those in developing countries, there are still some unanswered questions relating to the implementation of the said provisions. These questions have stirred up serious discussions on the global level leading to serious antagonism between developed and developing countries.

¹ Peter Drahos and Ruth Mayne, **Global Intellectual Property Rights: knowledge, Access and Development**, Palgrave Macmillan, 2002. See article by Peter Drahos page 1.

² Ibid page 13 article by Stuart Macdonald.

³ WIPO, **WIPO Intellectual Property Handbook**, Geneva, 2001.

⁴ MSF, **MSF campaign for access to essential drugs**. Available online at <http://www.accessmed.org.uk>.

⁵ Article 6 parallel imports and article 31 compulsory licensing

Doubt has been cast on “intellectual property and its role as a promoter of development in the area of public health because health is crucial to the survival and welfare of mankind.”⁶ But intellectual property rights especially as promoted in the TRIPS Agreement do not seem to promote the right to health. The question of ensuring that developing countries especially in Africa have access to essential medicines is very crucial now more than ever before because of the HIV/AIDS pandemic and resistance to known cures for other diseases like malaria and tuberculosis. But how can this be achieved when almost all essential medicines exist only under patent protection, which has rendered them too expensive for the poor in developing countries? Some medicines have not been invented since the diseases for which they are intended are in the neglected category affecting only the poorest of our world today and which diseases have seen no real investment into research for an effective cure? For the World Trade Organisation and indeed the whole international community through the United Nations, access to essential medicines has become a test of the ability for the multilateral system to respond to a proven and urgent need.

The turn of the century has seen desperate efforts being made by developing countries to improve access to affordable drugs to treat infectious diseases like malaria, tuberculosis and HIV/AIDS, which are killing people on a daily basis. Malaria has been identified as a deadly killer in Africa affecting all age groups including expectant mothers.⁷ The HIV/AIDS infection rate for example is beyond acceptable levels especially when it appears in combination with other communicable diseases.⁸ The situation in developed countries has been controlled, but for developing countries especially in Africa, the situation has spun out of control causing desperation. It must be noted that the prevalence of these diseases continues to inhibit economic development and thus perpetuates poverty. On the international level, institutions such as the WHO and programmes such as the Global Fund to fight AIDS, Malaria, and Tuberculosis and the Roll Back Malaria Venture are already in place for the control of such diseases, but the question that comes to mind then is how can this be effectively used to ensure that it delivers what it promises and who are the major players?

The 21st century is an age of sustainable development and its realisation cannot be divorced from good health. The right to health as enshrined in the

⁶ WIPO, **Intellectual Property and Human Rights**, Geneva, 1998. Page 65 article by Silvia Salazar.

⁷ Ninety percent of deaths due to malaria occur in Africa south of the Sahara mostly among children. Malaria kills an African child every 30 seconds ... Pregnant women and their unborn children are also particularly vulnerable to malaria, which is a major cause of perinatal mortality, low birth weight and maternal anaemia. Source: 2001-2010 United Nations Decade to Roll Back Malaria. www.rbm.who.int

⁸ In Southern African countries the infection rate is as high as 20% of the population. In 2001, Botswana had an infection rate of 38.8%, Swaziland 33.4%, Zimbabwe 33.7%. Source joint United Nations Programme on HIV/AIDS, Report of Global HIV/AIDS epidemic 124 of 2000.

Covenant on Economic Social and Cultural Rights⁹ implores states to provide an adequate standard of health for the citizens. States are called upon to respect, protect and fulfil the right to health. Multilateral Agreements from the 1986 Uruguay Round to the 2001 Doha Declaration on Public Health are all efforts towards realisation of the right to health. However, it must be mentioned here that these efforts are not complete as there are some unfinished business still to be discussed. There are issues of how people in developing countries can have access to essential medicines and also how research and development in diseases such as malaria and tuberculosis can be encouraged.

Adoption of the Doha Declaration in 2001 was seen as a huge step forward in the fight for access to essential drugs. However, problems of implementation have arisen in relation to use of compulsory licensing by developing countries. Gaps have been identified in the TRIPS Agreement and the Doha Declaration and what remains is how to fill them and are the parties willing to do so? What are the arguments for and against the system? It must be remembered that even as we tackle the issue of access to drugs, most developing countries do not have manufacturing capacities to be able to benefit from the compulsory licensing system.

People in developing countries continue to live in abject poverty with no access to basic necessities of life such as clean water, shelter, clothing and healthcare. When talking about pharmaceutical industry involvement in the provision of healthcare, the issues of patents and profits arise and the major obstacle to be overcome is how to balance the equation: maximum profit and provision of healthcare. It has been argued that “few investments are wiser than those in good health. Investments in health can make a major contribution to poverty reduction and economic growth: countries with high levels of good health grow faster”.¹⁰ This statement holds true and it is hoped that it could be a reality for Africa as well and the time is now.

There is an urgent need to reach an agreement on how to tackle this problem of ensuring availability of functioning health care systems for all. But who is responsible for this and how is it to be implemented? During my research, I came to the conclusion that this problem cannot be solved without the active participation of developed countries but especially of the US, the pharmaceutical industry 80% of which is in the US and the developing countries themselves. The history of the TRIPS Agreement has revealed the major roles played by the US government and the pharmaceutical industry in its adoption and therefore an effective solution can only be found with their active participation. However, as will be seen in this thesis, the US is the most unwilling player to find a lasting solution to the problem. This is seen in the manner in which it opposes the inclusion of flexibilities in the TRIPS Agreement to allow developing countries access to essential medicines. This is also evident in how the US has gone back on its word

⁹ Article 12 Covenant on Economic Social and Cultural rights, 1966.

¹⁰ The European Community Development Policy paper (2000) 212 of 26.4.2000.

regarding the implementation of the Doha Development Agenda.¹¹ The TRIPS Agreement was born out of coercion and it remains to be seen whether sovereign states are still willing to be coerced into blindly accepting proposals by one country. The Cancun meeting flopped as a result of the realisation by developing countries that without being united, they will always be pushed into accepting unworkable solutions, which only favour the US and other developed countries.

The main objective for my thesis therefore is to analyse the extent to which the TRIPS Agreement ‘actually’ protects public health in developing countries. Central to this analysis is a critical discussion of the options available to developing countries in terms of access to pharmaceuticals. I will also look at the attitudes of WTO members and the pharmaceutical industry towards public health in developing countries. This aspect will focus on discussing the conflict between maximum profit on one hand and public policy oriented perspectives or the needs of society on the other hand with the aim of striking a balance between the two. This thesis will also test the commitment of WTO Members to the realisation of their obligations under the TRIPS Agreement. In addition the thesis will look at what problems, if any, arise from compliance or failure to comply by developing countries with multilateral agreement regulations.

THESIS OUTLINE

With that in mind, the thesis has been structured in such a way that **chapter one** deals with the history of the intellectual property system from the early stages of patents to the controversial TRIPS Agreement highlighting both the advantages and disadvantages of patent systems for developing countries especially. **Chapter two** has been devoted to discussing the relationship between the TRIPS Agreement and public health. Central to this discussion has been the post TRIPS developments notably the 2001 Doha Declaration on TRIPS and Public Health. The chapter has further discussed the legal options available to developing countries under the TRIPS Agreement and the Doha Declaration on access to cheap pharmaceuticals. This chapter has also looked at the controversy that arose between South Africa and the Pharmaceutical industry relating to use of these legal options to access cheap antiretroviral drugs.

Chapter three has been devoted to discussing one of the problems arising in the use of compulsory licensing by developing countries that do not have manufacturing capabilities. This problem was identified by trade ministers at Doha and a solution is still being sought for it. The chapter has made a detailed discussion of the proposals by the major players of how this problem could be solved bringing out the pros and cons for each proposal.

¹¹ MSF, **As US balks on medicine deal, African patients feel the pain**, article by Roger Thurow and Scott Miller staff reporters of the Wall Street Journal. Available online at <http://www.msf.org/page.cfm?articleid=D61D0B7-FDB8-45E1-ADE7D308F7A96F3> information accessed on 05-06-03

In the final analysis, **chapter four** has been devoted to discussing the TRIPS Agreement and the two visions in conflict with each other, that is to say maximum profit on one hand and public policy oriented perspectives on the other. The aim here was to find a balance between these two opposing claims of rights. In conclusion, **chapter five** has tried to reconcile the issues identified within this study and made recommendations for the future.

RESEARCH METHODOLOGY

This thesis has heavily relied on research conducted at the RWI library using Text Books and the Internet. It has also been informed by WIPO publications donated to me by the organisation through Professor Mpazi Sinjela. Furthermore, in order to have a clear insight into the subject, I undertook study tours, collected useful information and further conducted interviews with various people dealing with infectious disease control in Zambia. At the National Malaria Control Centre (NMCC) based at Chainama Training Institute in Lusaka, I talked to the National Malaria Control Coordinator Dr. John Chimumbwa, the Health Promotions Specialist Mr. George Sikazwe and a Pharmacist as well as Consultant Mr. Caesar Mudondo. I also visited the Zambia Integrated Health Programme (ZIHP) where I spoke to Dr. Mubiana especially on the issue of patents for essential drugs. In addition to this, I visited and collected some information from the Tropical Disease Research Centre based in Ndola. I also had the privilege of attending several meetings on the Roll Back Malaria programme including the Southern Africa malaria Control (SAMC) conference hosted by Zambia from the 21st to the 25th of July 2003 at the Pamodzi Hotel in Lusaka where I had the privilege of meeting various people from the region.

As for the methodology itself, I used mostly the ‘road-map’ theory, which allowed concurrent use of theory testing and theory building. The reason why I used this method is because the thesis is based on previous findings while remaining open to new information and discoveries. This has enabled me to investigate the nature of the problem and to develop relevant knowledge and practical understanding of how the problem could be tackled leading to ways of how the problem could finally be solved.

2 HISTORICAL DEVELOPMENT OF INTELLECTUAL PROPERTY RIGHTS

2.1 What is intellectual property

Property is a bundle of exclusive rights in an object and anything is capable of being owned as long as it is possible to prevent others from using it. Property is both tangible and intangible. Intellectual property therefore is an incorporeal private property, which has creativity, innovation and market distinctness of certain kind as its subject matter. Simply stated, intellectual property means “the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields”.¹² Intellectual Property is divided into two main branches being industrial property and copyright. Industrial property is the branch that seeks to protect the legal rights through patents for inventions, trademarks for brand identity and designs for shapes while copyright comprises literary and artistic works. For purposes of this paper, particular attention will be paid to patents for pharmaceuticals.

2.2 What is a patent?¹³

A patent is a grant issued by the government conferring the exclusive right to make, use or sell an invention for a period of time generally 20 years counted from the date of filing of the patent. It is a contract between the state and the inventor whereby the latter agrees to disclose and publicise his invention to the society in return for state assurance of protection. In this way, a patent is said to perform two functions; as an inducement to the inventor on one hand and as an essential factor in scientific and technological progress on the other.¹⁴ It must be noted that in today’s global economy, most scientists engaging in research and development in various fields are doing so because of good patent protection systems, which guarantee to them exclusive rights to work and develop the inventions.

Most companies in the world today are relying on immovable products of the human mind to compete favourably. As noted above patents are rights granted by the state and until such a grant and recognition by the state, patent rights do not legally come into being. In the grant of patent rights, it is important that a balance is struck between private and public interests, that is to say the rights of the inventor in terms of rewards for patented goods on one hand and the rights of the general public in terms of access to

¹² WIPO, **WIPO Intellectual Property Handbook**, Geneva, 2001. Page 3.

¹³ Patents have been one of the most hotly debated topics on access to essential medicine since the creation of the WTO and the conclusion of the TRIPS Agreement in 1994. Dr Bernard Pecoul of MSF Campaign for Access to Essential Medicine says that “patents are not god-given rights. They are tools invented to benefit society as a whole, not to line the pockets of a handful of multinational pharmaceutical companies”.

¹⁴ WIPO, **Intellectual property and human rights**, Geneva, 1998. Page 68.

patented products on the other. “Getting the balance right is very important for governments of developing countries as they work to protect public health while making their patent laws TRIPS compliant.”¹⁵ The process of granting patents is regulated by legislation in all the countries in the world. Most patent offices require that an inventor clearly describe the invention in detail so that ‘a technical person with average skill in that area of specialisation is able to carry out the process by following the instructions.’¹⁶ It is also important that as patents are granted, their validity is subjected to scrutiny. ‘Most developing country patent laws are modelled on developed country systems, but the practice of contesting the validity of patents has not been established whereas in developed countries patents are usually challenged.’¹⁷

2.2.1 Criteria for patentability

In order to be patentable, an invention must meet three universally accepted requirements or criteria being firstly, the invention must be *novel* meaning that it must not have been previously known to the public within a given area and further it must not have been anticipated anywhere in the world. There are two types of novelty namely relative for the former situation and universal for the latter. Universal novelty is the international norm currently in use. Secondly, the invention must be *non-obvious* that is to say; it must contain sufficient innovativeness to merit protection. An invention is considered as involving an inventive step if it is not obvious to a person skilled in the art. Thirdly the invention must be *industrially applicable or useful*.¹⁸ The reason for having inventions is to have practical solutions to problems being experienced in industry on a daily basis and as such an invention must be useful to the extent of making life easier for those that it is intended for.

2.2.2 Characteristics of Patents

Patents can be granted for all types of processes and products including but not limited to chemicals, drugs, plastics and engines for as long as they meet the above criteria. There are basically four generally accepted characteristics for patents. The first one is *territoriality*. Legislation in various jurisdictions lays down the specific requirements to be fulfilled for grant of patents. This necessarily means that patents are only valid within certain territories upon successful filing. The second characteristic is *duration*. It must be mentioned here that patents are of temporary validity

¹⁵ Medecins Sans Frontier, MSF Campaign for Access to Essential Medicines, Drug Patents under spotlight. Page 2. Available at <http://www.msf.org/content/page.cfm?>

¹⁶ WIPO, 1998 supra note 6 page 69.

¹⁷ MSF, supra note 4

¹⁸ United Nations, **Intellectual Property Rights and Foreign Direct Investment**, New York, 1993. Page 5. See also WIPO, **WIPO Intellectual Property Handbook: Policy Law and Use**, Geneva, 2001. Pp 17-20

because they are limited in time and vary from one invention to the other. Currently, 20 years seems to be generally acceptable. After the expiration of the patent period, the invention falls in the public domain and can be used by anyone. Thirdly, patent rights are also *transferable*, meaning that a patentee can upon following laid down procedure and publicising the issue for the security of third parties, lawfully transfer his/her patent rights in an invention. The fourth and last characteristic is that patent rights are *exclusive* in nature. This means that a patentee is allowed freedom to work his/her invention to the exclusion of all others for the period of the patent both within a given territory and also internationally.¹⁹

2.3 What are the justifications for the grant of patents?

It has been argued that patents encourage investments in research and development by providing investors with security that they will be entitled to some part of the flow of benefits that come from any new technology.²⁰ Patent systems have a long history and have developed as a way to promote innovation by either importation of new technologies into a country or by making new inventions. There are basically four theories to justify the existence of intellectual property rights. These are the moral (labour) theory, the personality theory, utilitarian theory²¹ and the exchange for secrets theory.²²

2.3.1 Moral (Labour) Theory

This theory stems from John Locke who argued that “every man has property in his own person”.²³ From this Locke deduced that whatever a man removes out of the state that nature has provided and mixes with his labour becomes his property.²⁴ In this line of thinking, intellectual property would seem to follow naturally since the individual must surely be permitted the fruits of his mental as well as his physical labour.

2.3.2 Personality theory

Personality theory is derived from the assumption that an individual’s personality is intrinsically linked to his thoughts and ideas as they are

¹⁹ WIPO 1998 Supra note 6 page 70.

²⁰ Julian Morris, Rosalind Mowatt, W. Duncan Reekie, Richard Tren, **IDEAL MATTER: Globalisation and the Intellectual Property Debate**, Centre for a New Europe, 2002. Page 12.

²¹ Palmer, T, **Are Patents and Copyright Morally Justified?: The Philosophy of Property Rights and Ideal Objects**, Harvard J. Law and Public Policy 13(3), 1990, page 817.

²² Anthony D’Amato and Doris Estelle Long, **International Intellectual Property Law**, Kluwer Law International, London, The Hague, Boston, 1997. Page 19.

²³ John Locke, **Two Treatises on Local Government**, Cambridge University Press, 1698/1988. Page 287.

²⁴ Ibid page 288.

expressed in external phenomena. Hegel in 1952 in his book entitled “The Philosophy of Right argued that “it is only through the development of his (man’s) own body and mind, essentially through his self-consciousness’s apprehension of itself as free, that he takes possession of himself and becomes his own property and no one else’s”.²⁵ This means that a person must be allowed to enjoy the fruits of his/her labour and because of the personal nature of the investment such fruits are only identifiable with the maker or creator. This is also called private property.

2.3.3 Utilitarian theory

Utilitarian theory assumes that the objective of society should be the attainment of the greatest good for the greatest number of people.²⁶ This is the principle employed by many economists where the outcome of any policy is evaluated in terms of its overall impact on the wealth of society taking into account any externalities that may pertain. This theory is not prescriptive with respect to desirability of IP but rather it calls for empirical evaluation of costs and benefits arising from particular forms of IP.²⁷ “In particular, the benefits of stimulating innovation, creativity and reputation building must be weighed against the costs of patent races, monopolistic pricing and innovation suppression.”²⁸

2.3.4 The exchange for secrets theory

This theory presumes a bargain between an inventor and the society whereby the inventor surrenders the possession of secret knowledge in exchange for the protection of a temporary exclusivity in its industrial use. This is based on the presumption that industrial progress is desirable but can only be achieved if inventors reveal their secrets. This theory also tries to prevent over investment by companies in trade secrets to protect their inventions. “ In order to avoid the social waste that would come from over-investing in trade secrets, the exchange for secrets theory says that patent protection is an economically efficient alternative.”²⁹

²⁵ Ibid page 838.

²⁶ Julian Morris, Supra Note 20 page 19.

²⁷ Ibid

²⁸ Ibid

²⁹ Anthony D’Amato, supra note 22 page 19.

