

UNIVERSITY OF THE WESTERN CAPE

FACULTY OF LAW

“The TRIPS ‘Flexibilities’ and Access to Essential Medicines in the Developing World: Are They Sufficient and is Our Implementation Adequate?”



A mini thesis submitted in partial fulfillment of the requirements for the LLM Degree in the Faculty of Law, University of the Western Cape

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Abbreviations and Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-retroviral
BI	Boehringer Ingelheim
COMESA	Common Market for East and Southern Africa
EC	European Commission
EU	European Union
FTA	Free Trade Agreement
GATT	General Agreement on Trade and Tariffs
GSK	GlaxoSmithKline
HIV	Human-Immunodeficiency Virus
IPR	Intellectual Property Rights
MFN	Most Favoured Nation
LDCs	Least Developed Countries
SACU	Southern African Customs Union
SADC	Southern African Development Community
R & D	Research and Development
TRIPS	Trade Related Aspects of Intellectual Property Rights
US	United States
USTR	United States Trade Representative
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



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1. Chapter 1: Introduction

1.1 Aims of the Study

The underlying rationale behind the protection of intellectual property rights (IPRs) is to strike a balance between the interests of IPR holders on the one hand and users of protected knowledge on the other hand.¹ The thesis seeks to achieve the following objectives:

- To create a good understanding of the historical development of the primary and secondary legal instruments related to the IPRs/public health debate. It is important to create this understanding in order to fully appreciate the significance of developments in the area.
- To determine to what extent a balance is struck by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) with reference to the flexibilities provided for in the Treaty, read together with the subsequent World Trade Organization (WTO) Ministerial Declarations and TRIPS Council Decisions.
- To evaluate the extent to which selected developing and least developed country (LDC) members of the WTO have taken measures to implement the said flexibilities, taking cognizance of their relevant strengths and weaknesses.
- To suggest ways in which select countries in the developing world specifically India and Zambia can take greater advantage of the flexibilities to promote better access to medicines while taking into consideration various opportunities and threats that are foreseeable.

¹ This principle is well enunciated in the Objectives of the TRIPS Agreement in Article 7.

- To identify Public Health aspects of TRIPS that the developing country and LDC WTO members would do well to address in further negotiations.

1.2 Background to the Study

The TRIPS Agreement extends to all WTO members the obligation to confer the range of IPRs traditionally enjoyed only in the first world. Ostensibly developing countries and LDCs benefit from the innovations triggered by strengthened IPRs, as well as from the provisions that are supposed to encourage the transfer of technology. The Agreement has been criticized, however, for being weighted in favor of special interests in developed countries, with few tangible benefits for people in the developing world.² A further and crucial criticism of the IPRs provided for by TRIPS is that they result in higher prices for essential drugs which restrict access to these crucial medicines for the poor.³

It was in this vein that from the onset of The Uruguay Round negotiations, the developing world strongly objected to IPRs being incorporated into the multilateral trading regime. The objections were made with particular reference to subjecting inventions related to public health and nutrition to strict patenting rules.⁴ WTO members like the United States of America (USA) and Switzerland on the other hand represented the interests of their pharmaceutical industry constituency (Pharma).⁵ It was these countries whose interests prevailed at Uruguay as IPRs were placed firmly within the realm of the WTO.⁶

² See, Frederick M. Abbott, "*The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference*", Florida State University College of Law, Public Law and Legal Theory Working Paper No 36, (2001), (Hereinafter, Abbott (2001)), : 'The developing countries and LDCs were placed under great political and economic pressure to accept terms that did not adequately take into account their specific interests'

³ See, Report of the High Commissioner, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, para 42

⁴ See, statements made by Indian delegate, Note by the Secretariat, Meeting of Negotiating Group of 12-14 July 1989, Negotiating Group of Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN. GNG/NG11/14, 12 September 1989, at, e.g. para.79.1.

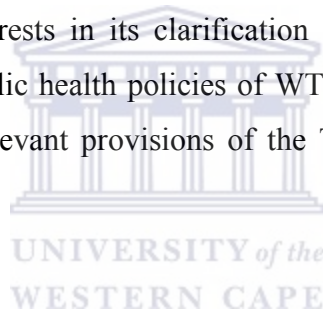
⁵ This abbreviation is frequently used by Frederick M. Abbott; I will do the same interchangeably.

Despite requiring developing countries to enforce stringent patent protection and exclusive rights,⁷ there were provisions in the TRIPS Agreement that left various policy options or flexibilities available for the developing countries to utilize.

Initially use of the flexibilities was curtailed in that developing countries that attempted to take advantage thereof were subjected to aggressive campaigns by developed countries and Pharma.⁸

The balance created by TRIPS was thus perceived to be firmly in favor of the North. The Doha Ministerial Declaration on TRIPS and Public Health in November 2001 is hailed as a turning point in redressing this imbalance.⁹

The value of the Declaration rests in its clarification of the relationship between the TRIPS Agreement and the public health policies of WTO members and in its definition of the flexibility of several relevant provisions of the TRIPS Agreement, in particular with regards to patents.¹⁰



In attempting to utilize the flexibilities a number of developing countries have issued compulsory licenses in the past few years.¹¹ Notwithstanding these efforts, further

⁶ See, Frederick M Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO", (2002) 5 Journal of International Economic Law, (hereinafter, Abbott, Lighting a Dark Corner), p 469 – 505.

⁷ See Article 27(1)TRIPS and Article 28 TRIPS

⁸ See Request for Consultations by the United States, Brazil Measures Affecting Patent Protection, WT/DS199/1, G/L/385,IP/D/23,8 June 2000, Request for the Establishment of a Panel by the United States, Brazil Measures Affecting Patent Protection, WT/DS199/39, January 2001, and the case brought by 39 pharmaceutical companies against Nelson Mandela and the South African Department of Health.

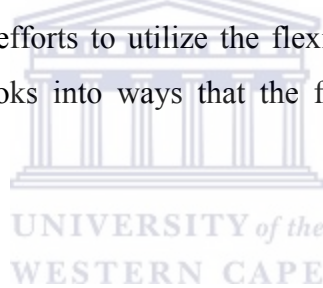
⁹ The Doha Declaration on the TRIPS Agreement and Public Health (2001) WT/MIN(01)/DEC/2. (Hereinafter, the Doha Declaration).

¹⁰ See Paul Vandoren, "Classification of the Relationship between TRIPS and Public Health Resulting from the WTO Doha Ministerial Declaration", (2002) 5. Journal of World Intellectual Property, 5-13.

utilization of the flexibilities by countries in the South is necessary to promote greater access to essential medicines. It is thus necessary to evaluate the factors that have to date hindered more meaningful use of the flexibilities and are likely to pose future threats to their utilization in order to suggest solutions to these obstacles and to facilitate greater access to essential medicines.

1.3 Problem Statement

The debate on the protection of IPRs in the domain of public health has been a heated one. Since the inception of the TRIPS Agreement, a huge divergence in the interests and thus perspectives of IPR holders as compared to those of the users of protected products has become evident. The challenge thus is to strike a balance between these deeply divided interests in the arena of public health. The thesis examines how the TRIPS Agreement has attempted to strike this elusive balance through the so called flexibilities. It assesses selected countries' efforts to utilize the flexibilities so as to tilt the balance towards their direction and looks into ways that the flexibilities could be used more meaningfully by the same.



1.4 Scope

The thesis will be limited to issues that arise from the patent protection provided by TRIPS in the domain of public health in developing countries and LDCs, the comparative analysis portion will focus on India and Zambia.

1.5 Significance of the Study

¹¹ See Tenu Avafia, Jonathan Berger and Trudi Hartzenberg, *"The Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A study of producing and importing countries"*.

Available at:

www.iprsonline.org/unctadictsd/docs/Trade%20and%20Competition%2030%203%2006%20final%20Edit1%202%202_.pd (Last Accessed on 5th September 2006). (Hereinafter, Avafia, Burger and Hartzenberg).

Two thirds (63%) of all adults and children with HIV globally live in sub-Saharan Africa, with its epicentre in southern Africa. One third (32%) of all people with HIV globally live in southern Africa and 34% of all deaths due to AIDS in 2006.¹²

Other pandemics such as malaria and tuberculosis are still rampant. Of the estimated one million malaria deaths that occur annually in the world, 90% are in Africa.¹³ In addition the extent of the damage that could be done by the recent strain of extreme drug resistant tuberculosis¹⁴ has not yet been determined.

Zambia like many sub Saharan African countries is disproportionately affected by diseases such as HIV/AIDS and malaria with an HIV/AIDS prevalence rate among pregnant adult women of 18-20% and approximately three million clinical cases of malaria every year resulting in 50 000 deaths annually.¹⁵

When one considers these statistics it becomes apparent that access to affordable medicines is crucial for countries where these deadly diseases are so prevalent. Therefore it is imperative for governments in these countries to develop policies and legislation that are geared to addressing these pandemics as effectively as possible. This reality underpins the thesis and it is intended that as a result of the analysis undertaken therein, some guidelines will be proposed that may prove useful to developing country and LDC governments in their domestic policy and in the multilateral arena.

1.6 Methodology

¹² See UNAIDS/WHO "AIDS Epidemic Update: December 2006" (Available online): http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf (Last accessed on 12th December 2006)

¹³ *ibid*

¹⁴ See, The Guardian, "Scientists discovered the strain in August 2006 among HIV-infected patients in the Kwazulu-Natal region". Available at: <http://observer.guardian.co.uk/world/story/0,,1863850,00.html> (Last accessed on 23rd August 2006).

Scientists discovered the strain in August 2006 among HIV-infected patients in the Kwazulu-Natal region. 'Fifty two of the 53 infected people are already dead'

¹⁵ See, UNAIDS. 2005. Report on the Global Epidemic. Available at: <http://unaids.org/epi/2005/doc/EPIupdate2005.pdf>

The research essentially entails two methodologies: a literature review and comparative analysis of relevant international instruments and the laws of India and Zambia. This will be done in order to gauge the potential utility of the TRIPS flexibilities and their implementation in the selected countries.

Thus, primary and secondary sources relevant to the TRIPS/public health debate will be essential. These include Treaties, WTO Declarations and Decisions, WTO Panel and Appellate Body decisions, WTO communications, domestic legislation of various countries, books, articles and internet websites.

1.7 Overview of the Chapters

The thesis consists of the following five chapters:

Chapter 1

The first chapter contains the introduction which sets out the context and scope of the research, identifies the major issues to be addressed and outlines the methodology.

Chapter 2

The second chapter describes the historical development of the TRIPS Agreement, the provisions of the Treaty that have come to be called flexibilities and the related WTO Declarations and Decisions on the implementation of the flexibilities.

Chapter 3

The third chapter contains a critique of the TRIPS Agreement. It seeks to address the question of whether the flexibilities read in conjunction with the related WTO instruments are sufficient to strike an acceptable balance between the interests of IPR

holders on one hand and the public health interests of users in the developing world on the other.

Chapter 4

The fourth chapter examines the extent to which India and Zambia have implemented and utilized the TRIPS flexibilities. It identifies and comments upon the factors which facilitate meaningful utilization of the flexibilities by such countries, as well as the prevalent obstacles.

Chapter 5

The final chapter considers and concludes as to what extent the TRIPS flexibilities are sufficient to advance access to medicines in developing countries and LDCs and the extent to which India and Zambia have made adequate use of the TRIPS flexibilities in the context of public health. Finally, some recommendations are proposed that may assist the countries to use the flexibilities to a greater extent.

2. Chapter 2: Laying the Basis

The Historical Dimension: An Illustration of the Build - up to TRIPS

This introduction is necessary to appreciate important historical facets of the drive to place IP within the realm of the multilateral trading system at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).

Most developing countries had originally acquired their patent laws via the colonial experience. This trend can be seen for instance in the case of the Philippines. While they remained a Spanish Colony it was Spanish patent law that applied. After December 1898 when the US took over the administration of the Philippines, patent applications went to the US Patent and Trademark Office (USPTO) for assessment under US law until 1947 when the Philippines adopted an independent patent system largely based on US patent law.¹⁶ Similarly India acquired a patent law in 1856 while under British rule.¹⁷

After World War II many developing countries became independent states. Some of them began to review the operation of the IP systems that had been left to them by their colonizers. So, for example, after independence India decided to redesign their patent law to suit her own national circumstances being a country with a low research and development (R&D) base, with a large population of poor people and having some of the highest drug prices in the world. Thus in 1970 a new patent law was passed which allowed the patenting of methods or processes that led to drugs, but did not allow the patenting of the drugs (pharmaceutical products) themselves. Further, patent protection for pharmaceuticals was only granted for seven years as opposed to fourteen years for

¹⁶ See, Arthur Wineburg, “Intellectual Property Protection in Asia”, (1999) 2, Lexis Law Publishing, Charlottesville, Virginia, quoted in Peter Drahos, “Developing Countries and International IP Standard Setting” Available at: http://www.iprcommission.org/graphic/documents/study_papers.htm (Last accessed on 11th January 2007). (Hereinafter, Peter Drahos).

¹⁷ See Peter Drahos, p 12.

other inventions. This law became the foundation stone for a highly successful Indian generics industry.¹⁸

During the same period Brazil, Argentina, Mexico and the Andean Pact countries all passed laws that saw patent rights in the pharmaceutical area weakened. Developing country generic manufacturers thus became a threat to the western pharmaceutical cartels that had dominated the international pharmaceutical industry. Mexico's entry into the manufacture of steroids in the 1960s, for example, contributed to the end of the European cartel that had dominated production until then.¹⁹

The new IP standards adopted were as varied as they were novel as they were enacted to meet the individual situations and needs of the respective states. This was unfavorable to technology based industries as they preferred a legal framework that would maximize predictability and uniformity.