2.4 The Development of the Global Intellectual Property system from 1474 to 1995

2.4.1 The Territorial Period

The development of the Patent system in Britain can be traced back to 1449 when a patent was granted to a Flemish glassmaker for a method of making stained glass windows³⁰. But however, the first conscious acknowledgement of patents was in 1474 in Venice when patents were by law granted “with the objective of stimulating great and ingenious men ... to discover and build devices which are very useful and advantageous”.³¹ During the 16th Century, English Monarchs, having discovered that the sale of monopoly privileges was very lucrative, granted patents on an indefinite basis regardless of whether or not they were novel. This had the effect of raising prices for all commodities on patents such that it became imperative to revoke some patents and limit the period for others. After this period, the British patent system basically developed through judicial interpretation and there was no deliberate effort made towards regulation. An important judicial innovation at this time was that the patentee had to describe in writing the nature of the invention and the manner in which it was to be performed.³²

In the Americas, the framers of the US constitution saw the promotion of technological development as essential to the wealth of the new Republic and as such included a provision in the 1787 Federal Constitution giving congress a right “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries”.³³ In 1790, the Patent Act was elaborated further and specified that new inventions could be granted patents for a term of 14 years as long as the invention was novel and useful.

2.4.2 The International Period

The territorial period was dominated by the principle of territoriality, which is that intellectual property rights did not extend beyond a given territory.³⁴ As states continued to interact with each other, it became important for them to have some international co-operation of some kind. This manifested itself through various bilateral agreements whereby works by nationals of one country could be protected in another country based on certain rules. Further due to the emergency of the problem of free riding, the United Kingdom

³⁰ Julian Morris, Supra note 20, page 12

³¹ Ibid. Venetian Decree of 1474.

³² Patent office 2000: Five Hundred Years of Patents, UK Patent and Trademark Office: also found at <http://www.patent.gov.uk/patent/history/fivehundred/index.html>

³³ Article 1 section 8.8 1787 US Federal Constitution.

³⁴ WIPO 1998 supra note 6 page 16.

whose artists were most affected started negotiating bilateral treaties with other states to protect the works. The USA on the other hand being leaders³⁵ in piracy did not bother much about such agreements and therefore remained isolated.

In order to solve the piracy problem, the UK passed legislation which embodied the principle of reciprocity. This meant that foreign works could only be protected in the UK if the relevant states agreed to protect UK works. As a result of this many bilateral agreements were concluded between the UK and other European states.³⁶ The USA engaged in the idea of national protectionism where only works by its own citizens and residents could be protected and no foreign works were ever protected in that country³⁷. All this activity was in the area of copyright. Industrial property was not left out, some parts of it notably trade marks became subjects of bilateral agreements working on the principle of national treatment. This meant that states recognised the importance of not discriminating between works of nationals and foreigners in the regulation of intellectual property. States were therefore able to secure protection for works of their nationals in foreign countries.

2.4.3 The Global Period

The 19th Century saw a lot of activity as far as patents are concerned. There was recognition by many states that an international framework for the regulation of intellectual property was desirable. Action had to be taken and one such move was the adoption of the Paris Convention for the Protection of Industrial Property in 1883. Before this time, 'it was difficult if not impossible to obtain protection for industrial inventions in various countries because of differences between the systems operated by the countries. In 1873, there was to be held an international exhibition of inventions in Vienna upon invitation by the government of the Austria-Hungary Empire. The US and a few other countries were not happy with the level of legal protection for the inventions at the fair. The US was worried that many of the inventions would benefit the Austrian public without due return to the inventors.'³⁸ This outcry led to a number of meetings and conferences to discuss ways of bringing about an international understanding on patent protection. The result of these was the Paris Convention, which in 1883, was signed by 11 countries. The number has risen over the years and also the Convention has been revised several times.

³⁵ Every work written by a popular author is almost co-instantaneously reprinted in large numbers both in France, Germany and in America. Taken from the Hansard (1837). Cited in WIPO, Intellectual Property and human rights, 1998. Page 16

³⁶ WIPO, supra note 6 page 17.

³⁷ Ibid

³⁸ WIPO Intellectual Property Handbook, 2001 page 241

The Paris convention established the principles of national treatment, the right of priority and special agreement.³⁹ The Paris Convention was an outgrowth of a period of globalisation when the grant of patents in many countries was seen as a desirable solution to recover the costs of investments. With increased international trade in the current period of globalisation, attempts have been made to solve some problems through international harmonisation of patent laws. It must be mentioned here that the US had a big role to play during the run up to the creation and adoption of the Paris convention because unlike in issues of copyright where they were leaders in piracy, the US citizens and companies were directly affected by inadequate legal protection for inventions. Because it favoured them, the US government fought hard to have some legal framework of an international nature in place.

2.5 The History of the TRIPS Agreement

The international period tolerated a lot of free-riding basically because there was no enforcement mechanism in place.⁴⁰ As such in the area of copyright the US who were not even members of the Berne Convention took advantage to free ride on other people's work. However in industrial property many US companies especially in the area of pharmaceuticals relied heavily on returns from their inventions and therefore the lax system of protection did not favour their operations. "For pharmaceutical companies like Pfizer, intellectual property was an investment issue. They wanted to be able to locate production anywhere in the world safe in the knowledge that their intellectual property would be protected."⁴¹

Ideas then to link intellectual property to trade started to float among various groups including lawyers and business enterprises. The result was that in the 1980s the US reformed its trade laws directed at countries whom the US thought had weak intellectual property systems. The amendment in 1984 of the US Trade Act included intellectual property in the section 301 trade process. This was further strengthened by the inclusion of more section 301 processes.⁴² The US has used these provisions in its trade relations and countries caught up in these arrangements face economic trade sanctions for failing to provide intellectual property protection to the level

³⁹ National Treatment means that member states must grant the same protection to nationals of the other member states as it grants to its own nationals. Right of Priority means upon filing an application for a patent, a person has up to 12 months within which to file similar applications in other countries members of the Paris Convention. Special Agreements refers to a situation where two or more countries can enter into an agreement to apply only to them but in compliance with the Convention.

⁴⁰ The only enforcement mechanism under the various intellectual property treaties were appeals to the International Court of Justice and most countries had made reservations to the clause.

⁴¹ WIPO Intellectual Property and Human Rights 1998, supra note 6 page 20

⁴² The 1984 Trade Act amendment authorised the US government to take retaliatory action against countries failing to give adequate protection to intellectual property and this was done through the 'regular 301', special 301, and super 301 processes.

required by the US. The section 301 process was conducted in such a way that it covered many companies in several countries doing business with the US companies and so surveillance was effectively done. There were specific rules and objectives formed by the Office of the United States Trade Representative (USTR) to be followed by the countries and no country was immune from the section 301 process.⁴³

However, this was not the end of the story. The problems in intellectual property faced by the US during the 1980s were global in nature. Although there was an international framework to regulate intellectual property, the US chose to push the issue of intellectual property in the Uruguay Round of Trade Negotiations. There were various reasons for this but most convincing of them is that the US was beginning to lose power in the world economy. The loss of competitiveness combined with losses like the Vietnam War all started to ring a different bell in many minds, the loss of US power to strong competitors.⁴⁴ US Companies were worried about loss of profits due to the piracy of their inventions and products. The booming businesses in Asia and Japan begun to bring confusion in the US business arena. However, many countries were not sympathetic to the US situation when it faced a massive free rider problem maybe because of US action in the area of copyright.

Therefore the US had to find a way out and action had to be taken immediately. The US “chose to solve its problem through forging a link between the international trade regime and the development and enforcement of intellectual property standards.”⁴⁵ This was essentially because the bilateral and unilateral efforts using trade tools only provided a short-term answer for improving intellectual property protection abroad. In order to ensure its efforts were not in vain the US formed the Advisory Committee for Trade Negotiations, which had the task of providing direct input by the US business sector into US trade policy. Basically the US was trying to use coercion to achieve its global protectionist paradigm and it initially sought to do this through the 301 processes⁴⁶. The plan was that once the US had a number of countries supporting its idea at a bilateral level there would be little resistance at the multilateral level, and in fact there were also worries by many countries that resistance to US proposals at the trade negotiations could trigger the 301 processes. The US therefore sailed through with its proposals although not so easily⁴⁷ and re-established its position in the world economy.

⁴³ Section 301 process had three important categories namely priority foreign country, priority watch list and the watch list. A country on any of these lists is in constant communication with the US Administration until it conforms to the laid down standards.

⁴⁴ Peter Drahos, **Intellectual Property**, Ashgate, 1999. Page 420.

⁴⁵ Ibid page 421

⁴⁶ Ibid

⁴⁷ While the US under the umbrella of 301 had a great deal of success in negotiating satisfactory outcomes it was “a slow and painful process”. Interview with Michael Keplinger, US negotiator at TRIPS 27 October 1993 in Washington. Quoted in Peter Drahos page 425.

2.6 The Uruguay Round of Trade Negotiations

At the GATT, the US was more prepared than any other country to negotiate the TRIPS Agreement. The US had done a lot of hard work in trying to establish its position in the world economy and was therefore at an advantage. It is the only country that sent experienced trade negotiators with expertise in intellectual property. It is said that “the GATT is a place where deals are traded freely and not a place where deals about free trade are made.”⁴⁸ And the US having mastered the system of deal making was at an advantage. The US and US business community pushed their intellectual property objectives using all possible agents to the highest level and they succeeded. The Uruguay Round of Multilateral trade negotiations held under the framework of the GATT was concluded on 15th December 1993 with the establishment of the world Trade Organisation which was formally adopted on 15th April 1994 in Marrakech. For the first time in the history of the development of intellectual property, the negotiations included intellectual property rights relating to international trade and the result of these negotiations was the Agreement on Trade Related Aspects of Intellectual Property Rights (The TRIPS Agreement) and is binding on all WTO member countries. More than one hundred countries signed the final Act and there is no way in which a country wishing to side-step the TRIPS Agreement could do so since it is an annex to the WTO.⁴⁹

2.7 Developing Countries at the GATT Negotiations

The purpose of the TRIPS Agreement is to eliminate distortions in international trade relating to intellectual property rights.⁵⁰ However at the GATT far from reducing these distortions, industrialised nations like the US pushing the agenda for intellectual property had a clear objective of universalising the standards of protection worldwide. Developing countries negotiated the TRIPS Agreement with the hope that with increased standards of intellectual property protection, they will have access to industrialised nation markets for their textiles and agricultural products and also they would benefit from technology transfer. Furthermore the US strategy of coercion using the section 301 process was in play during the negotiations and ‘developing countries that attempted to organise resistance to several aspects found themselves subject to the process.’⁵¹ In the belief that little resistance to accepting the TRIPS Agreement might cause some restraint on the US in the use of the 301 processes, many developing countries reluctantly negotiated increased standards of protection for

⁴⁸ Ibid page 426

⁴⁹ WIPO, Intellectual Property and Human Rights, 1998 page 21.

⁵⁰ The preamble to the TRIPS Agreement commences with a statement of desire by member states ‘to reduce distortions and impediments to international trade and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade’

⁵¹ Peter Drahos, supra note 44. Page 427

intellectual property rights and further acquiesced in making important concessions in terms of reform of their intellectual property legislation. It is said that ‘members of the WTO agreed to a common set of international rules against a background of long running bilateral pressure on selected developing countries to strengthen patent laws. Now all members are expected to implement new laws that look very much like those in the US and Europe.’⁵²

However ‘developing countries had realised long before the adoption of the TRIPS Agreement that pharmaceutical patents would mean increased prices for drugs, an increase in profits and payments for companies abroad and also a greater penetration of markets by foreign firms’.⁵³ As such for a long time developing countries refused to negotiate patent protection for pharmaceuticals⁵⁴, but however it became impossible politically to stall the negotiations and therefore the TRIPS Agreement came into being. The agenda at the GATT was quite broad and allowed for a give and take situation for all countries. Developing countries also hoped that with the dispute settlement mechanism under the WTO, there would be great restraint on the US in its use of the 301 processes and coercion. However, the US has continued using threats in its trade relations.

2.8 What is TRIPS Agreement?

The TRIPS Agreement is the most comprehensive international legal instrument on intellectual property rights. It embodies provisions of some earlier instruments like the Berne Convention of 1971, the Paris Convention of 1967, the Rome Convention of 1961, the Treaty on Intellectual Property in Respect of Integrated Circuits of 1989, the General Agreement on Tariffs and Trade of 1994 and the WTO Dispute Settlement Understanding also of 1994. Under this agreement member states are obliged to provide patent protection with respect to both pharmaceutical products and processes whereas under the Paris Convention, members could exclude certain products from patent protection.⁵⁵ Member countries are further required to be TRIPS compliant irrespective of their level of development, needs and priorities.⁵⁶ The TRIPS Agreement has changed the way states conducted issues of intellectual property under international conventions whereby they took up obligations to the extent they wished to be bound. “Cherry picking

⁵² Jean O. Lanjouw, **Intellectual Property and the Availability of Pharmaceuticals in Poor Countries**, Centre for Global Development working paper No. 5, April 2002.

Available online at <http://www.cgdev.org/wp/cgd-wp005.pdf>

⁵³ Report of an ASEAN workshop on the TRIPS Agreement and its impact on Pharmaceuticals, Jakarta, May 2-4, 2001, page 11. Available online at www.who.or.id/currentevents/Drugs

⁵⁴ Views of developing countries ranged from uneasy acceptance to outright rejection and in fact the potential effect of the new regime on health in these countries raises active concern elsewhere. See Jean O. Lanjouw. Supra note 52.

⁵⁵ The 1970 Indian patents Act allowed only process patents for pharmaceuticals and not product patents. Note 1 page 293

⁵⁶ WIPO Intellectual Property Handbook, 2001 Supra note 12 page 293

previously enjoyed by member states has been replaced by a packaged deal and it is either a member takes it in its entirety or leaves it.⁵⁷ States are unable to side step the TRIPS Agreement because it is an integral part of the WTO Agreement and binds all member states. It entered into force on 1st January 1995.

2.9 Transitional Arrangements under the TRIPS Agreement

Members states of the WTO have been given grace periods after entry into force of the Agreement establishing the WTO to apply the TRIPS Agreement.⁵⁸ In relation to patents, the TRIPS Agreement provides that patents shall be available for products and processes in all fields of technology provided they are new, involve an inventive step and are capable of industrial application.⁵⁹ However, member countries may exclude or prevent the commercial exploitation within their territories of certain inventions in order to protect public safety including human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because it is prohibited by law.⁶⁰

This provision means that member countries cannot legislate or amend their own laws to prevent patents in the fields enumerated above. This seems to be a contradiction in terms because an act found to be contrary to public order or safety must be outlawed so that it is never practised. The situation as it exists now begs the question then of how and who determines public safety especially when this applies to developing countries in the area of access to pharmaceuticals. It seems to be that developing countries are obliged to follow the rules and standards obtaining in developed countries whether these are workable or not. Article 27 and 70.8 on patents for pharmaceuticals are quite controversial. They essentially oblige member states of the WTO to provide patent protection for pharmaceuticals for a mandatory period of 20 years. It must be noted that people in developing countries are in urgent need of access to cheap pharmaceuticals to treat infectious diseases like malaria, tuberculosis and HIV/AIDS. As such an obligation to provide patent protection for the essential drugs for such a long period of time could be said to be against public order and safety because it restricts access.

⁵⁷ Ibid

⁵⁸ Developed countries were generally required to be TRIPS compliant by January 1, 1996 (article 65.1); developing countries in the process of transformation into free market economies by January 1 2000 (article 65.2 and article 65.3); developing countries obliged to extend product patent protection to types of products not previously patentable in those countries by January 1, 2005 and least developed countries by January 1, 2006 extendable upon motivated request (article 66.1)

⁵⁹ Article 27.1, TRIPS Agreement, 1995.

⁶⁰ Article 27.2

It must be noted however, that the political decision to be bound by the TRIPS Agreement has already been made and what remains now is for countries especially developing ones to make the most out of it. This can be done by for instance taking advantage of the legal options available to developing countries on access to pharmaceuticals as will be discussed later in chapter two of this paper.

2.10 The Politics of patent monopoly: Arguments for and against patent monopoly

Among the many publicly acclaimed advantages for the grant of patents are firstly the promotion of innovation by either encouraging the importation of new technologies into the country or by making new inventions. Secondly, adopting a patent system is supposed to encourage investment of resources in making inventions. Research and Development for new medicines and in particular the progress in modern western medicine is often cited as a good example. It is said that patent protection has three main advantages being to encourage more foreign direct investment, to promote transfer of technology and encourage local research and development.⁶¹ However, R&D into medicines for neglected diseases like malaria is an example of the exact opposite of this claim. For neglected diseases also known as diseases for the poor, a patent holder cannot make high profits by charging high prices and so little R&D is conducted on these diseases.⁶²

‘Developed countries have always argued that increased levels of intellectual property protection in developing countries has the potential of producing both short and long term benefits for those countries in terms of encouraging technology transfer and investment, stimulating local innovation, encouraging domestic investment in local technology-based industries and also promoting exports by opening markets.’⁶³ However, developing countries have not seen these benefits and as a result of opening markets, developing countries are flooded with products from developed countries most of which are beyond their means and sometimes tend to be so cheap as to stifle local production.

It is worth mentioning here that patent systems have evolved and continue to evolve in line with a given country’s economic and industrial progress. This actually qualifies the assertion that industrial property is a tool for economic and industrial development. Depending on how it is handled and managed, industrial property is capable of influencing the entire

⁶¹ WIPO, **Post graduate Specialisation Course on Intellectual Property, collection of papers**, Turin, Italy, 2001. Page 293-294

⁶² Medecins Sans Frontieres and the drugs for neglected diseases working group, **Fatal imbalance- The crisis in Research and Development for Drugs for Neglected Diseases**, Geneva, September 2002.

⁶³ Frederick Abbott, Thomas Cottier and Francis Gurry, **The international intellectual property system: commentary and materials, part one**, Kluwer Law International, The Hague. London. Boston, 1999. page 7 note 16.

development of a country in which it is applied. Countries in the western world have been designing their patent laws according to their specific levels of development and needs. Patent protection for pharmaceuticals in industrialised nations was not an automatic or overnight event. It is said that “once they had achieved a certain level of development of their pharmaceutical industries, the developed countries amended their legislation to include patent protection for pharmaceuticals.”⁶⁴ The current trend of global patent protection or universal patent rules is not following this traditional way of doing things and has met with opposition especially from developing and least developed countries.