All this occurred while the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) administered by the World Intellectual Property Organization (WIPO) was in operation. In fact a study undertaken by WIPO in 1988 for the negotiating group that was dealing with TRIPS in the Uruguay Trade Round revealed that of the 98 members of the Paris Convention, 49 excluded pharmaceutical products from protection.²⁰

These events from the perspective of pharmaceutical industry leaders in the north indicated that WIPO had failed to secure their interests in higher and standardized patent regimes. They were also seen as catalysts for thriving generic industries in countries like

¹⁸ Ibid

¹⁹ G. Gereffi, *The Pharmaceutical Industry and Dependency in the Third World*, Princeton University Press, Princeton, New Jersey, 1983, quoted in Peter Drahos (note 1).

²⁰ See, WIPO (1988) 'Existence, scope and form of generally internationally accepted and applied standards/norms for the protection of intellectual property', WO/INF/29 September 1988, issued as GATT document number MTN.GNG/NG11/W/24/REV.1., quoted in Peter Drahos (note 1).

India, Brazil, Mexico and Argentina that were eroding the northern monopoly in the pharmaceutical industry.

WIPO was not an ideal forum from which to protect the northern interest in strengthened IP laws as their proposals could always be defeated by developing country blocs whose national interests conflicted with the interests of developed countries. Another perceived inadequacy of WIPO was the lack of an effective prohibitive enforcement mechanism. Pharma's dissatisfaction with the protection of their interests during the 1970's was encapsulated in the words of then General Counsel to Pfizer Lou Clemente who declared:

“Our experience with WIPO was the last straw in our attempts to operate by persuasion”.²¹

The US responded in the 1980's by adopting a policy of forum shifting by pushing for IPRs to be made a multilateral trade topic under the GATT. This US drive marked the birth of the TRIPS agreement.

2.2 The Incorporation of IP into the Multilateral Trading System

As noted above, there had been a trend in the 1970s toward developing countries adapting their IPR systems in line with their varied levels of development. This conflicted with the interests of various industries in the industrialized countries (including pharma) which led the industrialized countries together with concerned industries in the 1980's to take the baton from the Anti - Counterfeiting Coalition and seek to reverse the direction of change from greater flexibility toward a tightened IP system.²²

²¹ See 'Pfizer: Protecting Intellectual Property in a Global Marketplace', Harvard Business School, 1992, 8, quoted in Peter Drahos (note 1).

²² The Anti Counterfeiting Coalition refers to the group of trademark holding firms which in the 1973-1979 GATT Tokyo Round, unsuccessfully lobbied for the inclusion of an anti - counterfeiting code in the GATT.

The convergence of several factors explain the predisposition of certain industrialized countries, particularly the US to identifying strengthened IPRs for their industries with national interests and the priority given to reforming the IP system worldwide. The most pressing of the said factors as advanced by Professor Correa are as follows:²³

First, technology had become a crucial factor in international competition, particularly for the production of technology intensive goods and services. This trend was reflected by the increase of R&D expenditure by industrialized countries since the 1970s with growing participation of the private sector in R&D. Half or more of R&D expenditure in these countries was funded by the private sector, particularly by big companies in science intensive industries such as pharma.²⁴

Secondly, the reduction of Trade barriers in developing countries increased the chances of direct exports to those countries, strengthened IPRs were seen as necessary to allow industrialized countries to trade rather than diffuse their technology. They thus sought exemption from the obligation to exploit patented inventions locally or to transfer technology to local firms as many developing countries required in their patent laws.

Thirdly and perhaps most crucially, US leadership in manufacturing and technology was challenged by the catching up of Japan and a few other countries, including Newly Industrialized Countries (NICs) which became aggressive competitors in technology intensive industries. The erosion of US technological leadership coupled with the high US trade deficit were perceived in the US as resulting from open IPR systems that allowed other countries to imitate US innovations and gave rise to the proliferation of counterfeiting and piracy.

²³ See, Carlos M. Correa, “Intellectual Property Rights, The WTO and the Developing Countries: The TRIPS Agreement and Policy Options”, Published by Third World Network, (2000).

²⁴ Ibid.

The monopoly position conferred by strengthened IPRs was thus seen as an instrument for neutralizing the relative loss in competitiveness of US products and services as well as preventing further catching up based on imitative paths of industrialization.²⁵

The above factors together with industrialized countries losing faith in WIPO's ability to protect their interests made the dispute settlement mechanism within the GATT seem very attractive as it allowed cross retaliation for non - fulfillment of specific obligations. The incorporation of IP into the GATT framework thus became a crucial issue for industrialized countries. This forum shifting however could only be achieved at the negotiation table.

2.3 The TRIPS Negotiations

The Uruguay Round introduced multilateral negotiations on IPRs which resulted in the TRIPS Agreement. The treaty is by coverage the most comprehensive instrument on IPRs in existence establishing minimum standards on 7 categories of IPRs including most crucially, patents.²⁶ The treaty was a welcome result for industrialized countries and their industries.

The developing countries and LDCs were ambivalent throughout the negotiations as they foresaw the minimum standards having a whole host of serious implications for their development. Of particular relevance to this paper are the implications arising from the ability of the patent holder to exclude direct competition and charge higher prices for patented medicines than would have occurred in a competitive market making the medicines unaffordable in countries disproportionately affected by disease.

²⁵ Ibid

²⁶ Copyrights and related rights, including computer programs and phonograms and databases, trademarks, geographical indications, industrial designs, integrated circuits and undisclosed information (trade secrets) were the other protected categories.

In spite of the concerns of developing countries, the TRIPS Agreement extended globally (among WTO members at least), the standards of IP protection traditionally enjoyed only in the industrialized world.²⁷

Many in the south are of the view that the process of drafting the TRIPS Agreement was not a real 'negotiating' process, for the exercise hardly involved any give and take in that developing countries made considerable concessions in agreeing to the higher levels of protection of IPRs demanded by industrialized countries, while they were not in any way compensated by advantages in this or other areas of the Uruguay Round negotiations.²⁸

This view can be juxtaposed with the northern perspective that the TRIPS agreement was produced as a result of bargaining amongst sovereign and equal states all having the capacity to conclude treaties and which agreed to TRIPS as part of a larger package of trade-offs in which there were gains for all.

The theory of democratic bargaining propounded by Professor Drahos may serve as an objective standard from which to gauge the legitimacy of the TRIPS negotiation process.

The theory comprises 3 elements that should be fulfilled in order to legitimize a bargaining process. Firstly, the condition of representation meaning all relevant interests must be represented in the process. Second, the condition of full information that is all those involved in the negotiation must have full information about the consequences of various possible outcomes. Finally, the condition of non - domination, ie no party must coerce others.²⁹

²⁷ See, Paul Vandoren, "Classification of the Relationship between TRIPS and Public Health Resulting from the WTO Doha Ministerial Declaration", (2002) 5. *Journal of World Intellectual Property*, 5-13

²⁸ See, South Centre, 'Trade-Related Intellectual Property Rights. A New Regime', Available at: <http://www.southcentre.org/publications/trips/tripsmaintexttrans-01.htm> (Last Accessed on 13th January 2007)

²⁹ See Peter Drahos (note 1)

With regard to the first element, the north would argue that the condition was met in that developing country leaders like India and Brazil sent negotiators.

The south on the other hand would argue that the first condition of the theory was not met because exclusion was practiced, the TRIPS negotiations therefore failed to meet the first condition on those grounds.

The most convincing evidence in favor of the southern view is that the negotiations involved the use of non-representational circles of consensus. This describes a process which emerged in the GATT framework whereby the issues were first placed before a smaller group to be meted out and then expanded to create larger circles until the goals of those in the inner circle had been met.³⁰ The first three circles included US, Europe, Japan and Canada (Quad) respectively and it was in these three groups that much of the real negotiating was done and where the consensus and agreement that mattered was obtained. The circles of consensus meant effectively that the TRIPS Agreement was very much a product of the first the Quad states, therefore developing countries and LDCs were excluded from any groups which mattered.

The use of circles of consensus also makes it difficult to claim that the second condition of democratic bargaining, namely full information, was fulfilled. The composition of the circles meant the US and Europe could move amongst all the key groups. This allowed them to soak up more information than anyone else about the overall negotiations and whenever they needed higher levels of secrecy they could reform into a smaller negotiating group.

The third condition of democratic bargaining one could argue was the condition of democratic bargaining which was breached in the most egregious fashion during the TRIPS negotiation process, an argument difficult to contend.

³⁰ See, Christophe Bellmann, Graham Dutfield and Ricardo Meléndez - Ortiz, "Trading in Knowledge Development Perspectives on TRIPS, Trade and Sustainability", ICTSD (2003), Published by Earthscan Publications

To support this argument it can be pointed out that in 1988 the US adapted Section 301 of its Trade Act 1974 to meet its IP objectives. This required the United States Trade Representative (USTR) to identify foreign countries that denied adequate and effective protection of IPRs or denied fair and equitable market access to US IP holders. Also significant were changes to the system of Generalized Special Preferences (GSP). The President in deciding whether a developing country's products were to gain preferential treatment under the GSP system had to give 'great weight' to its protection of foreign IPRs.

Section 301 proved instrumental to US interests three years after the Uruguay Ministerial Declaration in 1986. India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia continued to argue for a narrow interpretation of the Ministerial mandate on the negotiation of IP that is only to "clarify GATT provisions relating to IPRs and counterfeit goods" and to "develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods".³¹

The US broke the resistance of these 'hard liners' using the amended or Special 301 which swung into action in the beginning of 1989. When the USTR announced the targets of Special 301, five of the ten developing countries that were members of the hard line group that were opposing the US agenda found themselves listed for bilateral attention. Brazil and India, the two leaders, were placed in the more serious category of Priority Watch List, while Argentina, Egypt and Yugoslavia were put on the Watch List.³²

Thus for many developing countries, gaining access to the closed and subsidized agricultural markets of developed countries was a carrot that proved too hard to resist; while the threat of US trade sanctions was a stick that mandated compliance. These

³¹ See Peter Drahos, p14.

³² Ibid

realities point strongly towards the argument that the TRIPS negotiations failed at least to meet the democratic bargaining condition of non - domination as Special 301 and the threat of losing out on market access were ever prevalent factors throughout the negotiations that resulted in the TRIPS Agreement.

2.4 The TRIPS Flexibilities Identified

The aim of this section is to create a good understanding of what is meant by the term “TRIPS flexibilities” and to clearly identify which of these flexibilities will be discussed in the remainder of the thesis.

The TRIPS flexibilities refer to the ability of WTO Members to exploit creative solutions to transpose into national law and practice those concepts that the TRIPS Agreement simply enunciates but does not define.³³

The flexibilities to be discussed were selected based on the availability of data and relevance to developing countries and LDCs; they are as follows:

Transition periods; patentability criteria and exemption from patentability; parallel importation; as well as compulsory licensing and government use.

2.4.1 Transition Periods:

Transition periods constitute the amount of time available for a WTO Member to bring itself into full conformity with the obligations of the Agreement.³⁴ The periods prescribed to developing countries have lapsed. Accordingly, developing countries were obliged to implement the TRIPS Agreement by enacting patent legislation that complied with the

³³ See, “Advice on Flexibilities under the TRIPS Agreement”. Available at: http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (Last Accessed on 12th May 2007).

³⁴ See Articles 65 and 66(1) TRIPS of the TRIPS Agreement.

treaty's minimum standards of IP protection by 2000.³⁵ With regard to pharmaceutical patents, the deadline for implementation in countries that previously did not grant such protection of a compliant product patent regime was 2005.³⁶

Although the developing country deadlines for full implementation have passed, meaningful usage of the developing country transition period by countries such as India has facilitated access to affordable generic medication in many developing countries even to this day.³⁷ The use of other flexibilities by developing countries will assume tremendous importance in years to come now that they must comply with the TRIPS Agreement.

Full TRIPS compliance is crucial not just for developing countries which have had to bring their patent laws into compliance, particularly India with its' significant pharmaceutical manufacturing capacity. It is crucial for LDCs with limited to no pharmaceutical manufacturing capacity because these countries have relied heavily on India to supply affordable generic medicines.

With regard to LDCs, a decision by the WTO's TRIPS Council in 2005 extended the transition period for least-developed countries by seven and a half years. The transition period was due to expire on 1 January 2006; 11 years after the TRIPS Agreement came into force.

The decision does not affect the transition period for patents for pharmaceutical products, which was agreed in 2002 pursuant to paragraph 7 of the Doha Declaration; least-developed countries will not have to protect these patents until 2016.³⁸

³⁵ See Article 65.2 TRIPS of the TRIPS Agreement.

³⁶ See Article 65.4 TRIPS of the TRIPS Agreement.

³⁷ For instance in 2003, the Malaysian government issued a compulsory license to import generic ARVs from India to be used in public hospitals.

³⁸ See Article 66.1 TRIPS and Council for TRIPS, "Extension of the transition period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for certain obligations with respect to

2.4.2 *Patentability Criteria and Exemption from Patentability:*

The TRIPS Agreement requires that member states grant patents to inventions that meet the criteria of novelty, inventive step and industrial applicability.³⁹ Yet innovation in the pharmaceutical industry as in other technology based sectors has shifted away from the premise of absolute novelty towards a situation where innovation is no longer based on technological breakthroughs but on the routine exploitation of existing technologies. Therefore pharmaceutical companies often make minor improvements to existing drugs and identify new uses of known products as a means of extending commercial benefits derived from existing products. When patents expire, new patent applications can thus be used to prolong market exclusivity.⁴⁰

Developing countries and LDCs must not fall into the trap of granting patent protection for such innovations. There is sufficient scope within the interpretation of the patentability criteria of the TRIPS Agreement to exclude such ‘innovations’ from protection.