Patent monopoly has the immediate negative effect of raising prices for patented goods and one can understand why the patenting of pharmaceutical products is such a hot issue on the discussion table worldwide but especially in developing countries. Patents for pharmaceutical products touch on a very sensitive issue of life and the right to health. This is more important and crucial now than ever before due to the HIV/AIDS pandemic. People in developing countries feel the pinch from high prices for drugs to treat communicable diseases. On the other hand, the chemical and pharmaceutical industry depends to a very large extent on very expensive research and development to produce new inventions and hence the need to have patent protection so that the inventors are allowed to reap some benefits. This is especially so because these pharmaceutical products can easily be copied. It is also said that ‘the patentability of pharmaceutical products provides an incentive for the pharmaceutical industry to engage in creative efforts since there is assurance that the originator can reap some financial rewards from their efforts’.⁶⁵

As noted above patent monopoly has the tendency of raising prices for patented goods. This may be bad for the moment but when analysed from the point of view of encouraging innovation, patent monopoly is a useful tool for economic and social development. When we talk about patents for pharmaceuticals, it must always be remembered that although the prices for essential medicines now seems such a terrible obstacle for poor people, patent protection guarantees quality of the products and as such promotes the health of the end consumers. The puzzle to be solved is what happens to those that cannot afford expensive patented products especially medicine? How can the equation between profit and right to health be balanced?

2.11 Problems arising from strict implementation of TRIPS

⁶⁴ WIPO Intellectual Property and Human Rights, 1998, Supra note 6 page 71.

⁶⁵ WIPO Intellectual Property Law Handbook, Supra note 12 page 300.

Patent monopoly at all times means high prices for protected commodities. This is acceptable if the price is only an inconvenience and one has an option. But when it relates to health, the situation is different; it becomes a matter of life and death. Accordingly, it is quite crucial that careful decisions are made to distinguish what should or should not be patented. Before the coming into force of the TRIPS Agreement, states had a leeway to decide the subject matter for patents and what was to be patented varied from time to time depending on a country's stage of development.⁶⁶ "The patenting of essential goods such as medicines and foods was for a long time thought to be self-evidently against public interest and indeed, in 1986 when the Uruguay Round WTO trade negotiations were launched, more than 50 countries were not granting patents on pharmaceutical."⁶⁷

In developed countries, extensive pharmaceutical patent protection and high drug prices have not yielded a health crisis this far because the majority of the population can afford to pay either on their own or through insurance schemes and other public services. The situation is different in developing countries where people have to pay for drugs from their own pockets and lack health insurance schemes. Excessive prices for essential drugs become a question of life and death. The pharmaceutical industry has argued time and again that "without patents, there will be no new medicines".⁶⁸ This argument does not hold true because the poor nations of the world for instance in Africa accounts for about 1% of the world's medicine market. This means that if no patents were ever granted in Africa and the pharmaceutical industry makes no sales, their profits will not be affected in any meaningful way because they in fact depend on OECD markets for income generation. It is therefore not true that lack of R&D in malaria for example is because of lack of patent protection, instead it is because the drugs are meant for those unable to pay for them. In other words, there is no profit and the market is not as good as the one for drugs for other diseases like HIV/Aids.

Patent protection must have as its guiding principle the need to serve the public interest. Therefore, looking at the TRIPS Agreement, it seems clear that there is need for varying standards to apply to developed and developing nations. There is increasing consensus that the benefits of intellectual property depend on a country's level of development and also a growing concern that the one-size fits all approach of the TRIPS Agreement is damaging for poor countries. For the moment it is correct to conclude that developing countries are being asked to implement an unworkable system which will only perpetuate the suffering of the people. Because of the differences in the levels of economic and technological development, uniform rules as established by the TRIPS Agreement cannot work and the whole intellectual property system risks becoming a circus. It is important

⁶⁶ Op cit

⁶⁷ UNCTAD, The TRIPS Agreement and Developing Countries, New York and Geneva, 1996.

⁶⁸ Ibid

that a country's patent system responds to its public interest and needs. Patents were designed to ensure that the public benefits from innovations, but it is very clear that people in developing countries are currently not getting their part of the patent bargain as profits are being put before public health.

This problem has been exacerbated by the fact that developing countries have not made full use of the options available in the TRIPS Agreement to design patent systems that best correspond to their own needs and development objectives. Many of these countries still have patent laws shaped by the colonial masters and are often through the so-called technical assistance, highly influenced by ideas from developed countries. It is important that governments in developing countries strike a balance between private and public interests as they make their laws TRIPS compliant. The TRIPS Agreement sets out the minimum standards for patent protection that WTO members must abide by. Unlike in the days before the TRIPS Agreement, members cannot rule out granting patents in particular fields of technology.

2.12 TRIPS Agreement criticised

The TRIPS Agreement has received criticisms from various quarters and in a report initiated and published by UNDP, governments have been urged to negotiate the replacement of the WTO Agreement on intellectual property with a system fairer to developing countries. The rules as contained in the TRIPS Agreement especially on patents for drugs are said to be detrimental to the needs and interest of developing countries. In the same report, experts conclude that the relevance of TRIPS is highly questionable for large parts of the developing world. The UNDP report asserts that "countries at low levels of human and technological capability cannot benefit significantly from TRIPS". The authors further say that the experience of developed countries shows that strong patents follow industrial development rather than lead it and suggest that a fairer system would be one of an intellectual property ladder where less strict rules apply to developing countries and these countries are allowed to progress from one level to the next depending on their level of development.⁶⁹ It is my well considered view and understanding that this report is a neat summary of the fears of developing country governments who face a health crisis exacerbated by high prices for drugs and a lack of R&D in diseases like malaria which continue to claim the lives of many people indiscriminately. Rather than set strict rules, WTO member states should instead find a way in which R&D could be encouraged even for diseases not common to the western world.

⁶⁹ Natasha McDowell, **WTO Patent Rules 'should be scrapped'**, *SciDev. Net Articles: articles2.asp?id=260220031632011&t=N&c=1&r=1&hl=WTO%20patent%20rules%2, 27.05.2003.*

2.13 Conclusion

This chapter has focused on discussing the development of the world intellectual property system from the early stages of patents to the controversial TRIPS Agreement. It has brought out some of the advantages and disadvantages of patent monopoly especially as these relate to access to pharmaceuticals. The next chapter will focus on discussing the TRIPS Agreement as the binding international treaty in intellectual property and its relationship to public health. Questions of provision of cheap drugs to developing countries will be dealt with in this chapter.

3 THE TRIPS AGREEMENT AND PUBLIC HEALTH

3.1 Introduction

The previous chapter has traced the development of intellectual property through to the TRIPS Agreement. An attempt has been made to give a critical outlook of the implications of the TRIPS Agreement for developing countries. This chapter looks at the TRIPS Agreement and its implications for public health especially as it relates to access to affordable medicines. The debate on access to pharmaceuticals for developing countries has been the centre of serious controversy in recent years with the realisation that the TRIPS Agreement has some inherent imbalances on access to affordable medicines. But what is the relationship between the agreement and public health and further are developing countries able to use the agreement to their advantage in terms of protecting public health? What are the consequences, if any, of allowing the free use of the options in the TRIPS Agreement? These issues will characterise the discussion in this chapter as we try to discover the relationship between the TRIPS Agreement and public health in developing countries.

3.2 Relationship between TRIPS and Public Health

Intellectual property rights as established by article 7⁷⁰ do not exist in a vacuum nor are they intended to promote only a handful of private rights. They are intended to benefit society as a whole.⁷¹ In the context of pharmaceuticals, if member countries are faced with situations where patents rights for essential drugs are not exercised in compliance with the objectives set out in article 7, they are free to use the legal options available under the TRIPS Agreement, these being compulsory licensing and parallel imports. This view is supported by article 8 which requires member countries to take measures to protect public health and prevent the abuse of IPRS by holders. Abuse of patent rights manifests itself in the form of excessive prices for patented products and further through offering for sale insufficient amounts to meet the public demand.⁷² In this way,

⁷⁰ 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 economic welfare, and to a balance of rights and obligations.

⁷¹ Dr Bernard Pécoul of MSF says that “patents are not god-given rights. They are tools invented to benefit society as a whole, not to line the pockets of a handful of multinational pharmaceutical companies.” MSF Campaign for Access to Essential Medicines. Available online at <http://www.accessmed.msf.org>

⁷² WIPO, **Postgraduate specialisation course on intellectual property, collection of research papers**, Turin, Italy, 2001. Page 309.

pharmaceutical companies create scarcity from abundance and as such take advantage by raising prices to unreasonable levels in most instances.

Although the TRIPS Agreement is in total support of public health, developing countries have faced enormous pressure from the US on the implementation of the Agreement through its continued use of the 301 processes. As such realising the possibility of restrictive interpretation of the agreement, ‘developing countries put forward a joint statement to the TRIPS Council, asking the Doha Ministerial Conference to take steps to ensure that “the TRIPS Agreement does not in any way undermine the legitimate right of WTO members to formulate their own public health policies and implement them by adopting measures to protect public health”.⁷³ Indeed this request was duly incorporated in the Doha Declaration on public health which is discussed hereunder.⁷⁴ Therefore the relationship between the TRIPS Agreement and Public Health is one of trying to balance the needs of patentees on one hand and those of the public on the other.

3.3 The Doha Declaration on TRIPS and public Health, 2001.⁷⁵

The growing international condemnation of the excessive prices for patented drugs finally forced ministers meeting in Doha in November 2001 to address the issue of global patent rules. Interest groups⁷⁶ campaigning against the TRIPS Agreement alleged that global patent regulations would exacerbate the health crisis ravaging poor countries. This is because the TRIPS Agreement obliges all States members of the WTO to grant minimum 20-year patents latest by January 1, 2006 irrespective of their stage of development.⁷⁷ This patent protection system means that pharmaceutical companies are protected from generic competition globally and the result is high prices for essential drugs. This is not good for developing countries because as we have seen in chapter one, the benefits of intellectual property depend on a country’s level of development and an abrupt strengthening of intellectual property protection in developing countries is damaging for these countries.

The Doha Declaration was the result of a text tabled by developing countries at the 4th ministerial conference in Doha, Qatar. The proposal

⁷³ Ibid page 310.

⁷⁴ Paragraph 4 Doha Declaration on the TRIPS Agreement and Public Health, 14th November 2001. WT/MIN(01)/DEC/2. Available online at http://www.wto.org/english/thewto_e/minist_e/min01_e/minded_trips_e.htm. Information accessed on 02-10-03 at 13:26hours

⁷⁵ See Annex I

⁷⁶ Campaigns are usually by NGOS like Médecins San Frontières, Oxfam International and Third World Network,

⁷⁷ WIPO, **Postgraduate specialisation course on intellectual property, collection of research papers**, Turin, Italy, 2001. Page 293.

sought to ensure that the “TRIPS Agreement supported rather than undermined public health.”⁷⁸ These countries face a health crisis especially in the wake of the incurable HIV/Aids pandemic and other communicable diseases like malaria and tuberculosis, which are curable and preventable. The health crisis has been exacerbated by lack of access to essential medicines. The Doha Declaration states in part that “the TRIPS Agreement does not and should not prevent governments from taking measures to protect public health”.⁷⁹ This provision affirms the primacy of public health over intellectual property rights, but does not in any way undermine them. The Declaration further affirmed the rights of governments to use the legal options available in the TRIPS Agreement as discussed hereunder. It also extends the grace period for least developed countries to comply with the TRIPS Agreement by a further 10 years to 2016. It must be noted that the “adoption of this declaration recognised the potential lethal side effects of the TRIPS Agreement and gave teeth to the measures that countries can use to counteract them.”⁸⁰ This is because by further strengthening the legal options available to developing countries, the Doha Declaration has given developing countries a green light to use them without fear of reproach from developed countries. Integrating this declaration into national legislation could bring real improvements in the health sectors of these nations. However, one thing that must be kept in mind is that what is written on paper and agreed to by the parties is not what always happens in practice.

Looking at the history of the TRIPS Agreement as discussed in chapter one, it is expected that the US which has always been uncomfortable with the provisions of the TRIPS Agreement on access to cheap drugs is not happy with the provisions of the Doha Declaration which have the effect of reducing excessive profits by pharmaceutical companies.⁸¹ The Doha Declaration on access to cheap pharmaceuticals has been criticised by many scholars supporting strong IP protection. It has been argued that the health of a nation is fundamentally dependant on creation and maintenance of stable institutions especially of rights to property and freedom of contract.

⁷⁸ Oxfam Briefing Paper, **TRIPS and Public Health: the next battle**. Available online at <http://www.oxfam.org.uk/policy/papers/15trips/15trips.html>. Information accessed on 06-06-03

⁷⁹ Paragraph 4 Doha Declaration, 2001.

⁸⁰ MSF, **Green light to put public health first at WTO Ministerial Conference in Doha**. A joint statement by Medecins Sans Frontieres, Oxfam, Third World Network, consumer Project on Technology, Consumer International and Health Action International. Article dated 14-11-01. Available online at http://www.msf.org/content/page.cfm?ArticleidB0c05D47_6F67_4AD8_AAB653407F91F9C1. Information accessed on 02-10-03 at 3:19pm

⁸¹ Some developing countries have stated that “ever since the end of the Uruguay Round, all countries, developed and developing alike have been racing against time to ensure due compliance at the national level with the provisions of the TRIPS Agreement. However, during the transition period granted to the developing countries, we have seen selective unilateral pressures unleashed against countries that have tried to exercise their legitimate interests in full compliance with the letter and spirit of the Agreement.” Honduras and Dominican Republic, quotation reproduced in WIPO publication at page 310. See note 7 above.

Such that when a state interferes with property rights through actions like compulsory licensing and parallel imports of patented goods, it risks undermining incentives to invest more.⁸² Martin Krause has further argued that strong IP protection in developing countries will lead to technological innovation and foreign direct investment.

This argument may be true in the long term, but there is still the issue of immediate access to affordable medicines. It must be noted that the objective of the promotion of technological innovation and the transfer and dissemination of technology places the protection and enforcement of intellectual property rights in the context of the interests of society because as we have noted above, IPRS do not exist in a vacuum. Such an objective is essential for the promotion of health policies as it encourages the development of domestic production of pharmaceuticals. As such a clear balance between protection of IPRS and public interests must be struck so that the implementation of the TRIPS Agreement is in full compliance with the objectives set forth in article 7; that is to say a balance between the mutual advantage of producers and users of technological knowledge, social and economic welfare and the balance of rights and obligations⁸³ of all the players.

It is important that the flexibilities in the TRIPS Agreement in relation to access to cheap pharmaceuticals are not assessed in a shallow one-sided manner, which focuses only on the issue of profits leaving out the public policy perspectives and the needs of society. Any assessment of these provisions should take into account the fact that global patent rules are being introduced at a time when there is a very huge gap in the technological and industrial development between the developed and developing worlds. Developing countries depend on industrialised nations for the transfer of modern technology and in fact, the benefits of modern science have to be shared if global harmonisation of rules is to work. This is evident even from the grace periods given to developing and least developed countries for becoming TRIPS compliant. It must be noted that intellectual property protection is relatively new in many developing countries especially in Africa and so its implementation is likely to meet several obstacles. The issue becomes very crucial when it comes to health and access to medicine, as this is a problem requiring immediate attention.

The one-size-fits all approach of the TRIPS Agreement has been said to be a disservice to the developing countries for it prevents them from making use

⁸² International Policy Network, **TRIPS and Healthcare: Rethinking the Debate. The Compulsory Licensing Anomaly** Article by Martin Krause. Available online at http://www.policynetwork.net/IPhealth/rethinking_the_debate_0701_krause.htm. Information accessed on 30-09-03 at 13:00 pm.

⁸³ TRIPS: Council Discussion on Access to Medicines: Developing country Group Paper. This is a paper presented by a group of developing countries to the TRIPS Council for special discussion on intellectual property and access to medicines, 20 June 2001. Available online at http://www.wto.org/English/tratop_e/trips_epaper_develop_w296_e.htm Information accessed on 08.10.03

of new technologies to improve their lot. It has been argued that if developed countries had to adhere to the prevailing standards of IP protection during their periods of industrialisation, it is doubtful that many of them would have attained the level of development they have attained. And yet developing countries are being asked to adhere to the minimum conditions set by TRIPS which effectively prevent them from taking the same technology path as the developed countries. Martin Khor concludes therefore that “TRIPS is a protectionist device designed to advance the monopoly privileges of global corporations and also to prevent developing countries from being successful competitors to developed countries.”⁸⁴ In the same way, Correa Carlos concluded that “the strengthening and expansion of IPRS are likely to adversely affect the conditions for access to and use of technology, and thereby the prospects for industrial and technological development in developing countries... Under the TRIPS agreement, reverse engineering and other methods of imitative innovation – that industrialised countries extensively used during their own processes of industrialisation – shall be increasingly restricted, thereby making technological catching-up more difficult than before.”⁸⁵

This writer agrees with this assessment and further states that the TRIPS Agreement is an IPR protective shield for the US Corporations especially pharmaceutical companies seeing that about 80% of the world’s pharmaceutical industry is in the US. This conclusion finds support in the way the US sought to solve its trade problems by creating ‘a marriage of convenience’⁸⁶ through linking intellectual property rights to international trade as discussed in chapter one. Furthermore, the pharmaceutical industry claims to spend so much time and money on R&D for new medicines and as such even as early as 1984, the US recognised the need to have a long patent period in its Patent Restoration Act and stated that “if the United States is to avoid further erosion of its competitive position, a new framework for growth must be envisioned ... in which intellectual property rights are protected and in which investment and innovation are encouraged.”⁸⁷ These were the initial ideas towards making IP a trade issue and thus global protection which manifests itself in the TRIPS Agreement.

Although the Doha Declaration has been strongly criticised as being “one imaginary step forward and two real steps backwards in that although it has addressed the issue of access to pharmaceuticals, it is completely silent on other areas such as agriculture which are equally beneficial to developing

⁸⁴ Peter Drahos and Ruth Mayne, **Global Intellectual Property Rights: knowledge, Access and Development**, Oxfam International, Palgrave, 2002. Article by Martin Khor, page 206.

⁸⁵ Correa Carlos, **Implementing the TRIPS Agreement: General Context and Implications for Developing Countries**, Penang, Third World Network, 2000. Pages 18-19

⁸⁶ Gadbaw, R M, **Intellectual property and International Trade: merger or marriage of convenience?** Vanderbilt journal of Transnational law 22, 2:223-242, page 64.

⁸⁷ Miller W, **Productivity and Competition: A Look at the Pharmaceutical Industry**, Columbia Journal of World Business, 1988. Page 88.

countries”⁸⁸, it is my contention that it is in fact a victory for developing countries because at the time of the Doha Ministerial meeting, the most pressing issue for developing countries was access to pharmaceuticals and these countries got what they wanted. Although the realisation of the right to health is dependant on many aspects, affordable drugs are an important component of it. And in that sense therefore, this legal instrument is a victory for developing countries because now they can use the options without fear of unilateral actions and threats by the US. As will be seen later, South Africa was able to withstand enormous pressure from the US because of the legality of its laws under the TRIPS Agreement and the Doha Declaration has reinforced this.