2.4.3 *Parallel Imports and Exhaustion of IPRs:*

Due to a wide range of market factors, the price of brand name and generic medicines may be lower in one country than the other.⁴¹ Thus parallel importation refers to the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. A patent

pharmaceutical products,” 1 July 2002, WTO document IP/C/25 and Council for TRIPS, “Extension of the transition period under Article 66.1 for least-developed country Members,” 30 November 2005, WTO document IP/C/40

³⁹ See, Article 27.1 of the TRIPS Agreement.

⁴⁰ See, Carlos M. Correa, "*Ownership of Knowledge - The Role of Patents in Pharmaceutical R&D*". Available at: <http://www.iprsonline.org/resources/health.htm>. (Last Accessed on 13th January 2007)

⁴¹ Tenu Avafia and Savita Mullapudi Narasimahan, ‘*The TRIPS Agreement and Access to ARVs*’, United Nations Development Programme (2006). (Hereinafter, Avafia and Narasimahan).

holder may have the exclusive right to manufacture his product and to put it on the market but once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the subsequent resale of that product since their rights over the product have been exhausted by the act of selling the patented products.⁴² The flexibility of members to determine their own regimes for international exhaustion is enunciated in the TRIPS Agreement and reaffirmed in the Doha Declaration.⁴³

2.4.4 *Compulsory Licensing and Government Use:*

A compulsory license refers to authorization by the State to a third party to exploit a patented invention, generally against remuneration to the patent holder.⁴⁴ The TRIPS Agreement does not set out grounds for the grant of a compulsory license leaving countries with a large degree of flexibility to determine the grounds based on their public health requirements.⁴⁵ This flexibility has been reaffirmed by the Doha Declaration.⁴⁶

Government use of patents for public non commercial use is available under the TRIPS Agreement. This is similar to compulsory licensing in that it involves the non voluntary exploitation of a patented invention against remuneration to the patent holder; the crucial difference however is that it does not necessitate negotiation with the patent holder. This facilitates more expedient availability of generic equivalents of patented medications.⁴⁷

⁴² Vélasquez & Boulet (1999) quoted in Sisule F Musungu and Cecelia Oh, *'The use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?'*. Available at: <http://www.southcentre.org/publications/SouthPerspectiveSeries/TheUseOfFlexibilitiesInTripsFinal.pdf> (Last Accessed on 13th January 2007) (Hereinafter, Musungu and Oh).

⁴³ See Article 6 of the TRIPS Agreement and Paragraph 5(d) of the Doha Declaration.

⁴⁴ Intellectual Property Rights: Implications for Development: UNCTAD-ICTSD Policy Discussion Paper, Chapter 6 Available at: http://www.ictsd.org/pubs/ictsd_series/iprs/PP/PP_3CH_06.pdf (Last Accessed on 13th January 2007)

⁴⁵ See, Article 31 of the TRIPS Agreement.

⁴⁶ See paragraph 5(a) of the Doha Declaration.

⁴⁷ See Article 31(b) of the TRIPS Agreement

Thus it can be seen that notwithstanding the success of developed countries in bringing a comprehensive agreement on trade related IPRs into the multilateral trade framework, the developing countries were able to negotiate these flexibilities into the TRIPS Agreement.

These provisions should be read together with The Doha Declaration of 2001 and the TRIPS Council Decision of 2003,⁴⁸ which clarify and supplement the policy options available



⁴⁸ Council for Trade Related Aspects of Intellectual Property Rights “Implementation of Paragraph 6 of the Doha Declaration on Public Health”.IP/C/W/405 (Aug. 30, 2003), (hereinafter, August 30th 2003 Decision), The Doha Declaration and the August 30th 2003 Decision will be discussed at length in Chapter 3 below.

3. Chapter 3: Are the TRIPS Flexibilities Sufficient?

3.1 Introduction

As mentioned above,⁴⁹ in the context of patents and public health, the TRIPS Agreement is charged with the responsibility of advancing a balance of interests between innovators or producers of knowledge in the pharmaceutical sector and users of that knowledge. This chapter analyzes the manner in which the TRIPS Agreement attempts to strike that balance and concludes by answering the first question posed in the title of the thesis regarding the TRIPS flexibilities in the current context, namely, "are they sufficient".

3.2 Pertinent Features of TRIPS that Advance the Interests of Producers

3.2.1 Rights Conferred



Article 28 of the TRIPS Agreement is one of the most important provisions for the pharmaceutical producers because it is the provision that prescribes the exclusive rights that WTO Member states are obliged to confer unto products and processes qualifying for patent protection.

The pharmaceutical industry considers the protection of patent rights to be a critical precondition for private investment in research and in the development of new drugs. The importance of patent protection in the pharmaceutical industry can be attributed to the ease with which new chemical entities can be imitated in comparison with the large R&D outlays and long product cycles associated with research-based drugs. Thus, the

⁴⁹ See the section in Chapter one setting out the aims of the study

pharmaceutical industry is particularly dependant on the patent system to recoup its R&D costs, generate profits and fund further R&D projects.⁵⁰

The essence of patent rights is thus the exclusion of all forms of competition as noted by the Panel in the *EC - Canada case*.⁵¹ The Panel stated as follows:

“The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity...”

Article 28.1(a) confers a negative right on the holder of a patent on product to stop all third parties who do not have the owner’s consent from making, using, offering for sale, selling or importing the said product.

It is important to highlight that with regard to the making of patented pharmaceutical products by unauthorized third parties, the exclusive right applies even if an independent method or process of producing the product was used. It is also pertinent that it is an infringement of this provision for a third party to make a patented product, regardless of the purpose of the third party's action.

Under the Paris Convention, the act of importation was not enumerated as an exclusive right of the patent.⁵² Thus, the TRIPS regime grants greater protection with regard to pharmaceutical products than existed previously. This is a welcome result for pharma because the exclusive rights conferred by TRIPS represent an avenue to exclude competition from countries that had created successful pharmaceutical industries by not

⁵⁰ See, The Final Report of the Commission on Intellectual Property Rights. Available at: http://www.iprcommission.org/graphic/documents/final_report.htm. (Last Accessed on 14th May 2007). (Hereinafter, IPR Commission, Final Report) , p 34.

⁵¹ *Canada – Patent Protection for Pharmaceutical Products* WT/DS 114/R (Hereinafter, EC- Canada).

⁵² Lionel Bently and Brad Sherman, "Intellectual Property Law", Oxford University Press, New York (2001), p. 490.

adopting product patent regimes and imitating pharmaceuticals originating from developed countries.⁵³

The result for IP users is a limitation of their opportunities to import less expensive generic copies of pharmaceutical products. This consequence is what necessitated a number of developments to try to reconcile exclusive patent rights under TRIPS with the public health interest in the developing world. These developments include *inter alia*, paragraph 6 of the Doha Declaration and the ensuing August 30th Decision which will be discussed at length below in the current chapter.

It is important to note that in an attempt to consider the interests of the developing world, the exclusive right of importation was expressly subjected to the principle of exhaustion of IPRs in footnote 6 to Article 28.⁵⁴

Article 28.1(b) has two parts; the first part confers unto a patentee, the exclusive right to use a patented process (method of making a product). The second part grants exclusive rights with regard to a product that is directly obtained from a patented process; the said exclusive rights include using, offering for sale, selling and importing.

As opposed to patented processes which were generally protected by countries under the Paris Convention, the extension of protection to products directly obtained by the patented process, as provided for under Article 28.1(b), had not obtained broad acceptance before TRIPS. Such extension had been applied in some developed countries, often with considerable controversy. The extension was not provided, however, in the laws of most developing countries where process patents generally only covered the right

⁵³ See, Chapter 2 above, the section entitled "The Incorporation of IP into the Multilateral Trading System" and Peter Drahos, p8.

⁵⁴ Exhaustion of IPRs will be discussed at length below in the section entitled, "Parallel imports and Exhaustion of IPRs".

to exclude others from the domestic use of the process, but not to impede the importation of products manufactured abroad with the patented process.⁵⁵

Article 28.1(b) of the TRIPS Agreement addresses an important lacunae for producers as without such extension, a process patent granted in country A could not be invoked in cases where the patented process has been utilized in country B and the resulting product is imported into country A. The extension of the protection to the product obtained directly by the patented process addresses this problem.

The extension of rights to cover products directly obtained by a patented process is greatly strengthened when read together with Article Art 34.1 of the TRIPS Agreement. Article 34.1 obliges members to empower their judiciary to reverse the legal burden of proof in civil proceedings concerning infringement of Article 28.1(b) from the patentee (he who asserts) to the alleged infringer. I.e. the alleged infringer can be ordered to prove that the process used is different from the patented process.

Shifting the evidential burden strengthens the rights conferred with regard to a product directly obtained from a patented process because proving that a product is directly obtained by a patented process may not be a simple matter. This is evident when one considers that Article 28.1(b) applies when a product has been directly obtained by the patented process, and not merely when it is obtainable by it. The difference is important, since in the chemical sector the same product may, in many cases, be obtained through different processes and it may thus be difficult for the patentee to prove whether a product has been directly obtained by his patented process.⁵⁶

Article 33 of the TRIPS Agreement provides that the exclusive rights conferred on a patentee must not end before twenty years from the date of filing. This principle has been

⁵⁵ UNCTAD-ICTSD, "Resource Book on TRIPS and Development" Available at: www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (Last Accessed on 20th May 2007). (Hereinafter ICTSD Resource Book), p 421.

⁵⁶ Ibid.

underpinned by the WTO Panel in the *Canada -Term of Patent Protection* case,⁵⁷ where the panel dismissed Canada's attempts to legitimize patent laws that conferred a period of effective exclusive rights for a period less than twenty years.⁵⁸

3.2.2 *Non Discrimination*

The second portion of Article 27.1 is known as the "non discrimination" clause. It forbids WTO Member states from discriminating in terms of availability or length of patent protection based on the place of the invention, the field of technology or whether the products are imported or locally produced.

The Paris Convention contained no equivalent to the non discrimination clause. Parties to the Convention could accordingly discriminate with regard to patentability based on whatever grounds were deemed in accordance with their national interests. As a result, before the TRIPS Agreement, more than fifty countries including India did not grant patent protection for pharmaceutical products.⁵⁹ Article 27.1 erased this flexibility.

It was expressly permissible under the Paris Convention to grant a compulsory license and thus inhibit a patentee's exclusive rights on the basis of the patent having not been worked locally, that is, if the patented product was not produced domestically. The TRIPS regime is less clear as to the consistency of compulsory licenses on the grounds of failure to work locally with the non discrimination clause. An example of a patent regime with non working as a ground for compulsory licensing is Brazil's 1996 Industrial Property Act which stipulates that a patent shall be subject to compulsory licensing if the patent is not worked in the territory of Brazil.⁶⁰

⁵⁷ *Canada- Term of Patent Protection*, WT/DS170/AB/R (Report of the Appellate Body) (Hereinafter *Canada- Term of Patent Protection*).

⁵⁸ See, *Canada-Term of Patent Protection*, para103.

⁵⁹ ICTSD Resource Book. p 370.

⁶⁰ Anna Lanoszka, "The *Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries*", p 10. Available at <http://ips.sagepub.com/cgi/reprint/24/2/181> (Last accessed on 19th February 2007).

This Brazilian provision would have been expressly permissible under the Paris Convention but it was challenged under the TRIPS regime by the US and EU under the DSU. In settlement, Brazil agreed to a deal in which it would consult with the US before issuing a compulsory license for a product patented by a US company. This is a considerable limitation of Brazil's ability to determine its own national policy in favor of the protection of the interests of US pharmaceuticals brought about by the non discrimination clause of TRIPS as opposed to the previous lack of such restriction.

There is however, a strong case to argue that a failure of local working ground is TRIPS compliant. Three arguments to that effect follow below:

First, paragraph 5(b) of the Doha Declaration expressly confirms what was already evident from Article 31 of the TRIPS Agreement, that WTO Members are free to determine the grounds for issuing compulsory licenses.

The second argument is that in the *EC-Canada* case,⁶¹ the Panel distinguished between discrimination and differentiation made for *bona fide* purposes. The Panel made it clear that the conduct prohibited in Article 27.1 is discrimination while differentiation for *bona fide* purposes is permitted. Thus there is a strong case to argue that a local working requirement backed by the threat of non voluntary use is a differentiation for a *bona fide* purpose, namely, facilitating the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations as envisaged by the objectives of the TRIPS Agreement as set out in Article 7.

Finally, although the Panel accepted the presumption of EC and Canada that non discrimination applies to non voluntary use, it can be argued that this presumption was accepted in the context of the Panel interpreting Article 30 and that Article 27.1 deals

⁶¹ *EC- Canada*.

with patentability requirements while non voluntary use is subject to Article 31, a self standing Article. As such the non discrimination clause does not apply to compulsory licenses.⁶²

Moreover, the decision of the US to not pursue the case can be regarded as indicating the weakness of its claim against Brazil.

The non discrimination clause is fundamental to the interests of the industrialized countries and pharma as it allows them to invest in developing countries and LDCs without the fear that their patents would be targeted for discriminatory treatment. Another crucial effect of the provision is that it achieves one of the main objectives that industrialized countries had when they sought to place IP within the multilateral trading system, namely the ability to trade rather than diffuse their technology through relief from the obligation to exploit patents locally (although this may be limited by local working requirements).⁶³

For the developing world, this has an adverse impact on their interest in the transfer of technology. The provision also has the effect of obliging them to accord the same level of protection for inventions in terms of duration and effect to inventions that make different contributions, some of them significant and some less so.⁶⁴

3.2.3 *Mailbox and EMRs*

From the perspective of pharma, duly represented by industrialized governments at the Uruguay Round negotiations, there needed to be a mechanism to protect their interests

⁶² ICTSD Resource Book, Page 423.