3.4 Legal Options available to developing countries under the TRIPS Agreement

It is a fact of life that developing countries depend for technological advancement on transfer of technology from developed countries⁸⁹ and also that while strong IPR protection in developed countries may lead to and often does lead to increased profits and more innovation, in developing countries the main effects are felt in terms of the high prices to be paid for protected goods and technologies. This is because developing countries have not yet attained a high level of intellectual property existence. In fact IP protection is quite new in many countries while in developed countries, the concept of protection was only introduced in their legislation after they had attained a high level of industrial development.⁹⁰ That is why during the negotiations leading up to the adoption of the TRIPS Agreement, member countries included provisions which developing countries could use legally especially in the area of access to pharmaceuticals.⁹¹ These provisions encourage price competition and access to protected goods. The legal options open for developing countries to use are parallel importation and compulsory licensing.

3.4.1 Parallel Imports or Grey market

⁸⁸ Julian Morris, Rosalind Mowatt, W. Duncan Reekie and Richard Tren, **IDEAL MATTER: Globalisation and the Intellectual Property Debate**, Centre for a New Europe, 2002. Pages 70-74.

⁸⁹ Developing countries account for only 4% of world research and development expenditure making them depend on industrialised nations for technology transfer. UNDP (1999) Human Development Report, New York.

⁹⁰ See WIPO, Intellectual Property and Human Rights, 2000. Pages 13-34 an article by Peter Drahos.

⁹¹ Article 6 parallel imports and article and 31 on compulsory licensing

Article 6 of the TRIPS Agreement recognises the possibility of legally admitting parallel imports based on the principle of exhaustion of rights.⁹² Parallel imports take place when a product is imported into a country by a third party without the authorisation of the IP title holder or his /her licensees in those cases where the product has been lawfully put on the market anywhere else in the world. The importation by the third party parallels the importation by the IP titleholder or his licensee.⁹³ It must be noted that parallel importation does not refer to importation of illegal or counterfeit products, but to importation of patented goods from the cheapest legitimate international source. Parallel imports can legally be used by developing countries to source cheaper drugs because they have the effect of reducing prices. This is because once patented goods have been sold, the purchaser and those claiming rights under her/him have rights to deal with the product as if it were not patented and exercise all the normal rights of an owner, including the right of resell.⁹⁴ South Africa has used this option to purchase anti retroviral drugs for HIV/Aids patients.⁹⁵

It must be emphasised that parallel imports have been in existence for a long time. In continental Europe for instance, the doctrine of exhaustion of IPRS is not subject to the discretion of the titleholder but is automatic. This is because the inventor is considered as having been fully rewarded through the first sale. In America too, the system is practiced and it is called the ‘first sale doctrine’.⁹⁶ Parallel imports are not a means of free riding on an inventor’s patent rights and remuneration which the patentee has already received with the first sale, but they are a means of ensuring that patents work ‘to the mutual advantage of producers and users of technological knowledge’⁹⁷ in a global economy. In this way apart from reducing prices of patented commodities, parallel imports also serve as an inducement to compete in the globalisation process. Scholars have argued that “ parallel imports reduce prices and encourage foreign title holders to establish themselves locally in order to monitor the market and adjust business strategies to changing conditions.”⁹⁸ In this way, patent holders are able to

⁹² Article 6 states that for purposes of dispute settlement under the TRIPS Agreement, subject to the provisions of articles 3 and 4 nothing in the Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

⁹³ Peter Drahos and Ruth Mayne, **Global Intellectual Property Rights, Knowledge, Access and Development**, Palgrave Macmillan, Oxfam, London, 2002. Page 43.

⁹⁴ Ibid

⁹⁵ MSF Access to Essential Medicines Report, **South Africa: Public Opinion forces ‘Big Pharma’ to back down**, available online at <http://www.msf.org/.../page.cfm?articleid=BA36A296-6D30-4537-97F60157AB82AC8>. Information accessed on 05-06-2003.

⁹⁶ Peter Drahos and Ruth Mayne, Supra note 1 page 44.

⁹⁷ Article 7 of the TRIPS Agreement 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 development, provided that such measures are consistent with the provisions of this Agreement.

⁹⁸ Reichman, J, **Implications of the Draft TRIPS Agreement for Developing countries as competitors in an Integrated World Market**, Geneva, 1993. Page 7.

supply the local market at reasonable cost and earn the much-needed profit. Further, it is my opinion that local initiatives are also likely to develop leading to growth in the relevant industries because the local people will have a chance to learn and imitate the technologies depending on how openly the companies conduct their businesses. It is also hoped that there will be a transfer of technology and foreign direct investment through the local establishment of industries in developing countries.

Parallel imports come in the wake of different prices for the same product by the same patent holder in two or more countries. Parallel imports are of particular importance to the health sector because “pharmaceutical companies generally set different prices for the same medicine throughout the world.”⁹⁹ And as such consumers can shop around for the cheapest source. It is also said that parallel imports prevent market segmentation and price discrimination in international trade¹⁰⁰ leading to harmonisation. The situation is such that if the price is going to be low in one country and another country where the price is too high imports the cheap goods, then the patent holder will be forced to reduce the local price in order to compete with the imported goods and therefore this prevents market segmentation and price discrimination. Price differences are a result of various factors relating to production of particular goods. These factors include differences in inflation rates from one country to another, differences in marketing and sales strategies of patent holders, the general demand for the product to mention but a few. It is often difficult to isolate these factors when analysing price differences.¹⁰¹ But whatever the situation, parallel imports especially in relation to access to pharmaceuticals have the important effect of allowing a large number of people to benefit.

By Article 6 of the TRIPS Agreement, governments are free to incorporate the principle of exhaustion of rights in their national legislation and as such are able to determine the extent to which this principle is applied within the jurisdiction. When prices are too high in the domestic market, the government can decide to import from a cheap source so as to make the product affordable for many people. This action prevents anti-competitive practices by patent holders and further encourages local competition. For developing countries this is a very powerful tool for increasing access to affordable medicine for many people. Furthermore in situations where the local manufacture of a patented drug through the authority of a compulsory licence is not possible, parallel importation is a relevant tool to ensure access to medicine.¹⁰² Although parallel imports are legal and quite useful for countries all over the world, both developed and developing, when it comes to use by developing countries especially in Africa of this principle, the US and the EU are very uncomfortable and claim that parallel imports

⁹⁹ WIPO 2001 Turin supra note 61 page 306.

¹⁰⁰ Ibid

¹⁰¹ Bale, Harvey, E, (1998) the conflict between parallel Trade and Product Access and Innovation: the case of Pharmaceuticals. Found in the Journal of International Economic Law, (1998) at pages 637-653. Oxford University Press.

¹⁰² TRIPS Council Discussion on Access to Medicine, Supra note 83

could undermine ‘differential pricing’ if cheaper goods flow back into developed country markets.¹⁰³

This indeed could be true if the product in question is intended for developing countries only. In such a case there is need for safeguards to be put in place on the international as well as national levels so that the products intended only to benefit the poor do not flow back to developed country markets. If merchants within developed countries were to import back the goods from developing countries, to some extent the profit margins of the patent owners will be affected and this might negatively affect future production. But it must be noted that the scenario is the same if parallel imports take place in developed countries, because the drug is already on offer in that country except much too expensive and an international source is cheaper. Besides even for parallel imports in developed countries, the patent holder will have received his remuneration in the first sale.

For this reason it is this writer’s well considered view that ‘parallel imports’ is not the same as ‘differential pricing’ and the two operate on different levels in the course of trade. As noted above, parallel imports have the potential to reduce ‘price discrimination’ and prevent ‘market segmentation’, but this cannot be said of differential pricing. Differential pricing is when a product is put on the market to benefit only a specified group of people and not the general public and as such before the product is supplied certain safe guards will be in place to protect the interests of the patent holder.¹⁰⁴ Differential pricing could be likened to tiered pricing, a system which sets different prices for specific markets. In that case worries about product re-importation to developed country markets are reasonable. However, the current scenario refers to a situation where the product or in this case the drug is offered cheaply anywhere in the world other than in the importing country. The drug could well be on the market in the importing country but much too expensive for people to afford and as such a cheap international source provides the answer to the problem. This was actually the centre of controversy in the South African case with the Pharmaceutical industry as we shall see later. Antiretroviral drugs were on sale in South Africa but much too expensive and so the government amended its legislation to allow parallel imports and compulsory licensing. Therefore the argument by the US and the EU is misplaced and merely intended to hinder the use of a provision legally available to developing countries.

Despite the legality and desirability of parallel imports and in spite of the fact that it is widely used even by developed countries, the US questioned section 15 (c) of the South African Medicines and Related Substances

¹⁰³ WTO News: 2001 news Item. Governments share interpretations on TRIPS and public Health. Available online at

http://www.wto.org/English/news_e/news01_e/trips_drugs_010620_e.html

¹⁰⁴ Safeguards could include things like the packaging, the presentation of the product, use of different trade marks to distinguish differentially priced goods from the others, labelling including special enforcement procedures in importing as well as exporting countries.

Control Amendment Act of 1997.¹⁰⁵ The amendment came in the wake of the HIV/Aids pandemic and high prices for antiretroviral drugs. The South African government amendment to its legislation is legal under the TRIPS Agreement because as discussed above, the TRIPS Agreement allows parallel imports of patented essential commodities in article 6, and based on the principle of exhaustion of intellectual property rights in the first sale, the amendment was not contrary to the spirit of the TRIPS Agreement. However, despite that the US government and the international pharmaceutical industry put enormous pressure on the South African government to eliminate the measures which were perceived to be ultra vires the South African Patent law and the constitution.¹⁰⁶

However, the South African government being committed to its obligation to realise the right to health for its people and standing on solid legal ground, did not succumb to this pressure. It must be emphasised that ‘the application of the principle of exhaustion of rights in the health sector may be of particular importance, in that by allowing the importation of a patented medicine from a country where it is sold more cheaply than in the importing country, access to the product may benefit a larger number of patients while ensuring to the patent owner some level of remuneration for the invention in the country in which it was sold first.’¹⁰⁷ The acceptance of parallel imports is consistent with the TRIPS Agreement and the obligations undertaken by member countries under that agreement to protect public health.¹⁰⁸

Seeing that some developed countries like the US are fond of using threats even for legal actions taken by developing countries as happened in the South African case, the Doha Declaration reaffirmed the principle of parallel imports in paragraph 5(c) which provides that “governments have rights to authorise importation of patented goods from the cheapest legitimate international sources without challenge.” This provision recognises the importance of realising the right to health through provision of cheap and affordable medicines to those that cannot afford the very expensive patented drugs. The legal principle incorporated in parallel imports is that of ‘exhaustion’, that is the idea that once a company has sold its product, its patent is exhausted and it no longer has rights over what happens to the product.¹⁰⁹ It must be mentioned here that the application of

¹⁰⁵ The section stipulates that ‘the minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public’ and in particular conditions on which any medicine put on the market by the patent holder or with his consent may be imported by a third party in South Africa.

¹⁰⁶ MSF, **South Africa: Public Opinion forces ‘Big Pharma’ to back down**, Access to Essential medicine report dated 01.11.01 and accessed on 05-06-03. Available online at <http://www.msf.org>

¹⁰⁷ Peter Drahos and Ruth Mayne, supra note 1 page 46.

¹⁰⁸ Article 8 of the TRIPS Agreement, 1995

¹⁰⁹ Maskus K E and Chen Y, **Vertical Price Control and Parallel Imports: Theory and Evidence (online)**, World Bank Research. Abstract from World Bank Working paper number 2461. See also Carlos Correa, **Integrating Public Health Concerns into Patent Legislation in Developing countries**, South Centre, Geneva. www.twinside.org.

parallel imports is a complicated matter for it brings out the fierce arguments between interests of intellectual property owners based upon the right to exclusive use on one hand and on the other hand, those of the society based on ethical and public health goals which seek to make healthcare universally available to all at affordable cost. But be that as it may, the option can legally be used by developing countries.

3.4.2 compulsory licensing

A compulsory licence is when a government authorises local manufacture or importation of copies of medicines or other goods without the consent of the patent holder but in compliance with certain procedures and in exchange for a reasonable royalty.¹¹⁰ This is provided for under article 31 of the TRIPS Agreement and was further reaffirmed in paragraph 5 (a) and (b) of the Doha Declaration on Public Health. These provisions are to the effect that the government has a right to determine what constitutes a national emergency for the grant of compulsory licenses. The Doha Declaration has clarified the fact that each Member is free to determine the grounds upon which compulsory licences may be granted. This is very useful in that it has corrected the wrong conception held by many countries that some form of emergency was a pre-condition for the grant of compulsory licences under the TRIPS Agreement.¹¹¹ It further makes it clear that in determining what constitutes a national emergency or extreme urgency, circumstances may include but are not limited to those relating to HIV/Aids, tuberculosis and malaria.

The TRIPS Agreement itself makes no specification as to the grounds upon which a compulsory licence can be granted, but alludes to cases of ‘national emergency or extreme urgency’¹¹², dependency of patents, licences for governmental non-commercial use and licences to remedy anti-competitive practices.¹¹³ Compulsory licensing in the TRIPS Agreement is part of an attempt to strike a balance between promoting access to existing drugs and promoting research and development for new drugs. Article 31 does not use the term compulsory licence but uses the phrase ‘other use without the authorisation of the right owner’.

Before the government can grant a compulsory license, attempts must have been made to obtain from the titleholder a voluntary licence but to no avail. “National laws can provide for the granting of such licences whenever the title holder refuses to grant a voluntary licence on reasonable commercial terms and also for other reasons such as public health or public interest at

¹¹⁰ Peter Drahos, *Supra* note 44 page 48.

¹¹¹ For further discussion of this matter, see Oxfam briefing paper on TRIPS and Public Health: the next battle. Available online at <http://www.oxfam.org.uk/policy/papers/15trips/15trips.html>

¹¹² Article 31 (b) TRIPS Agreement, 1995.

¹¹³ Peter Drahos and Ruth Mayne, *supra* note 1 page 49.

large.”¹¹⁴ Even without prior notification to the patent holder, compulsory licences can be granted especially in cases of emergency and for public non-commercial use, but the patent holder shall be informed after the use of the invention has taken place ‘as soon as is reasonably practicable’.¹¹⁵ Anyone granted a compulsory licence has the right to produce or import the product which is the subject matter of the licence. It must be noted that ‘although IP protection covers many different systems, compulsory licensing is invariably identified with pharmaceutical product patents, not with other forms of IP protection or even other types of patents’ possibly because most people think and believe that pharmaceutical industries are monopolistic and exploitative.’¹¹⁶ This belief finds support in the way the pharmaceutical industry conducts its business and how prices for essential drugs are set. Indeed this was evident in the South African case referred to above. Usually companies are obsessed with the pursuit for profit at whatever cost. Martin Khor in support of this belief states that “consumers are becoming aware that prices of many IPR-protected products are jacked up, in some cases many times above the cost of production, because the corporations owning a patent or copyrights can prevent competition from others or potential producers. Prices of some consumer products are fixed by companies owning IPRS far above the levels that would prevail had there been free competition and the most outrageous example is pharmaceutical drugs.”¹¹⁷

Compulsory licences have been extensively used by developed countries like the US to remedy anti-competitive practices¹¹⁸ and also for governmental purposes. For instance “under 28 United States Code s. 1498, the US government can use patents or authorise third parties to use patents for virtually any public use without negotiation”¹¹⁹ A patent holder cannot claim injunctive relief for this use but is entitled to adequate compensation by virtue of article 31 (h)¹²⁰ of the TRIPS Agreement. In fact most countries provided for modalities for compulsory licences before the adoption of the

¹¹⁴ Ibid

¹¹⁵ Article 31 (b)

¹¹⁶ International Policy Network, **TRIPS and Healthcare: Rethinking the Debate, The Compulsory Licensing Anomaly**, article by Bibek Debroy, July 2001. Available on line at http://www.policynetwork.net/IPhealth/rethinking_the_debate_0701_debroy.htm. Information accessed on 30-09-03 at 12:56 am.

¹¹⁷ Peter Drahos and Ruth Mayne, supra note 1. Page 203-204.

¹¹⁸ Scherer on use by the US of compulsory licensing to remedy anti-competitive practices in that country stated “compulsory patent licensing has been used as a remedy in more than 100 antitrust case settlements, including cases involving Meproamate, the antibiotics tetracycline and griseofulvin, synthetic steroids and most recently several basic biotechnology patents owned by CibaGeigy and Sandoz which merged to form Novartis. My own statistical analysis of the most important compulsory licensing decrees found that the settlements had no discernible effect of the subject companies’ subsequent research and development expenditures.” Reproduced in Peter Drahos and Ruth Mayne, supra note 1 page 50.

¹¹⁹ Peter Drahos and Ruth Mayne, supra note 1 page 75.

¹²⁰ This article states that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

TRIPS Agreement and these have been retained and expanded.¹²¹ Compulsory licences are regarded as crucial elements in those countries' patent laws and are mechanisms used to promote competition and prevent abuse of patent rights monopolies.

In the UK too, compulsory licensing is used. In 1961, 'the antibiotic tetracycline was sold at a comparatively high price by the patent-holder Pfizer. The British Minister of Health therefore authorised the use of the so-called "Crown Use" (government use) provisions of the UK Patent laws to import generic tetracycline from Italy without permission from Pfizer to supply the National Health Service. Pfizer responded with a legal challenge but the House of Lords ruled in favour of the Crown.'¹²² A more recent example is that of Canada in 2001 on October 18, when the Canadian government took a decision to override Bayer's patent on ciprofloxacin, an antibiotic used to treat anthrax. This was intended to make available the drug to protect the public because "Canadians expect and demand that their government will take all steps necessary to protect their health and safety".¹²³ In the same way therefore, developing countries should be able to use this provision to access cheap drugs.

Member countries are free to grant compulsory licences for the importation of goods which are under patent in their own domestic jurisdiction for as long as the said goods are produced in a country where the patent is not in force. And developing countries want to be able to take such measures to protect their health. The best public policies about compulsory licensing of essential medicines are those that serve the interests of the public and also address the ethical dilemmas. Patents are used to restrict access to inventions for reasons of encouraging future R&D, but however, the world must be alive to the fact that patents if unchecked especially in relation to health could result in illness and death even when it could be avoided. Therefore the restrictions must be reasonable and acceptable.

However, despite the legitimacy of compulsory licensing, some countries that have provided for them in their legislation have faced the threat of unilateral retaliations or the suspension of aid, by some developed countries. This has been done by the US through its 301 trade processes. A good example of this occurrence is the dispute between the US and South Africa in relation to an amendment of legislation by the South African government aimed at allowing parallel imports and compulsory licences for patented medicines.¹²⁴ Like parallel imports, compulsory licensing has the potential to promote local initiatives especially if they are directed at local production of patented goods. In fact in the area of pharmaceuticals, compulsory licences constitute an important tool for governments to promote

¹²¹ Peter Drahos and Ruth Mayne, *supra* note 1 page 49.

¹²² MSF; **TRIPS "safeguards" in use in developed countries**, available online at <http://www.msf.org>

¹²³ MSF *ibid*

¹²⁴ Peter Drahos and Ruth Mayne, *supra* note 1 page 49

competition and increase access and affordability of drugs without depriving the patent holder of reasonable compensation.¹²⁵ The problem arises when compulsory licences are issued for production when the country has no manufacturing capabilities and in fact this is the problem that many developing countries face after 2016. How can this problem be overcome? The possible answer to this question will be provided later in the paper, as an attempt will be made to discuss the balance of rights under articles 30 and 31 of the TRIPS Agreement.

Like parallel imports, there are some concerns relating to the use of compulsory licensing. This concept legally allows a government to override a patent and there is no negotiation or injunctive relief for as long as compensation is paid. But who determines how much is to be paid to the patent holder, and is that acceptable? What should be the basis for determining the amount to be paid, is it to be based on royalty or what? And most important who should administer the whole process, is it the government, an NGO or private company? Since there is no negotiation before the licence is issued, should there be a procedure for filing for claims by the patent holder? It is submitted that the system of compulsory licensing is very complicated and needs to be handled carefully in order that it does not in the end hamper trade. There are no clear cut answers to these questions and may be that explains why the pharmaceutical industry is so much against the practice. But it is available and must be used to benefit the general public.

There are also concerns about the possible abuse of this mechanism especially by developed countries themselves since they have manufacturing facilities. However, compulsory licensing is a powerful negotiating tool, because even if the poor countries do not actually import generics or manufacture locally, the mere option to do so is an essential bargaining tool in negotiating price reductions for patented drugs with big pharmaceutical companies. Industrialised nations also use compulsory licensing as a negotiating tool. In fact this happened when the US government negotiated a low price for anti-anthrax medicine from Bayer in October 2001 and when Brazil halved the price of anti-retroviral drugs from Roche in the same year.¹²⁶ The US had threatened to override these companies' patents if they did not reduce the prices on their own. For fear of this and other trade sanctions, the countries reduced the prices.

The problem is still however that when the handful of generic manufacturing countries become TRIPS compliant which will happen by the year 2005, they will not be able to produce and export the cheap generic versions to other countries especially those in Africa that have no manufacturing capabilities. This means that unless the restrictions in the

¹²⁵ WIPO, **Post Graduate Specialisation Course on Intellectual Property**, collection of papers, Turin 2001. Page 303.

¹²⁶ Oxfam Briefing paper on TRIPS and public health. See supra note 78. For further reading see also Peter Drahos and Ruth Mayne, supra note 1 page 252.

TRIPS Agreement are interpreted in a flexible manner to allow exports of generics through the authority of compulsory licensing, developing countries with no manufacturing capabilities will become dependant on expensive patented medicines. This will aggravate an already desperate situation in the health sector. Oxfam International argues that “many people in developing countries live below the poverty datum line and have no health insurance schemes, therefore high medicine prices resulting from TRIPS restrictions on the production and export of cheap generic medicines will have grave consequences for people’s health.”¹²⁷

The question then is how to ensure that this mechanism benefits the people in developing countries who are in need and lack the means to purchase drugs. Totally against the use of compulsory licensing, Bibek Debroy argues that poor countries must comply with the requirements of the TRIPS Agreement and limit the use of compulsory licensing, because “while the introduction of product patents may adversely affect some powerful vested interests (especially generic pharmaceutical manufacturers) and thereby be costly both economically and politically in the short term, the benefits in the medium to long term in terms of increased foreign direct investment, technology transfer and local product development far outweigh these transitional costs.”¹²⁸

Although this argument may be true for the future, when we talk about access to drugs, the sick needing medicine cannot wait for the foreign investment which is not known when it will come through. In fact since the adoption of the TRIPS Agreement, there has been no real investments in developing countries. Charles McManis argues that it is not clear what impact the TRIPS Agreement will have on global economic development in the long term. He states that “notwithstanding the bland assurances of proponents of the TRIPS Agreement, there is little empirical support for the proposition that increased levels of intellectual property protection in the developing world will necessarily lead to increased levels of foreign investment in developing countries. Nor is there any clear theoretical presumption that stronger standards of intellectual property will always be welfare enhancing.”¹²⁹ It has further been argued that “there is ample cause for concern that higher levels of intellectual property protection will lead to or embed a stratification and concentration of intellectual property rights ownership in industrialised world enterprises.”¹³⁰ This has consequences for developing as well as developed countries but the most disadvantage will be

¹²⁷ Oxfam Briefing Paper, TRIPS and Public Health: the next battle, 2002. See note 78
supra

¹²⁸ International Policy Network, supra note 116.

¹²⁹ Charles McManis, **Intellectual Property and International Mergers and Acquisitions**, 66 University of Cincinnati law review 1283, 1286-1297 (1998). Reprinted in Paul Goldstein, International Intellectual Property law, 2001. Page 97.

¹³⁰ Frederick m Abbott, **The WTO TRIPS Agreement and Global Economic Development**, in Public Policy and Global Technological Integration 46(Frederick M Abbott & David j Gerber editions, 1997). Reprinted in Paul Goldstein, page 97.

to developing countries. In the face of such arguments, it is difficult to support the argument by Bibek.

It must be noted that compulsory licensing is not intended to benefit the generic manufacturing companies, on the contrary, it is a provision meant to alleviate the health problems being faced in many developing countries but even developed nations use it as we have seen above. Developing countries with generic manufacturing companies will still be able to use compulsory licensing to take care of their own demands and the strengthening of intellectual property protection will not really affect them. There may be a slight reduction in the profit margins since the companies will not supply many other countries, but it will be minimal compared to the health crisis that will prevail in other developing countries.

It is my contention therefore that the above argument is misplaced and could be very relevant for other utilities on patents for which people's lives do not hang in the balance. As we have noted in this paper, intellectual property rights are meant to benefit the society at large and what is crucial is striking a balance between private interests and public interests. It is strongly argued that "intellectual property rights must be weighed against the needs of people whose lives depend on the supply of affordable medicines."¹³¹ And as such it is important that developing countries take advantage of these legal provisions to make health care for the people a reality. Bibek further argues in the same paper that "the pharmaceutical companies must be deregulated and allowed to price discriminate on their own".¹³² However, there is no guarantee that if pharmaceutical companies were not regulated and patent protection was uniform in the world, the industry on its own would take the interests of the poor into account. It must be noted that in fact compulsory licensing promotes competition and good business behaviour because patents can be overridden in the case of anti-competitive practices. Furthermore, generic competition helps slash drug prices.¹³³

It has been argued that if developing countries took advantage of these legal provisions maybe some of the problems especially as regards access to cheap and affordable drugs will be a thing of the past, but these countries are unable to do so mostly because of pressure from some developed countries and also because of some restrictions contained in the TRIPS Agreement itself. The following section therefore discusses the restrictions contained in the TRIPS Agreement.

¹³¹ MSF, **MSF puts drug patents under the spotlight**, available online at <http://www.msf.org/page.cfm?articleid=6BE04D00-C80E-461D-A42754072ABC74D> information accessed on 05-06-03

¹³² Ibid

¹³³ For a comment on this see MSF report at <http://www.msf.org/page.cfm?articleid=0A4BF7FE-802D-4E4C-92487E4305CF183>

3.5 Restrictions in the TRIPS Agreement

During the ministerial conference at Doha, ministers recognised the fact that countries with no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of the legal options but especially of compulsory licensing.¹³⁴ This imbalance in the TRIPS Agreement concerns the way in which countries like India who have manufacturing capacities are restricted from producing and exporting inexpensive generic versions of new medicines to other developing countries.¹³⁵ Many developing countries especially in Africa cannot afford the expensive patented drugs and neither can they manufacture generics. Currently they are able to import these generics from other developing countries like India but this will not be possible once India and other generic manufacturing countries have become TRIPS compliant.¹³⁶ The TRIPS Agreement prohibits exports of cheap copies of patented medicines whether or not there are patents in force in the importing country and irrespective of the health needs.¹³⁷ This problem, although identified at Doha, remains unresolved to-date.

Apart from prohibiting competitors from producing and exporting cheap generic versions of patented drugs, the TRIPS Agreement also restricts the grant of compulsory licences to supply the domestic market predominantly.¹³⁸ This means that developing countries with manufacturing capacities can only issue compulsory licences to address their own health problems and cannot grant such a licence for purposes of addressing health problems in other countries however desperate the situation might be.

These restrictions represent fundamental unfairness within the TRIPS Agreement because they essentially favour rich industrialised nations who can override patents if prices are too high or supplies inadequate. The majority of poor countries especially in Africa, however will not have a chance to use compulsory licensing although it is legally available because they lack the capacity to do so and further they cannot use compulsory licensing to import medicines because TRIPS does not allow generic producing countries to export. It has been argued that “ the TRIPS Agreement should not prohibit the option of using compulsory licences for importation of the patented product as this may often be the only viable means to use a compulsory licence in countries where manufacturing capacity does not exist or the size of the local market does not justify local manufacturing, or where there is a need to promptly address an emergency situation.”¹³⁹ It must also be possible for compulsory licensees in different

¹³⁴ WIPO, Turin course compilation, page 304.

¹³⁵ Article 28 TRIPS Agreement, 1995.

¹³⁶ Oxfam briefing Paper, **TRIPS and Public Health: the next battle. Available online at <http://www.oxfam.org.uk/policy/papers/15trips/15trips.html>**

¹³⁷ See article 31 (f) of the TRIPS Agreement, 1995.

¹³⁸ Article 31 (f), TRIPS Agreement, 1995 provides that compulsory licences ‘shall be authorised predominantly for the supply of the domestic market of the member’ issuing it.

¹³⁹ WIPO, Turin course compilation page 305.

countries to import from each other. It is hoped that in future one ministerial meeting will address this issue and make health a reality for the people in developing countries. The 2003 Cancun meeting held in Mexico between the 10th and 14th of September failed to resolve this issue as parties could not agree on anything.¹⁴⁰

3.6 Conclusion

The TRIPS Agreement and its implication for public health in developing countries is a complicated system whose implementation has caused a lot of worry and anxiety. Most importantly a problem has been identified in the implementation of compulsory licensing. What then is the way forward in realising the objectives of the TRIPS Agreement for public health? There is no straight answer to this question. The next chapter will therefore focus on discussing some of the issues involved and proposals of how this web could be disentangled.

¹⁴⁰ The collapse of the Cancun meeting has been described as a victory for developing countries in that it presents them with a rare opportunity to assess the current GATT commitments. The unity shown by developing countries and their resolute to stand in the face of the usual arm-twisting tactics of the US and EU only highlights the growing friction between developed and developing countries. This stems from the developed countries' insistence on opening up the markets of developing countries while maintaining protection of their own markets through high subsidies and an impenetrable wall of tariffs." Excerpt from a letter by SGD. Rovik S. Obani, a Policy Advocacy Officer, Agricultural Trade Center of the Philippine Peasant Institute. Available online at http://www.ppi.org.ph/press_releases/press_3.htm. Information accessed on 9th October 2003 at 12:02 hours.

4 DEVELOPING COUNTRIES AND THE TRIPS AGREEMENT IN THE LIGHT OF PARAGRAPH 6 OF THE DOHA DECLARATION

4.1 Introduction

The previous chapter has discussed the relationship between the TRIPS Agreement and public health and a number of problem areas have been identified. One such problem lies in the interpretation of the TRIPS Agreement and the Doha Declaration on public health. During the fourth Ministerial Conference in Doha, trade ministers recognised the difficulties that developing countries without manufacturing capacities will have in making use of the legal options in the TRIPS Agreement but especially of compulsory licensing. They therefore agreed in paragraph 6 of the Declaration¹⁴¹ that there was need for an expeditious solution to be found to this problem and hence tasked the TRIPS Council to find a lasting solution by the end of the year 2002. Although this is a commitment that it should be difficult for any country to renege on, seeing how important public health especially in poor countries is, by March of the same year, there were clear signs that some WTO members were not committed to finding a lasting solution. This happened during the March TRIPS Council meeting.¹⁴² This chapter is dedicated to discussing the friction that has arisen between developed and developing countries on the issue of interpretation and application of this provision and what progress, if any, has been made towards finding a solution to it.

4.2 Follow up to the Doha Declaration

During the March TRIPS Council meeting, the US, the EC and developing countries all tabled papers that incorporated proposals of how best to deal with the problem identified in paragraph 6 of the declaration. Both the US and the EC were under pressure from powerful corporate lobbies to restrict the solution to cover only a small number of countries and further to narrow the definitions of manufacturing capacity.¹⁴³ This pressure had the potential

¹⁴¹ Paragraph 6 states that “We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”.

¹⁴² Oxfam Briefing Paper, **TRIPS and Public Health. The next battle.** Available online at <http://www.oxfam.org.uk/policy/papers/15trips/15trips.html> information accessed on 05-

06-03

¹⁴³ Ibid

effect of introducing cumbersome procedures that could make any solution practically unworkable.

3.2.1 The US Paper

Because of the enormous pressure, the US tabled a very controversial paper in which it proposed among other things a ‘moratorium on WTO disputes in cases where a government allows compulsory licences for export to selected developing countries’.¹⁴⁴ A ‘moratorium’ is a suspension or freezing of legal action against developing countries producing generics for export to other countries using compulsory licensing. Reacting to this proposal, developing countries led by Brazil stated that the proposal is unacceptable as it is only a temporary and not a permanent solution to the problem. This writer concurs with this reaction by developing countries because a moratorium brings in cumbersome procedures of selecting which developing countries will benefit from such suspension and leave out the rest. But the question is what criteria would be used to determine which countries could be eligible to export and which ones can import and who will decide anyway? And what happens if the US decided to lift the suspension over night and instead claim infringement of patent rights, which is very possible?

I say that it is possible for the US to change over night because the behaviour in relation to strong IP protection is one of double standards. This happened in the year 2001 when the US sought to purchase anti-anthrax drugs. While discouraging the use of compulsory licensing, Ruth Mayne states that “in an astonishing display of double standards the US government raised the possibility of licensing or importing generic drugs if Bayer did not reduce prices and step up supplies of its anti-anthrax antibiotics. Bayer quickly dropped the price by half.”¹⁴⁵ The pharmaceutical industry is always lobbying the US government to implement strict policies, is there any guarantee that if such a moratorium was to be implemented then, they would give notice or something if they were to think otherwise? All these questions are answered in the negative and as such the US proposal is to be discarded, as it is not workable. A moratorium can be ended at any time and therefore prevent generic production and exports bringing the situation to a stage worse than what it is now.¹⁴⁶

The US paper further proposed that the solutions should be focused on improving access to pharmaceuticals to treat diseases referred to in the declaration, these being HIV/AIDS, malaria and tuberculosis. Analysing this proposal, Oxfam states that “this proposal is based on a very partial

¹⁴⁴ Ibid

¹⁴⁵ Peter Drahos and Ruth Mayne, **Global Intellectual Property Rights: knowledge, Access and Development**, Oxfam International, Palgrave, 2002. Article by Ruth Mayne page 253.

¹⁴⁶ Most NGOs reject this waiver as it would only offer a temporary measure, would have to be reviewed annually and would waste a unique political opportunity to get a permanent solution. Peter Drahos and Ruth Mayne, page 256.

reading of the declaration and actually presents a complete misunderstanding of the intentions and desires of the trade ministers at Doha.” Again concurring with this assessment, this writer states that in fact it is a profit-oriented suggestion, which does not take into account the impact that will be felt by those in need. The US is a strong proponent of strong patent rules and any suggestion must be carefully analysed before it can be implemented otherwise the world will find itself engulfed in another ‘TRIPS type’ discussion. Fortunately, the Doha Declaration adopted a broad public health perspective and confirmed ‘that TRIPS does not and should not prevent governments from taking measures to protect public health’.¹⁴⁷ This should give developing countries some confidence in negotiating for better ways of protecting public health.

However, one thing that must be borne in mind is that of diversity, that is to say things are different in different countries. Developing countries must take the opportunity to use the TRIPS flexibilities to design patent systems that best suit their needs, for “what works for an OECD country may not work for a developing country” and furthermore, “every patent in force is either actually or potentially a barrier to access to an essential medicine. Even if there were only a single patent standing in the way of accessing a safe and effective yet cheap generic medicine, it would still be an obstacle that needs to be acknowledged and removed.”¹⁴⁸

4.2.1 The European Commission Paper

The EC on the other hand presented a much more positive paper with two possible solutions one being an interpretation of article 30 which allows exceptions to the patent rights. The interpretation suggested was so that generic manufacturing countries can be allowed to ‘export health products’ as an exception to the general rule. The second approach was that article 31 of the TRIPS Agreement should be amended to carve out paragraph (f). By this solution, it will be legal for any generic manufacturing country to issue a compulsory licence to manufacture and export to other countries as well. The EC is also ready to discuss production for export even to countries that do not provide pharmaceutical patents. One small problem with the EC paper is that it sought to limit these solutions to countries ‘facing serious health problems and exceptional circumstances’.¹⁴⁹ The question again arises as to who is competent to decide which countries are facing serious health problems. Almost all developing countries but especially those in Africa have crippling health problems such that if solutions to global health problems were limited to only a handful of them, the interests of making healthcare a reality will not be served. It is therefore important that since the instruments we are dealing with are global in nature, solutions should also be global in nature.

¹⁴⁷ Ibid

¹⁴⁸ MSF Reports, **Drug Patents under the Spotlight**, see <http://www.msf.org>

¹⁴⁹ Ibid

Be that as it may, this problem actually stems from the Doha Declaration itself. Paragraph 6 of the Doha Declaration states in part that “We recognise 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”. An analysis of this paragraph by Oxfam International has revealed that it has an inherent gap in that it seeks solutions only for countries with pharmaceutical patents that issue compulsory licences. This therefore means that if the EC proposal was accepted and the solutions were restricted to these countries only, then least developed countries that opt to avail themselves of the extended period granted by the declaration (up to 2016) for TRIPS compliance will not benefit from such solutions. Ruth Mayne of Oxfam strongly argues that “it would be absurd, damaging and quite contrary to the intentions of the ministers at Doha if the US and others insisted on excluding these categories of countries.¹⁵⁰ It is therefore incumbent upon developing countries themselves to remain united and resist any pressures for unworkable solutions that will only worsen their lot.