⁶³ See, Chap 2 above, the section entitled, “The Incorporation of IP into the Multilateral Trading System”.

⁶⁴ See, Lester Thurow, “*Needed: A New System of Intellectual Property Rights*”, Harvard Business Review, September – October: 1997, quoted in ICTSD Resource Book, p 424.

during the transition periods.⁶⁵ Therefore, industrialized Members pushed for and succeeded in attaining the inclusion of Articles 70.8 and 70.9.

Developing countries were of greater concern to pharma's interests than LDCs which generally lacked pharmaceutical manufacturing capacity and thus significant potential to pose a threat to pharma's commercial interests. There was however, the possibility that LDCs could develop manufacturing capacities during the course of the transition period.⁶⁶ Thus the applicability of Articles 70.8 and 70.9 to LDCs was necessary from the perspective of pharma and thus industrialized countries.

Article 70.8(a) obliges countries availing themselves of a transition period to provide a means by which patent applications can be filed i.e., a receiving point where such applications can be recorded and stored. Such a receiving point is commonly referred to as a "mailbox".

According to Article 70.8(b), countries must apply to those applications, the criteria for patentability laid down in Article 27.1 as if those criteria are being applied on the date of filing in that member or where priority is available or claimed, on the priority date of the application.⁶⁷

Article 70.8(b) is thus very important from the perspective of pharmaceutical producers in that it mandates the application of a priority date or in the absence thereof, a filing date

⁶⁵ See, Chapter 2 and the section on transition periods below.

⁶⁶ As noted above, the stated purpose of the transition period is to facilitate LDC efforts to develop a technological base, it is neither logical nor intended by the wording of TRIPS to exclude developing a technological base in the pharmaceutical industry from this objective.

⁶⁷ See Article 70(8) (b). Reference to the concept of priority in patent law makes Article 4 of the Paris Convention applicable to TRIPS. Under this doctrine, when a patent application is first filed in a member country of the Paris Union, the applicant thereby secures a priority date. From this priority date, a one-year period is counted during which that applicant may file in other countries of the Paris Union and such applications "shall not be invalidated by any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, and such acts cannot give rise to any third party right or any right of personal possession."

for patent applications that must be used as a benchmark from which time to assess patentability of subject matter in the mailbox.

Hence the effect of this provision is to prevent a situation where subject matter that is not patentable during a transition period could never be patentable when transition periods expire. Publication of the patent application in a foreign country or domestic availability of the product (at least one of these 'acts' inevitable during the transition period) would negate the novelty of the subject matter. This effect is achieved through the requirement that the examiner of the patent considers the state of knowledge as it existed as of the initial filing or priority date.

Article 70.8(c) requires that when the transition period expires, members are to grant patent protection for products successfully assessed under Article 70.8(b) for the remainder of the twenty year term of protection mandated in Article 33 counted from the date of filing in the member processing the application.

Article 70.9 obliges Members to provide exclusive marketing rights EMRs to subject matter which is subject to a patent application under Article 70.8(a). The EMRs must subsist for a period of five years after obtaining marketing approval in that member or until the Article 70.8 application results in a product patent being granted or rejected in that member, whichever period is shorter. This obligation is subject to the condition that a product patent must have been filed and granted in another member and marketing approval attained in that other member.

EMR is an ambiguous concept left undefined by the TRIPS Agreement and without precedent in most domestic legislation. The inclusion of EMRs in the final TRIPS package was regarded as a compromise between countries with an interest in early patent protection for pharmaceutical and agricultural chemical products and countries that sought a transition period for those products.⁶⁸

⁶⁸ ICTSD Resource Book, p760.

The term EMRs may be ambiguous but what is clear about the term is that it does not provide patent rights. Patent rights are clearly defined in Article 28 as allowing the patent holder to prevent third parties from making, using, offering for sale, selling or importing the product covered by the patent.

In contrast, EMRs do not apply to acts of making the product, they apply only to marketing the product. This means, the acts a business enterprise undertakes in connection with selling products that are already manufactured.⁶⁹ Therefore, the holder of the patent application may not prevent third parties from producing the product within the territory of the Member, but may prevent third parties from advertising, offering or selling the product to a person other than the patent applicant.

Since EMRs under Article 70.9 do not purport to restrict the ability of generic producers to make alternatives to brand pharmaceutical products, one could argue that the availability of those generic alternatives to the public is preserved.

The reality however is that granting EMRs to brand producers can be just as obstructive to the public's interest in affordable medicines (possibly more so) than patent rights. This is because allowing generic competitors to make a medicine which is subject to a mailbox application can not benefit the public if the producer of the generic medicine is unable to sell the same. In addition, EMRs are not IPRs and are therefore not subject to compulsory licensing. EMRs are thus a significant barrier to generic competition entering the market during the period of market exclusivity.

Furthermore, the five year period prescribed for the EMRs after attaining marketing approval (if the patent assessment takes longer than marketing approval) is a period significant enough for a brand producer to establish a virtual monopoly by employing vigorous, well funded and unchallenged marketing campaigns that may prove impossible

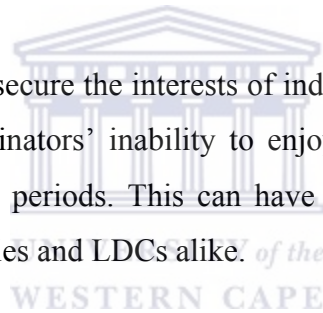
⁶⁹ Ibid, p775.

for generic competitors with smaller advertising budgets to emulate upon the conclusion of market exclusivity.

Therefore, the obligation that EMRs be granted in countries not applying pharmaceutical patent protection pursuant to a transition period secured the interests of pharma by granting their products a *sui generis* mode of protection in the absence of patent rights.

Obliging LDCs to grant EMRs would frustrate whatever benefits the LDCs could derive out of being exempted from the obligation to grant product patents for pharmaceuticals and thus the purpose of the transition period.⁷⁰ It was in this context that the General Council agreed to the recommendation of the TRIPS Council in 2002 to grant a waiver of the obligation in Article 70.9 for LDCs with respect to pharmaceutical products until 1 January 2016.

Mailbox protection and EMRs secure the interests of industrialized countries and pharma by placing a time cap on originators' inability to enjoy patent protection in countries taking advantage of transitions periods. This can have huge implications for access to medicines in developing countries and LDCs alike.



3.2.4 *Enforcement and Related Obligations Consolidating the Patent Holder's Rights*

Finally, Article 41.1 requires WTO Members to "... ensure that enforcement procedures ... are available under their national laws so as to permit effective action against any act of infringement of IPRs ..." Article 62.2 obliges members to "... ensure that the procedures for grant or registration ... permit the granting or registration of the right

⁷⁰ This is something the TRIPS Council recognized in the Decision on Least-Developed Country Members' Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WTO Document WT/L/478,(Hereinafter, Article 70.9 waiver).In this decision, the TRIPS Council in the introductory paragraphs considered "that obligations under paragraph 9 of Article 70 of the TRIPS Agreement, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration". Both the Decision on Article 70.9 and paragraph 7 of the Doha Declaration are to be discussed in detail below.

within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.”