4.2.2 Developing Country Paper

During the March TRIPS Council meeting, developing countries remained solidly united. A group of 41 countries presented a statement in which they proposed as key options the first being to delete paragraph (f) of article 31 and the second being that member states should agree to an interpretation of article 30 to allow production to address health needs in other countries. The statement further opposed any narrow interpretation of paragraph 6 or attempts to limit solutions to a certain category of countries although it pointed out that naturally the main beneficiaries of any solution would be the developing and least developed countries.¹⁵¹ The developing countries also proposed a general exception as is found in all other WTO Agreements. As has been noted before, patents were designed to ensure that the public benefits from innovations, but however in practice the situation is different, in many instances ‘patents hamper the public’s access to life-saving medicines since profits are usually put before public health’.¹⁵² The solutions proposed by the EC and the developing countries are not without problems. Let us for a moment consider the issues arising in the implementation of the proposed solutions.

¹⁵⁰ Oxfam Briefing Paper, **TRIPS and Public Health. The next battle.** Available online at <http://www.oxfam.org.uk/policy/papers/15trips/15trips.html> information accessed on 05-06-03

¹⁵¹ Oxfam Briefing paper, *ibid.*

¹⁵² MSF Reports, **Drug Patents under the spotlight.** See <http://www.accessmed.msf.org>

4.3 ANALYSIS OF THE PROPOSED SOLUTIONS

4.3.1 Solution under Article 30

Developing countries and NGOs have championed calls for a solution to be found in agreeing for an interpretation of article 30 to allow exports of health products without the consent of the patent holder. Article 30 allows for situations when an exception could be made to the rights conferred by patents.¹⁵³ Although exceptions for fair uses of patented goods are usually allowed for educational, research and other scientific non-commercial purposes, from proponents of this solution, it is understood that an exception to allow production of generic drugs for export would amount to fair use in the spirit of article 30 and would not conflict with the normal exploitation of the patent. The first problem with this suggestion is that it makes no mention of whether there will be compensation paid to the patentee or not, in which if the latter is the case then, there is an infringement of patent rights. Furthermore, if such was provided then it amounts to repetition because article 31 is dealing with the same issue of compulsory licensing which in article 31 (f) has created the problem at hand.

It has been argued that an article 30 solution could result in significant health gains although it does not solve the public health problem fully. This is because adopting such a solution has among other advantages, the fact that it provides the simplest and most direct answer for developing countries. However in the light of the complication stated above, the writer wonders how simple and direct such a solution would be. Oxfam argues further that the second advantage of the said solution is that it can be limited to the health problems the Doha Declaration seeks to address by restricting its application to exports of health products.¹⁵⁴ The side effects of restricting any solution have been tackled in relation to the US and EC papers discussed above. It is my contention therefore that finding a solution to the problem created in the TRIPS Agreement and identified by the Doha Declaration should not be restrictive as that will mean going round in circles. The Doha Declaration has not stated the list of health problems to be addressed, only examples of problems have been given and it is wrong to restrict solutions to these because that could not have been the intention of the trade ministers. Oxfam itself pointed this out in relation to the EC paper, but they seem to contradict themselves here.

The third advantage identified by Oxfam is that article 30 solution ‘allows the decision for a compulsory licence to remain in the country of consumption.’ Indeed it is neither logical nor desirable for an importing

¹⁵³ Article 30 provides that “members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the owner, taking account of the legitimate interests of third parties.

¹⁵⁴ Oxfam briefing Paper supra note 150

country to have to rely on an exporting country to issue a compulsory licence on its behalf which they claim would be the case under article 31 solution. I do not agree with this assessment because by their nature compulsory licences are issued to override patents by a country that seeks to acquire certain patented products to satisfy its domestic needs. In this case both the importer and exporter will have to issue compulsory licences. Therefore, an importing country could very well issue a compulsory licence without waiting for the exporting country to issue one. It is my further contention that in fact a compulsory licence issued by an importing country could encourage an exporting country to produce since they will be assured of a market.

The last advantage identified is that this solution allows for compensation to be paid in the country of consumption if the patent exists and if it does not then no compensation should be paid. They further say that it would be illogical for the exporting country to pay compensation, which would be the case under article 31 solution. Although they allude to the issue of compensation there are still outstanding questions as to who decides how much will be paid and whether the patentee can actually claim for such compensation. My contention is that by the provisions of the TRIPS Agreement, every compulsory licence issued is accompanied by payment of reasonable compensation¹⁵⁵ because it is assumed that every such licence will yield some profit for the licensee and would reduce the profit for the patentee. Therefore in such a case it makes sense for both the importing and exporting country to pay compensation. However, the above scenario is not the major problem with this solution. Deeper concerns lie in the fact that “the production of cheap generic versions of patented medicines is likely to become entirely dependant upon a complicated system of compulsory licensing and exceptions”¹⁵⁶ which is in no uncertain terms a nightmare for developing countries.

4.3.2 Article 31 Solution

By this solution, developing countries propose that the TRIPS Agreement must be amended by deleting paragraph (f) of this article which restricts the issuance of compulsory licences to supply the domestic market predominantly. This solution means that any developing country could issue a compulsory licence either for exporting or importing generic drugs. This seems to be a more straightforward solution compared to the article 30 solution, but however, it too has some inherent gaps as will be seen shortly.

By article 31 (g), a compulsory licence must cease to exist as soon as the circumstances which led to it cease to exist and are unlikely to recur. Competent authorities shall have the authority to review on motivated request the continued existence of such circumstances. However, public

¹⁵⁵ Article 31 (h), TRIPS, 1995.

¹⁵⁶ Peter Drahos and Ruth Mayne, *supra* note 1 page 256.

health concerns are by their nature perpetual circumstances. This means that if paragraph (f) was to be deleted then paragraph (g) would also have to be amended in some way so that an exception is made that for public health reasons, compulsory licensees need not apply for review of circumstances. Other problems with this solution have already been dealt with in the preceding section, but one thing needs to be mentioned here and that is the possible abuse of these mechanisms by developed countries themselves since they have manufacturing capacities.

4.4 Counter Arguments by Developed Countries

Of course the industrialised nations and the pharmaceutical industry has something to say. They argue that reinterpretations of the TRIPS agreement will not solve the health problems in developing countries which are rooted in poverty. As has been seen in chapter two, successful health care systems depend on various other aspects but access to essential medicines is a crucial component of such systems. They have also argued that most drugs under patent now will be off patent in 2005 when India and other generic manufacturing companies become TRIPS compliant.¹⁵⁷ However, it must be noted that as years go by, new diseases emerge and new cures for those and old diseases are found. Public health systems are dynamic and become complicated as new diseases emerge. Who ever knew that today the HIV/AIDS pandemic will spin out of control and cause this much debate?¹⁵⁸ No one and so the world must be seen in the light of dynamism whereby newer and more effective medicines would be discovered and the whole discussion process will be as it is now if a permanent solution is not found. Other arguments have centred on things like the system could be abused even by rich countries, but such arguments are just fishing for a reason why developing countries should be denied access to essential medicines. Safeguards could always be put in place to prevent such abuse. It is not surprising that such arguments are championed by the US. It remains an open question whether rich countries and the pharmaceutical industry will view compulsory licensing as a routine rather than an exceptional measure.

4.5 Proposed Statement by the TRIPS Council Chairperson

As already noted above, developed countries were under pressure from powerful lobbies to restrict the application of paragraph 6 of the Doha Declaration.¹⁵⁹ Trade Ministers upon identifying the problem tasked the

¹⁵⁷ Oxfam Briefing Paper supra note 150.

¹⁵⁸ MSF states that since the early 1990s when the TRIPS Agreement was negotiated, the world has changed drastically. A decade ago, no one anticipated that in 2001, a total of 36 million people worldwide – a vast majority of them in sub-Saharan Africa would be infected with HIV. Source MSF report **Poor patients at risk**. Available online at <http://www.msf.org/page.cfm?articleid=54BC277-CD8F-4DE4-AF65AA94E42BB5E>

¹⁵⁹ See Peter Drahos and Ruth Mayne, article by Ruth Mayne page 256.

TRIPS Council to find a lasting solution to it by December 2002. But however by March of 2002, there were signs that some WTO members notably the US were not committed to resolving this issue and this was evident from the statement by the chairperson of the TRIPS Council proposing changes to the said paragraph. This statement was clear evidence of developed country and pharmaceutical industry influence. In response to this, Médecins Sans Frontières¹⁶⁰ urged WTO members to reject this statement¹⁶¹ for it sought to restrict the application of paragraph 6 to address only national emergencies or other circumstances of extreme urgency whether essentially or otherwise.

MSF argued that this paragraph was not meant to only address national emergencies or other circumstances of extreme urgency essentially or otherwise and as such adoption of the Motta text would mean that countries with no manufacturing capacities are at a big disadvantage. In fact, after the parties had presented their respective papers to the council meeting as discussed above, developing countries were angry that the draft by the chairperson contained US proposals that had not even been discussed with them.¹⁶² They stated that the US proposals diluted the key developing country proposals and that meant that developing countries would not be able to use the TRIPS safeguards for preventive or contingency action.¹⁶³ Article 31 (h) of the TRIPS Agreement provides safeguards whenever a compulsory licence is granted and so the interests of the patent holder are already observed. They argue further that the paragraph in the Doha Declaration is about effective supply of a compulsory licence not whether or not that licence can be granted in the first place. Limiting the operation of the provisions of the Doha Declaration would mean going back to the years before its adoption.

MSF, like developing countries, argues further that the proposed text would indicate that the solution cannot be used for the production and purchase of products meant for the prevention of an emergency. This is really outrageous because for how long will a country have to wait and anyway why should a country wait for a situation to get out of hand before doing

¹⁶⁰ MSF, **MSF calls on WTO to refuse ‘paragraph 6’ change, open letter to WTO members signed by Ellen ‘t Hoen dated 08.02.2003** available at <http://www.msf.org.../page.cfm?articleid=2EA7AA16-950B-4E3A-9CB091725630F8E>. Information accessed on 05-06-03

¹⁶¹ The proposed statement reads in part “All delegations (the US, the EC and Developing Country group) have reconfirmed their commitment to the provisions of the Doha Declaration on the TRIPS Agreement and Public Health and to the need to respect fully its provisions. Secondly, delegations have made it clear that they see the system that we are establishing under paragraph 6 of the Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency and thirdly, delegations have recognised the need to avoid undermining the importance of intellectual property protection in the development of new medicines and have also reaffirmed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health....” source see note 160 above.

¹⁶² Peter Drahos and Ruth Mayne, article by Ruth Mayne, page 253-254.

¹⁶³ Ibid page 254.

anything about it? If such a situation was allowed to prevail, then the meaning of the TRIPS Agreement will be rendered redundant and only workable for developed countries. This kind of statement causes a major division between the haves and have-nots, which is not the intention of the global patent rules. If uniform rules apply worldwide, then the application and benefits must be uniform. The problem that confronts the application of the compulsory licensing provision in the TRIPS Agreement is not whether such licence could be granted at all, but whether such a licence could be used to export the products. This is what is sought to be addressed in paragraph 6 of the Doha Declaration.

4.6 Conclusion

The Doha Declaration was an important step forward in the campaign for affordable medicines. It affirmed the primacy of public health over intellectual property rights and the rights of governments to make full use of the public health safeguards in the TRIPS Agreement. Seeing how the situation of solving the compulsory licensing lacuna identified by trade ministers at Doha is being twisted, MSF have proposed a statement which they say is better than the one discussed above. The statement reads as follows: “Delegations have made it clear that they see the system that is being established under this proposed solution as being designed to promote access to effective treatments to address public health problems afflicting countries with insufficient or no manufacturing capacities in the pharmaceutical sector as called for in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”.¹⁶⁴

Despite so much publicity and discussion over the issue of implementation of the TRIPS Agreement and the Doha Declaration, little has been done to find a lasting solution. Developing countries are concerned about the slow implementation process and to that effect, a note on this issue was included in the Developing Country declaration to the 5th Ministerial Conference of the WTO. Developing countries stated that “we note with concern, that despite the commitment in the Doha Declaration to give the ‘utmost importance’ to implementation related issues, there has been little progress and that the majority of issues remain unresolved past the December 2002 deadline. We call upon all the WTO Members especially developed countries, to demonstrate the political will to seriously and effectively address in a substantive manner all of the outstanding implementation issues before the fifth ministerial conference.”¹⁶⁵

It is regrettable however that the fifth ministerial conference did not solve this issue either. The meeting flopped because developing countries were

¹⁶⁴ MSF article see note 19.

¹⁶⁵ ACP Declaration on the 5th Ministerial Conference of the WTO. Available online at http://www.sarpn.org.za/documents/d0000472/p428_ACP.pdf. Information accessed on 09-10-03 at 12:33 hours.

not ready to have their arms twisted by developed countries and so they walked out. It must be stated here that since the coming into being of the TRIPS Agreement in 1995 and the Doha Declaration in 2001, developing countries have for once put up a united front and opposed issues that do not favour them. It is important that this unity is maintained if any issues especially those related to access to essential medicines are to be positively realised for the people in developing countries. In fact a strong declaration on the interpretation of the TRIPS Agreement would help protect the lives of many people in developing countries because this will have an impact on how national legislation is assessed by the TRIPS Council in the future.

Having said this, let us now turn to the issue of balance of rights within the TRIPS Agreement. The next chapter will focus on discussing the conflict of interests between the rights of intellectual property owners and those of the public desiring to use the intellectual innovations. This will be discussed in the light of the TRIPS Agreement and how it hopes to strike a balance between the two.

5 THE TRIPS AGREEMENT AND THE TWO VISIONS IN CONFLICT WITH EACH OTHER: MAXIMUM PROFIT Vs PUBLIC ACCESS TO INNOVATIONS

5.1 Introduction

The urgent need to find a sustainable solution to the imbalance between intellectual property rights protection and saving lives has been particularly visible in recent years with the advent of the HIV/AIDS pandemic that has claimed the lives of many people. No one anticipated, for example, that by the year 2001 so many people worldwide would be infected with HIV/AIDS and that discussions of access to antiretroviral drugs would be so heated.¹⁶⁶ The prices of AIDS cocktails have been reduced through a powerful combination of generic competition and international public pressure calling upon the pharmaceutical industry to put the lives of people before profits. However this alone is not sustainable and as such long-term solutions at the international level are necessary to ensure that the gains of today are not lost. The TRIPS Agreement must not stand in the way of protecting public health. And if the experience with AIDS drugs is anything to go by, ‘the implications for the majority of the world’s population especially those in developing countries of full compliance with the TRIPS Agreement are daunting’¹⁶⁷ because prices for drugs will go up.

This is one side of the coin, there is also the issue of incentives being given to inventors. The pharmaceutical industry argues that without patent protection, there will be no incentive to spend huge sums of money on development of new drugs. In this situation of conflicting interests how can a balance be reached? The issue of access to affordable medicines for people in developing countries has been hotly debated in recent years but to date there is no permanent solution in place. It has been observed in chapter one of this paper that patents have the tendency to raise prices for protected goods beyond the reach of many. What then is the benefit to society if the people cannot have access to and use the innovations for which they have given the inventor a monopoly? Is it worth the trouble then to have patent systems in place if the end result is protecting only the individual rights? Questions from the developing world on lack of access to pharmaceuticals are many but unfortunately no answers. This chapter aims to explore the tension that exists between profit and private rights on one hand and the needs of society and expectations from patent systems on the other. The aim

¹⁶⁶ MSF, **Poor patients at risk**. Available online at <http://www.msf.org/page.cfm?articleid=549BC277-CD8F-4DE4-AF65AA94E42BB5E>.

Information accessed on 05-06-03.

¹⁶⁷ Ibid

is to try and see if a balance can be achieved between the two issues in the light of the TRIPS Agreement.

5.2 The Role of Patents in Access to Innovations

It has been said that patents encourage innovation and transfer of technology from industrialised nations to developing nations because with assurance that there would be a reward, multinational corporations are willing to invest in developing countries thereby causing a transfer of technology. Patents are contractual arrangements between the inventor and the society from which both parties expect to reap a reward and as such “a patent is said to be the outcome of a bargain between the inventor and society by which society grants to the inventor certain rights to work his or her invention in return for the inventor’s disclosure of the invention”.¹⁶⁸ Patent rights are statutory in nature and therefore a patent can also be said to be a reward or inducement that the state grants to the inventor for the contribution to the solution of a problem in technology or industry. This therefore means that an inventor is entitled to exclusive use of the patent and to remuneration arising from use by other people. The society on the other hand is entitled to the benefits that the invention brings in terms of access to its use. This contractual arrangement is what is referred to as the maximum profit/public access dichotomy. Both systems depend on each other to succeed. If the inventor does not gain reward for his or her invention, there would be little incentive to invent more; on the other hand if the society does not benefit from the invention, they will not be willing to grant periods of exclusive use. Getting this balance right is quite crucial when it comes to access to essential medicines.

5.3 Pharmaceutical Patents

The subject of pharmaceutical patents is very important for a number of reasons including the fact that it touches on sensitive areas of human existence; that of the health and quality of man’s/woman’s life. The pharmaceutical industry “depends to a very large extent on costly research and development programs for the production of new inventions which makes the grants of patents necessary more so because the chemical and pharmaceutical products are more often than not relatively easy to copy.”¹⁶⁹ Industry estimates the average cost of developing a new drug at about 500 million US dollars such that without a good incentive, the industry would not invest more. It has been argued that had it not been for the patent system, which rewards companies for risking millions of dollars on research, most of the vital drugs like the anti-Aids drugs would not exist.¹⁷⁰

¹⁶⁸ Taylor C and Z Silberston, **The Economic Impact of the Patent System**, Cambridge: Cambridge university press, 1973.

¹⁶⁹ WIPO, **Intellectual Property and Human Rights**, Geneva, 1998. Page 71.

¹⁷⁰ MSF, **Yes, drugs for the poor and patents as well**, article by Mike Moore, first appeared in the International Herald Tribune. Available online at

Tapon therefore argues that “the precision of a chemical or pharmaceutical patent specification makes the patent particularly easy to defend and thus enhances the value of the intellectual property”.¹⁷¹

For this reason, the pharmaceutical industry has done much to ensure that the patent system meets its own requirements basically the requirements of large companies operating with highly codified information on a route to innovation made linear by government regulation and social expectation.¹⁷² Set against the benefits society reaps from innovation in these industries where innovation is encouraged by patents must be the monopoly costs these industries insist provide the necessary incentives to innovate.¹⁷³ It must be noted that the industry recovers these costs from the consumer of the protected goods who has to pay for it. For people in developing countries, this is a very big problem because they cannot afford to pay for the expensive drugs. Critics of the TRIPS Agreement say that it has made the situation worse because by requiring developing countries to enforce pharmaceutical patents, the agreement enables drug companies to charge exorbitant prices that the poor cannot afford to pay.

On the issue of the cost of production of a new drug, MSF states that the approximate cost of 500 million US dollars is based on a paper written by J A Dimas and published in 1991. In that paper the cost was put at 231 million US dollars. Subsequent studies used higher figures which in the final analysis have been rounded off to the much-quoted 500 million US dollars. However this rounding off did not take into account the limitations and is thus not accurate especially that it was based on disputable assumptions.¹⁷⁴ It must be noted that although the price of medicines is not the only obstacle to providing treatment to patients in developing countries, it stands out as an important one. This is because the actual production cost of a drug is only a fraction of its commercial price. The commercial price is determined by several factors including patents ‘which are used to exclude competition on the market for a long time. Patent regulations especially as they are promoted now do not differentiate between a patient in a developed country and one in a developing country and as such the prices of medicines

<http://www.msf.org/page.cfm?articleid=7055188E-889C-4D21-81F9267AA3B191E>.
Information accessed on 05-06-03.

¹⁷¹ Tapon, F, **A Transaction Cost Analysis of Innovations in the Organisation of Pharmaceutical R&D**, Journal of Economic Behaviour and Organisation, volume 12 pages 197-213.

¹⁷² Peter Drahos and Ruth Mayne, **Global Intellectual Property Rights: knowledge, Access and Development**, Palgrave Macmillan, 2002. Page 22.

¹⁷³ Ibid page 23.

¹⁷⁴ MSF, **MYTH: A typical new drug costs US \$500 MILLION**, from the 2001 MSF publication Fatal Imbalance, by the MSF Access to Essential Medicines Campaign and the drugs for neglected diseases working group. Available online at <http://www.msf.org/page.cfm?articleid=3D264BB1-EA84-423E-97190AB4F9F9CEE>.
Information accessed on 05-06-03.

do not correlate with the patients ability to pay for them.¹⁷⁵ For the pharmaceutical industry the aim is to get the most for the drug put on the market. When multinational companies have exclusive marketing rights over medicines, they tend to demand high prices which are often unaffordable to the vast majority of people living in developing countries.

The problem of high drug prices has been made worse by the fact that the public sector has literally left drug development in the hands of the pharmaceutical industry which is a private venture. They are business men and women whose main aim is profit and as such the industry invests almost exclusively in developing drugs that are likely to be marketable and profitable according to its own needs and not the needs of the world at large. The price of a medicine is not determined by public health needs nor related to production costs, the major determinant in most cases are patents. In fact when discussions for the implementation of the Doha Declaration were held, drug companies led by the Pharmaceutical Research and Manufacturers of America expressed fears that “relaxing patents beyond those for a limited list of epidemics would set a precedent leading to much broader erosion of their intellectual property rights.”¹⁷⁶ Clearly one can see that the aim of the industry is profit.

The pharmaceutical industry claims that in order to innovate further, they must recover the costs they invest.¹⁷⁷ This necessarily means that for the society to benefit, first profits must be realised at the most or guaranteed at the least. This kind of thinking sets societal needs and requirements second to the monopolistic profit oriented demands of patentees. Society’s main concern is access to the innovation whereas the patentees primary goal is to gain the most from the product protected by a patent. It must be noted that patent systems are concerned with inventions and not innovations¹⁷⁸, an innovation being a product or service new to the market and an invention being merely a discovery.¹⁷⁹ The resources required for an innovation include those spent on design, production, marketing and those already spent on the invention itself. Therefore by protecting an invention, a patent system gives an incentive to an inventor to develop the invention because the inventor is in that case assured of a reward. Society then gets the innovation as its reward for the grant of patent rights. What is important is that the system must be balanced in the sense that ‘it must take into account

¹⁷⁵ MSF, **The role of Patents in Access to Essential Medicines**, Available online at <http://www.msf.org/page.cfm?articleid=47871B51-83A7-4960-BDD40D60958FC49> information accessed on 05-06-03

¹⁷⁶ MSF, **As U.S balks on medicine deal, African patients feel the pain**, by Roger Thurow and Scott Miller of The Wall Street Journal, available online at <http://www.msf.org/page.cfm?articleid=D61BD0B7-FDB8-45E1-ADE7D308F7A96F3>

¹⁷⁷ Manufacturers claim that without the exclusive right to produce innovative drugs and collect commensurate profits, they will not have enough incentive to research new treatments and in the long run, that will undercut medical science and harm those who suffer, both the rich and poor. Source see note 176 above.

¹⁷⁸ Kingston W, **Direct Protection of Innovation**, Dordrecht, Kluwer Academic, 1987.

¹⁷⁹ Schott, K, **Industrial Innovation in the United Kingdom, Canada and the United States**, London British North American Committee, 1981.

the needs and priorities of developing countries and follow the principles set out in the TRIPS Agreement. Patents should not only benefit the innovator but also those who need access to the innovation because patents are not an end in themselves.’¹⁸⁰ They are public policy tools intended to benefit society as a whole.

Innovation in the pharmaceutical industry is strongly influenced and possibly determined by what happens in research. This is because for these industries, innovation is a process almost a routine in which output is basically a product of input. Stuart argues that “it then behoves such industries to spend heavily on research and to protect as best they can, not only their innovation, but also the systems on which their innovation and hence their competitiveness are dependant.”¹⁸¹ The lengths to which these industries will go to protect the patent system are a measure of how crucial it is to their existence and their position is not negotiable or so they claim.¹⁸² Indeed this is often what is going on in the negotiations over the implementation of the TRIPS Agreement and the flexibilities relating to access to cheap drugs. It is really evident in the manner the US keeps changing positions and always making proposals that are totally unworkable.

For instance the Third World Network¹⁸³ report from a workshop held to discuss the issue of the use of flexibilities by developing countries shows that the US wants to give its own interpretation to the provisions of the TRIPS Agreement. It states that “the US presentation focussed on the virtues of the patent system and of the TRIPS Agreement striking the proper balance. The US view of the flexibility available was the exception allowed under Article 30 and the interpretation of this given by the dispute panel in the EC/Canada generic dispute, (under which generic manufacturers could submit for marketing approval before the expiry of the patent). At the same workshop, the US also insisted that the compulsory licensing rights under article 31 were subject to the article 27.1 patent rights and underscored the importance of ‘adequate remuneration’ for use of the compulsory licensing provision under article 31 (h). In the US view, article 6 about parallel imports not being subject to dispute did not mean that parallel imports were allowed. Essentially the US was trying to show its dissatisfaction with the flexibilities in the TRIPS Agreement and its pro patent position backed by large multinational corporations.

It must always be remembered that as these discussion are going on endlessly, and no solution is forthcoming of how people in developing

¹⁸⁰ MSF, **the role of patents in Access to Essential medicines**, Supra note 175.

¹⁸¹ Stuart Macdonald, **Exploring the Hidden costs of Patents**, in Peter Drahos and Ruth Mayne, **Global Intellectual Property rights: knowledge, Access and Development**, Palgrave Macmillan, 2002. Page 25.

¹⁸² Ibid

¹⁸³ By Chakravarthi Raghavan, **Patents Vs Public Health issue won’t go away**, Third World Network. Available online at <http://www.twinside.org.sg/title/away.htm>. Information accessed on 20-10-03 at 13:45.

countries could have access to affordable drugs, malaria, tuberculosis and Aids are killing more than 6 million people every year.¹⁸⁴ These deaths are a huge blow to development in these countries. There is therefore an urgent need to find effective ways of improving access to existing drugs while maintaining a good level of incentives to inventors to invest more. The equation must be balanced. The TRIPS Agreement tries to strike a balance between the short-term need to make vital drugs available to those who need them and the long-term equally vital need to encourage research into new drugs. It does this by providing 20-year patents to reward research and to improve access to drugs, it imposes some conditions and allows certain restrictions on patent rights. These procedures are to be carried out or implemented by governments. In this way social expectations are likely to be realised.

Defenders of drug patents base their reasoning on the general assumption that intellectual property protection is an inducement to scientific and technological development. Cohen quotes an unequivocal declaration by the president of one large pharmaceutical group who stated that “generic products are acts of piracy which will be eradicated like 17th Century piracy was”.¹⁸⁵ It must be noted that pharmaceutical industry is against the use of compulsory licensing and parallel imports to gain access to cheap drugs because they believe these acts erode their much-needed profits. For these industries, the patent system is so compatible with their method of innovation, so integrated with corporate strategy that it has to be defended at all costs. The defence has generally been done through attacks in order to secure a strategic position through maintaining and strengthening the patent system. The situation is such that “in one way or another, the minimum terms and conditions of the foreign patentee must be met if the innovation is to be brought to the underdeveloped world.”¹⁸⁶ When it comes to access to essential drugs, this is where the problem lies because people in developing countries cannot afford to pay high prices but they are also in urgent need of effective cures. Which way forward then?

A Global Health Fund to fight Aids, malaria and tuberculosis was established in the year 2001. The main objective is to help developing countries with insufficient funds to purchase drugs from international sources. Interest groups have raised concerns over the lack of a clear plan of how the funds are to be spent. MSF has observed that “without a deliberate strategy to ensure the funding can be used to purchase from generic producers, including those in the South, the fund will be mainly a subsidy to the European and American drug industries. Governments of rich countries

¹⁸⁴ MSF, **Yes, drugs for the poor and patents as well**, by Mike Moore. Available online at <http://www.msf.org/page.cfm?articleid=7055188E-889C-4D21-81F9267AA3B191E>. Information accessed on 05-06-03.

¹⁸⁵ Cohen D, **La propriété intellectuelle, c'est le vol**, *Le Monde*, 8-9 April, pages 1, 13.

¹⁸⁶ Carlos Primo Braga, **the Developing Country case for and against Intellectual Property Protection**, Reprinted in Paul Goldstein, *International Intellectual Property Law: cases and materials*, university casebook series, 2001. Page 65.

must put people's lives before profits of industry. An equitable pricing system and restarting research and development for neglected diseases are a key part of improving access to life-saving medicines in the developing countries."¹⁸⁷ The Pharmaceutical industry often argues that patent protection is essential to ensure sufficient research and development for new medicines and that the reason why there is little research in tropical diseases is because of weak patent systems in developing countries.¹⁸⁸ But however experience has shown that drug development for neglected diseases will not increase no matter how strong the patent systems are because the people suffering from these diseases do not represent a lucrative market, enough to drive research.¹⁸⁹ In my opinion, these considerations are profit oriented and do not take into account the needs of society. It is this imbalance that must be solved with the implementation of the TRIPS Agreement both now and after full compliance by all member countries. However, how that will be done is another issue for consideration, but what is certain is that there must be a pro public health interpretation of the TRIPS Agreement now in order to ensure that essential medicines are available in an effective and equitable manner to people in developing countries.

It has been stated that "the size of the pharmaceutical industry, its potential to contribute to public welfare and its experience with R&D makes the industry a force to reckon with."¹⁹⁰ The pharmaceutical industry is quite capable of using this power to extort advantages for itself and to impose costs on others. Costs are always imposed on the consumer through exorbitant prices for protected goods. The pharmaceutical industry gains a lot of benefits from patent systems than any other industry does and because it spends a lot on R&D, the industry feels entitled to pontificate on innovation in general and on national competitiveness too. Discussions of the costs and benefits of patent systems tend to emphasise the benefits while ignoring altogether or trivialising at the most the costs attendant to such a system. Proponents of strong intellectual property protection for example argue that "there is an urgent need to discover and develop new drugs to fight diseases such as malaria, TB, AIDS and various other diseases endemic in poor countries. At present, the incentive to invest in new drugs for developing country diseases is very low. In part this is because of inadequate product patent protection for pharmaceuticals in several poor countries. Under the TRIPS agreement, WTO member countries without product patent protection for pharmaceuticals must introduce such protection. This is likely to increase incentives to produce new drugs. Any disincentive to the companies that are responsible for the development of these products will inevitably be felt in increased disease, death and suffering. Attenuation of patents through parallel importing or compulsory

¹⁸⁷ MSF, **Global health Fund must not be a subsidy for the drug industry**, available online at <http://www.msf.org/page.cfm?articleid=90EC1273-80E3-4D63-86A0ABB1BC083B8>. Information accessed on 05-06-03.

¹⁸⁸ MSF, **The role of patents in Access to Essential Medicines**, supra note 175.

¹⁸⁹ Ibid

¹⁹⁰ Miller W, **Productivity and competition: A look at the Pharmaceutical Industry**, Columbia Journal of World Business, fall, pages 85-88.

licensing would reduce the potential profitability of developing and marketing new drugs and should be avoided if at all possible.”¹⁹¹

This argument clearly emphasises only the need to have strong patent protection in developing countries but does not take into account the urgent need by people to have access to drugs to treat diseases. It is not possible for a sick person to wait for a future investment in R&D before they can have access to a cure. In fact in developing countries, it is really difficult to see the benefits of strong intellectual property protection because there are always these monopolistic considerations of maximum profit. The pharmaceutical industry has to first look at the returns before it can invest and that is why we have diseases affecting mostly tropical climates like sleeping sickness seeing no real investment into R&D. When we look at diseases like malaria, tuberculosis and HIV/AIDS which have ravaged the developing countries, MSF states that ‘although people in these countries cannot afford to purchase the drugs because of high prices, many patients and travellers in the USA and Europe can afford to buy them. Therefore pharmaceutical industry is able to invest in such because there is a potential market.’¹⁹²

Only where the industry is able to reap a benefit in terms of profits does it invest. These are purely profit considerations but experience has shown that ‘there is little empirical evidence of the impact of strong intellectual property protection on domestic R&D in developing countries’¹⁹³ although analysts have recognised the importance of intellectual property protection for ‘developing countries wishing to develop their scientific and technological capacity and benefit from the accelerated rate of technological progress’.¹⁹⁴ In order for this to take place it is important that compliance with the TRIPS Agreement does not restrict the scope to imitate technologies from richer countries as this is a necessary step on the path to developing innovative capacities. But as the situation stands at present, TRIPS will do little to promote global research and development of interest to poor countries because of low purchasing power.

It must be emphasised however, that even as developing countries strive to attain high levels of technological advancement, access to drugs is an issue requiring immediate attention and in my opinion cannot be treated like any other aspect of intellectual property. This situation brings us back to the need to balance the conflicting interests. In that light therefore, it must be

¹⁹¹ Roger Bate and Richard Tren, **TRIPS and Healthcare: Rethinking the Debate: malaria and patents**, July 2001. Available online at http://www.policynetwork.net/Iphealth/rethinking_the_debate_0701_batetren.htm.

Information accessed on 22-10-03 at 11:49 hours.

¹⁹² MSF, **The world’s most neglected diseases**, by Gavin Yamey. Available online at <http://www.msf.org/page.cfm?articleid=34BA82AD-853E-4476-B45F4BE4F349CA5>.

Information accessed on 05-06-03.

¹⁹³ Carlos Primo Braga, *supra* note 186.

¹⁹⁴ Bifani P, **Intellectual Property Rights and International Trade**, in the Uruguay Round: Papers on selected Issues, UNCTAD/ITP/10. New York: United Nations, 179-80.

noted that the TRIPS Agreement is meant to allow the developing world the advantages that use of and investment in modern technology can bring while at the same time allowing the developed world to secure an adequate return on its R&D.¹⁹⁵ The problem arises with implementation of the Agreement. Therefore, an intellectual property rights system is needed which will guarantee more equitable sharing of the benefits of technological development and advances between the populations of developed and developing countries. Ways must be sought to correct the imbalance between the current unbridled exercise of private property rights and public interest. Further more, the failure of the intellectual property system now in force to provide incentives for research and development into neglected diseases should be addressed preferably through an international legal instrument.

5.4 Patents and Public Policy

When it comes to setting guidelines for the operation of patent systems, economists and policy makers find themselves in a big dilemma in the area of innovation. This relates to how to reconcile the aims of intellectual property which provides innovators with incentives by restricting use of the innovation and thereby guaranteeing to them extraordinary gains, with the society's interest in allowing maximum use of the innovative products by keeping their price low and ensuring diffusion, imitation and improvement.¹⁹⁶ It must be noted that a fair balance between the private and social benefits of innovation requires the development of a policy framework which ensures not only that new technologies are created, but also one that ensures that competitors are able to work and improve on them.¹⁹⁷ From a social and ethical perspective, it is essential that policy mechanisms ensure that innovation results reach those who need them and an obvious example is the case of pharmaceuticals. Intellectual property is a significant component of innovation policy but its impact varies according to the sectors in question and the level of development of the country where such policy is implemented. A sound IP policy should strike a balance between the right to exclude and the right to use innovations. Too strict a system may inhibit innovation and many would be adopters would have no access to needed products and too lax a system may be a disincentive to the innovator.

Developing countries account for about 4% of the world R&D expenditure and as such depend on industrialised nations for transfer of technologies.¹⁹⁸ This therefore means that very strict systems in these countries will manifest themselves in high prices for protected goods. For this reason it is unlikely that patent systems will stimulate local innovation especially that few developing countries have substantial scientific and technological

¹⁹⁵ Article 7 of the TRIPS Agreement, 1995.

¹⁹⁶ OECD, **Technology and the Economy: the key relationships**, Paris, 1992. Page 50.

¹⁹⁷ Ibid page 51.

¹⁹⁸ UNDP. **Human Development Report, New York**, 1999

infrastructure. Abrupt changes in the IP systems can also make access more problematic because this affects the potential bargaining power of the parties.¹⁹⁹ It must be noted that developing countries are in urgent need to access innovations especially pharmaceuticals. The TRIPS Agreement has made provision for these countries to adopt measures aimed at encouraging price competition and access to protected goods and technologies. James Love argues that “contrary to much of the debate over the WTO rules for IP, the TRIPS Agreement is fairly permissive on the issue of government decisions to authorise third parties to use patents without the permission of patent owners.”²⁰⁰ States are free to legislate at the national level how this freedom can be used. However, as Kumariah observes “how this freedom is exercised depends on the strengths and weaknesses of science and technology in the respective country. So far it would appear that very few countries have adequate resources to make use of the opportunities provided by TRIPS.”²⁰¹ As such James concludes that what TRIPS permits and what countries actually do are two different things and in the end it is national law and practice which will be decisive in providing access to inventions and innovations.

In my opinion however, national law and practice do not really have an effect when it comes to gaining access to essential medicines by developing countries. As has been seen in chapter three, the whole system of TRIPS safeguards is a complicated web relying on licensing agreements most of which are beyond the reach of governments and research institutes in developing countries. In practice it is difficult to see how fairly permissive the TRIPS Agreement is especially that as its effective implementation is being discussed, major proposals by developed countries are almost always tilted towards profits. Many NGO analyses are instructive of this point and in fact my discussion of the implementation of paragraph 6 of the Doha Declaration in chapter three gives a clear picture of what is going on now. In my opinion therefore, it behoves the international community to come up with a concrete solution on the issue in order for the TRIPS objectives and principles to be realised for all. The US and the pharmaceutical industry ‘strongly object to use by developing countries of the TRIPS safeguards and other measures aimed at making aids drugs as well as other life-saving drugs more affordable and available in developing countries because they claim they unfairly curtail corporate profits. The US government further takes the view that it has the right to demand that countries do even more to protect intellectual property than is required by the TRIPS Agreement and the so-called ‘TRIPS Plus’ argument.²⁰² As usual the US has been effecting

¹⁹⁹ Peter Drahos, **Negotiating Intellectual Property Rights: Between Coercion and Dialogue**, in Peter Drahos and Ruth Mayne, page 162.

²⁰⁰ James Love, **Access to medicine and compliance with the WTO TRIPS Accord: models for state Practice in Developing countries**, in Peter Drahos and Ruth Mayne page 74

²⁰¹ Kumariah Balasubramaniam, **Access to medicines: Patents, Prices and Public Policy- consumer perspectives**, in Peter Drahos and Ruth Mayne, 102.

²⁰² Willem Pretorius, **TRIPS and Developing Countries: How Level is the Playing Field?** In Peter Drahos and Ruth Mayne, page 191.

this strategy through threats of withdrawal of benefits such as aid already agreed upon.

Although the US is being this adamant in terms of seeking excessive profits and championing calls for increased IP protection, during its first 100 years, it was a relatively young and developing country which refused to respect international intellectual property rights on the ground that it was freely entitled to foreign works to further its social and economic development.²⁰³ The UK attacks and complaints on the US for not providing strong patent protection had very little or no effect since American firms wanted the freedom to imitate British innovations and put them on the market.²⁰⁴ The industrialised nations having fully used the provisions of the Paris Convention to enable their pharmaceutical manufacturers to strengthen their innovative capacity, now deny the same privileges to developing countries. One thing that must always be kept in mind is that the TRIPS Agreement was born out of coercion and this has followed its implementation as well. Shiva states that 'the TRIPS Agreement has not resulted from democratic negotiations between the larger public and the commercial interests or between industrialised countries and the developing countries. On the contrary, it is the imposition of values and interests of big multinational companies on the world at large'.²⁰⁵ What needs to be straightened is whether this coercion should be allowed to continue or not. Judging from the Cancun meeting, it would be correct to say that developing countries seem to be realising the negative effects of allowing the US tactics to continue, but the question is whether they are able to remain united and withstand the pressure.

Patent protection for pharmaceutical products is one area where the problem of finding a proper balance between the goal of providing incentives for future investments into new drug discovery and the goal of providing affordable access to existing drugs is really acute. It is crucial on one hand from the social and public health point of view that new drugs and vaccines to treat and prevent diseases are generated and on the other hand, it is important that incentives are provided to the inventors. Therefore a good patent system must effectively promote this balance of interests. We must always keep in mind that even as we discuss issues of access to drugs for the poor in developing countries, there are major differences in the positions taken by developed and developing countries on this issue. 'Developed countries see intellectual property protection as essential for their citizens to gain trade advantage for their creativity especially in the area of pharmaceuticals. Developing countries on the other hand while not being totally against the issue of intellectual property protection per se, always

²⁰³ US Congress, 1986 Office of Technology Assessment, 'Intellectual property Rights in an Age of Electronics and Information', Washington DC, page 228. Reprinted in Peter Drahos and Ruth Mayne, page 105.

²⁰⁴ Washington Post (1989) 6 December, quoted in SELA (1988) in Hobbelink, Patenting and the Third World. Reprinted in Peter Drahos and Ruth Mayne, page 105.

²⁰⁵ Vandana Shiva, **Protect or Plunder? Understanding intellectual property rights**, David Phillip, Cape Town, 2001. Page 96.

question why they have to pay large sums of money to use technology of absolute necessity like drugs.²⁰⁶ In this way matters of a domestic nature in developing countries are treated as trade issues by developed countries and are subjects of international negotiations.

5.5 Balance of rights during the Uruguay Round of Trade Negotiations

During the Uruguay round of trade negotiations, with developed countries championing the call for linking IP with international trade and developing countries resisting, the TRIPS Agreement was debated against a background of at least two visions in conflict with each other on the role of private property in international trade. Developing countries argued that intellectual property issues are not part of international trade and their legitimate place is with the World Intellectual Property Organisation. Developed countries under pressure from powerful lobbies argued that it is essential for effective protection of intellectual property that there is a link with international trade. Shiva argues that in fact the TRIPS Agreement was not negotiated by member countries, but rather “it was imposed by multinational corporations who used the US government to force it on other members.”²⁰⁷ She argues that the TRIPS Agreement is based on a highly restrictive concept of innovation which is weighted in favour of big corporations and against citizens in general and developing countries specifically. TRIPS is against the basic needs and survival of the people and in favour of trade.²⁰⁸ Basically developing countries were worried that the linkage of intellectual property to international trade would mean high prices for essential commodities like drugs²⁰⁹, and they were right. Patented drugs are very expensive and beyond the reach of many in developing countries. Be that as it may, it must be noted that it is really difficult to assess the impact that an intellectual property reform would have on the overall prices in economies characterised by high levels of foreign trade protection and price distortions. This is because most if not all, patents in developing countries are owned by foreign multinational corporations.

Under the commodity conception of private property, TRIPS embodies a form of IPR protection aimed at realising the maximum profit in the market place. Under the alternative view, TRIPS can be conceptualised as embodying a vision that balances the returns producers seek for their R&D and the benefits that IPRS extend to society. The second view gives a much

²⁰⁶ Vandana Shiva, **Protect or Plunder? Understanding intellectual property rights**, David Phillip, Cape Town, 2001. Page 94.

²⁰⁷ Ibid page 95.

²⁰⁸ Ibid

²⁰⁹ Carlos Primo Braga states that “a major concern in developing countries over strengthening intellectual property is that it would not only bring significant increases in prices, but would also impair the process of technological diffusion. Found in Paul Goldstein, **international Intellectual property law: cases and materials**, university casebook series, 2001. Page 73.

broader concept of realising the goals set by the TRIPS Agreement. The 'maximum profit possible' view of the commodity conception of IPRS is justified on the basis that it is only fair and reasonable to compensate owners of IP for their investment in R&D. According to this view, those who put their effort, labour and capital into the market should get a return or reward for their input without the risk of piracy. Producers have an incentive to produce only when these returns are guaranteed. This view is based on the notion of the sanctity of private property. It justifies intellectual property protection as a necessary pre-condition for promoting transfer of technology to developing countries.

Furthermore, it must be noted that although patent rights are not natural rights given the fact that they do not come into being until the government has given such recognition to their existence, multinational corporations have tended to argue that they are in fact natural rights and seek protection as "owners of intellectual property".²¹⁰ This attitude makes the TRIPS Agreement an enforcement mechanism for multinational corporation rights to monopolise all production, distribution and profit at the expense of people especially those in developing countries. However justifiable this view purports to be, it must be noted that it understates the invariable tensions generated in the context of public policy. In fact, when it comes to access to pharmaceuticals, it is this commodity logic of private property that is bringing in so much tension. Although the TRIPS Agreement has provided for safeguards, realising such in developing countries is nothing but a nightmare as it depends on complicated systems most of which are beyond developing country capabilities.

5.6 Conclusion

However, even in the face of this, it is my opinion that the TRIPS Agreement is based on the co-existence of these two opposing views. Private rights as well as human rights and public health issues such as HIV/AIDS, tuberculosis and malaria and other diseases all have a legitimate place in the TRIPS Agreement. Therefore in order for the patent systems to deliver what they promise to developing countries, their implementation must be evaluated both in terms of rewards to patentees and also in terms of social utility which relates to demands on access and affordability. It behoves the international community especially developed countries to come with a pro public health interpretation of the TRIPS safeguards and the implementation of the Doha Declaration for the balance of rights to be achieved.

Further, provisions in the TRIPS Agreement must be read and interpreted in the light of its objectives and principles set out in articles 7 and 8 respectively. This interpretation finds support and authority in the Vienna

²¹⁰ Vandana Shiva, supra note 206 page 97.

Convention on the Law of Treaties, 1969.²¹¹ In conclusion therefore, it is important to re-emphasise the fact that IPRS do not exist in a vacuum, but are supposed to and are intended to benefit society as a whole. Mere existence of strong patent systems do not necessarily result in the fulfilment of the objectives of the TRIPS Agreement. And as such, in the context of health policies, patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented drugs, in a manner conducive to social and economic welfare and to a balance of rights and obligations.

²¹¹ Article 31 of this convention provides that “a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose

6 CONCLUSION

6.1 Reconciling Issues

This paper set out to critically analyse the extent to which the TRIPS Agreement actually protects public health in developing countries. It was the aim of the paper to discuss the legal options available to developing countries on access to cheap pharmaceuticals. Furthermore, it was the aim to analyse the conflict of interests between profit and public access to pharmaceuticals. The paper has been well informed by various sources on what is currently obtaining in the area of access to pharmaceuticals for people in developing countries. After tracing the historical development and adoption of the TRIPS Agreement and analysing the difficulties being encountered in its implementation, it is my well reasoned conclusion that the TRIPS Agreement is a business document established or masterminded by large pharmaceutical companies aiming to reap as much profit as they possibly can from the market. The only unfortunate thing is that much as profit in a business enterprise would be justifiable, when it comes to essential medicines, the situation changes. The need to balance the demands of companies with the public access to the innovations becomes crucial. At the conclusion of this paper, there is still no concrete solution of how this could be done. On one hand a reward must be given to the inventor (company) and on the other hand human rights such as health must be considered.

Much as the TRIPS Agreement makes provision for flexibilities of how developing country governments could access cheap drugs that is to say by using parallel imports and compulsory licensing, as a way of balancing the conflicting interests, the TRIPS Agreement has made no provision for the implementation of these provisions. Governments are supposed to be free to decide how they will implement them, but it goes without saying that most developing country governments are unable to implement them. They neither have the resources nor the competence to undertake such ventures. Basically, the flexibilities favour industrialised nations who have manufacturing capacities and are able to parallel import essential drugs. We have seen how this has been done in chapters two and three. This actually reflects the unfairness embodied in the TRIPS Agreement.

At Doha, ministers realised this lacuna and tasked the TRIPS Council to find a lasting solution to the dilemma faced by countries without manufacturing capacities wishing to use the TRIPS flexibilities. It is with regret that I note here that long past the December 2002 deadline there is still no concrete solution in place. The September 2003 Cancun meeting failed to resolve the issue and in the mean time people continue to suffer. The launch of the Doha Development Agenda has been nothing but rhetoric. It must be noted that although the TRIPS Agreement in the manner it is being implemented now does not really protect public health in developing

countries, the political decision to be bound by its provisions has already been taken and what remains is for developing countries to make the most of it. It is important that developing countries remain united for any solution to work, further, the international community more specifically the USA must change its attitude towards the issue and allow for a free use of the TRIPS flexibilities. Discussions of how best to solve the problem are still going on and as such it is essential that some proposals which could be incorporated in such are made. What follows therefore are some proposals of what could be done.

6.2 PROPOSALS

Firstly, on the issue of use of compulsory licensing, the international community must agree that compulsory licences can be issued both for domestic consumption as well as for export. There should be no strings attached. This solution is long overdue and the earlier it is done the better for all. Allowing production for export is an important step although it is not an end in itself. Ways must be sought to reduce dependency of production of generics on the complicated system of compulsory licensing and exceptions. Many poor country governments do not have the legal and administrative capacity to implement the TRIPS or use the safeguards effectively and are also vulnerable to diplomatic and economic pressure especially from the US. Unless this web is disentangled now, generic production will be progressively curtailed leaving the large pharmaceutical companies to consolidate their hold on the markets and that means high prices for patented drugs.

Secondly, the public sector must take an active role in the manufacturing of drugs. Currently this task has been left in private hands and that is why we see profits being put before people's lives. Public policies such as tax incentives and patent protection must take into account the welfare of the people at large. Other ways could be through reducing costs of research and development through grants, tax credits and government support for clinical trials. Another way could be through creating a purchasing fund which will be responsible for purchasing of the new drug as soon as it enters the market. Some of these are happening like the Medicines for Malaria Venture and the Global Alliance for TB Drugs Development. However these efforts need to be stepped up. By taking an active role in drug development, the public sector will not rely on the market as is the case with the pharmaceutical industry but will be driven by need. This calls on governments to devote serious political will to the issue for it to succeed.

Thirdly, since the adoption and implementation of the TRIPS Agreement has caused so much confusion, member countries could move for a review. The Agreement was born out of coercion but at review, members could have a chance to discuss the issues and agree on workable ideas. The difficulties being encountered in its implementation is a clear sign that even though it was overwhelmingly signed by almost all the members, the Agreement was

really forced upon members by the US and the pharmaceutical industry. Therefore a review should ensure to remove monopolistic private concerns and centre on public issues of importance like access to cheap drugs.

The fourth proposal is that research institutes and laboratories together with manufacturing firms must be established in developing countries by the pharmaceutical industry. Most developing countries already have trained personnel but for some specialisation skills which could easily be acquired if firms operated in these countries. In this idea could also be included the development of traditional medicine. Speaking with Mr Ceasar Mudondo, a pharmacist and consultant for the National Malaria Control Centre in Zambia on the issue of traditional medicine, it was discovered that much as there are effective cures in traditional medicine, the healers are not regulated. This could present some problems and so it is incumbent upon the governments to work on a law to regulate the operations of traditional healers. India has done so and it can be done by any other developing country with the necessary political will to do so. When such is the case, issues of patents, how long the patent period should be and how much royalty the inventor gets would easily be handled at national level.

International affairs are daunted with unnecessary bureaucratic procedures which make decisions very slow. So as parties are working on some of the above proposals, here are some of the recommendations that could be implemented immediately as a long-term solution is being awaited.

6.3 RECOMMENDATIONS

In the first place, the pharmaceutical industry must engage in the system of tiered pricing, whereby patented drugs are supplied to developing countries in need at a lower price than is on the developed country market. A good-tiered system targeted at developing countries must also be able to prevent product diversion or re-importation of cheap drugs to the developed country markets. This would undermine prices and profits if it were allowed to happen and would defeat the whole purpose of tiered pricing. Therefore in order to preserve the confidence in the system, safeguards must be put in place to ensure that cheap drugs remain in the countries where they have been supplied. Such safeguards include measures like differential labelling, packaging, trademarks and presentation for example shape, colour and size of tablet. Further there must be special enforcement procedures through contractual arrangements between the exporter and importer and the distributor of the drugs. It is essential that these measures do not then affect the free movement of goods within the community.

Secondly seeing that lack of access to drugs also has a relationship to lack of buying power, donations could come in handy in crisis situations. This is not a sustainable solution because it is entirely dependant on the company's will to make a donation. However, it can be done.

Thirdly the WHO should get actively involved in the issue of purchasing drugs for needy countries. More concerted efforts must be made by other organisations as well. Governments could also purchase the drugs for supply to hospitals and all government clinics. This requires establishment of medical schemes where people would pay a reasonable fee as a cost sharing measure. Those who are capable can pay more than others. It is a fact that not everyone in developing countries is poor. Furthermore, massive public financing is needed to help strengthen health care services and subsidise the purchase of medicines. Developed countries should generously donate funds to the Global Health Fund which funds must be used to purchase drugs from the cheapest source available on the market.

Many developing countries are facing crisis situations because of the debt burden and they do not earn much foreign exchange since they depend on agriculture. Most farmers are subsidised in developed countries, which is not the case in developing countries. Therefore the prices on the international market are not favourable. So as a fourth recommendation, lending institutions like the IMF and the World Bank should either write off the debts or alternatively they should write off and freeze the interest so that countries owing pay what they borrowed in the first place. This will go a long way in alleviating the suffering of the people in developing countries where poverty is also a determinant of who has access to what resources.

In the fifth place, it is important that as countries struggle to have access to drugs for effective case management, they also step up their preventive measures. The old adage says 'prevention is better than cure'. One can never go wrong with prevention. In relation to HIV/AIDS, countries could promote abstinence as one sure way of preventing the spread of the disease. This is not the easiest of solutions and so countries can also promote condom use. The blood used in blood transfusion must be thoroughly screened to ensure that it is free from HIV virus. In relation to malaria, countries in co-operation with the international community should promote and advocate use of insecticide treated mosquito nets (ITNS), periodic home spraying should be encouraged together with other measures that a particular country can identify. It is essential that pregnant women receive prophylactic anti-malarial drugs during their pregnancies to protect both the woman and the unborn child. Effective case management is important. Lastly for tuberculosis, crowding must be discouraged and all those infected must be kept in seclusion.

6.4 FINAL THOUGHT

When all is said and done, it is important that people in developing countries have access to essential medicines for effective case management. The international community is called upon not to fail on this one. The US

must change its attitude towards the issue and respond to a proven and urgent need. Profits must not be put before the lives of millions of people in developing countries. Patent protection is essential to give an incentive to inventors but how much profit a company gets out of an invention must be subjected to scrutiny so that there is no exploitation. Intellectual property, as a human right, must be balanced against other human rights in its implementation. There must be fair co-existence between and among conflicting interests for any international system to work and stand the test of time.

Supplement A

WORLD TRADE ORGANIZATION	
	WT/MIN(01)/DEC/2 20 November 2001
	(01-5860)
MINISTERIAL CONFERENCE Fourth Session Doha, 9 - 14 November 2001	

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

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

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

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

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

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

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

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

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

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