3.3 The Effect of Protecting Producer Interests on Access to Medicines in the Developing World

The above provisions relating to the rights conferred unto a patentee; non discrimination; mailbox and EMRs; and enforcement related obligations represent the most extensive and comprehensive patent protection to be granted to pharmaceutical producers. As a result of these provisions, their interests are secured to the extent of conferring a minimum twenty year monopoly (even longer through the operation of EMRs and where a national patent system allows ever greening through incremental inventions).⁷¹

The monopoly position allows pharmaceuticals to charge prices well above the marginal cost of production. In a competitive market, a producer cannot for a sustained period of time charge a price for a product significantly over the marginal cost of production because this encourages new producers to enter the market, eventually bringing down the price of the product. By charging high prices in a competitive market, a producer undermines its own long-term well-being by encouraging additional supply from new market entrants.⁷² This natural economic barrier to high prices is eliminated by the pharmaceutical patentee’s ability to exclude competition (particularly generic competition).

What effect do increased prices facilitated by pharmaceutical patents have on the interests of the developing world in terms of access to medicines?

This debate has been ongoing for some time. Pharmaceutical producers represented by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) backed by industrialized countries, particularly the US, maintain that the exclusive rights

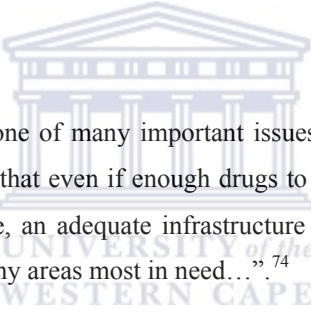
⁷¹ The concept of ever greening is discussed below in the section on the Article 27.1 patentability criteria.

⁷² See, Abbott (2001), Annex A.

conferred by TRIPS with regard to pharmaceutical patents do not adversely affect access to essential medicines in the developing world.⁷³ On the other hand, stakeholders in developing countries and LDCs argue the opposite.

The notion that the patent protection conferred unto pharmaceuticals under the TRIPS regime does not impede access to medicines in the developing world is based on the following arguments:

Regarding access to existing medicines, price is but one of the factors that influence access in the developing world along with healthcare infrastructure to support delivery. Therefore the reduction of prices is unlikely to increase access to essential existing medicines. An example of this line of argument can be extracted from the US intervention during a meeting of the TRIPS Council. The US delegation was of the following view:



“..The cost of drugs is only one of many important issues that must be addressed in any health crises....“We must recognize that even if enough drugs to treat every single HIV-positive person were provided, free of charge, an adequate infrastructure to deliver them and monitor their use does not appear to exist in many areas most in need...”⁷⁴

It is indeed true that healthcare infrastructure is one of the factors affecting access to essential medicines in the developing world; however, price is an inescapably crucial factor. This because *inter alia*, most poor people in developing countries pay for their own drugs and state provision is normally selective and resource-constrained. This is generally not the case in the developed world where costs are mainly met by the state or through insurance schemes.⁷⁵

⁷³ For example, Harvey Bale, director general of the IFPMA, said “...Access to medicines isn't about patents, but about investing in health services so the drugs get to the people that need them,” See IAC (SM) Newsletter Database, July 2, 2001, quoted in Abbott (2001).

⁷⁴ See, Abbott (2001), Annex A.

⁷⁵ UK IPR Commission, Final Report, p 35.

To say that price does not affect access to medicines is to argue that lowering the price of those products will not bring additional consumers to the market and thus amounts to a denial of the laws of supply and demand. It is undeniable that for those with limited resources, the ability to enter the market is strictly determined by price. As the price of the life-saving pharmaceutical decreases, all potential consumers with adequate resources will purchase it, or otherwise die.⁷⁶ Hence, to say that there are other factors affecting access to medicines is not an adequate argument to justify the assertion a highly inhibitive factor is not an issue.

The second argument against patents having an inhibitive effect on access to medicines in the developing world pertains to medicines that are not yet in existence but are to be invented in future. The argument espouses that protection of patent rights is a critical incentive for private investment in pharmaceutical research and in the development of new drugs that are used to treat diseases in the developing world. The twenty year monopoly rights conferred thus reward innovators for costs incurred in the course of R&D to develop the drugs.

This argument thus has 2 tiers, the first tier being that patent rights are an incentive to innovation of drugs to treat diseases in the developing world; while the second tier considers that the monopoly rights are fair compensation for R&D costs incurred.

The first tier is flawed in that patent protection offers little incentive for research on diseases that disproportionately affect developing countries due to the absence of a significant market.⁷⁷ There is a plethora of evidence to this end. For instance in 2002, it was estimated that 5% of money spent worldwide on pharmaceutical R&D was for diseases that predominantly affect developing countries.⁷⁸ Even HIV vaccine research is

⁷⁶ Ibid.

⁷⁷See, Commission on Macroeconomics and Health (2001), Final Report, p77. and Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH(2006)), Final Report, p 12

⁷⁸ UK IPR Commission, Final Report, p37.

targeted at subtype B of the virus which is prevalent in developed countries as opposed to subtype A and C which are prevalent in developing countries.⁷⁹

This dialectic in pharmaceutical research patterns is a consequence of the nonexistence of commercial incentive for the private sector which dominates pharmaceutical R&D to undertake research of specific relevance to the majority of poor people living in low income countries regardless of patent protection prevailing in those countries.⁸⁰ Therefore the incentive for R&D into developing world diseases is unaffected by the presence or lack of IP protection, the only relevant factor is whether there is a market demand sufficient to induce pharmaceuticals to commit their resources to research.

The final argument advanced in this context is that the monopoly provided by patent rights is necessary to compensate innovators for the costs incurred in pharmaceutical R&D because recovering the expenditures would not be possible if competitors were allowed to copy and profit from the innovations without incurring similar costs.⁸¹ This reasoning is *prima facie* logical and fair as indeed there are significant costs involved in developing drugs especially where there is no predecessor of the drug on which to base research and a high level of innovation is thus required.^{he}

A deeper perusal of this argument however reveals that granting a patent monopoly is a very imprecise instrument for achieving this objective because there is no direct correlation between the income obtained from the patent and the amount of R&D undertaken. A research company may spend very little to develop an important new drug if for example, they rely on the work of a university laboratory or operate under a government subsidy, but the company may nonetheless charge a substantial price for the drug. The result is that, pharmaceutical companies spend approximately 15% of their revenue on R&D while a much larger portion

⁷⁹ Ibid.

⁸⁰ CIPIH (2006), Final Report, p 12.

⁸¹ For instance, the panel in the *EC-Canada* case opined that, “. . . Patent laws establish a carefully defined period of market exclusivity . . . and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined.” See WT/DS/114/R, para. 7.55.

goes to other costs such as administration, advertising and promotion, yet these other costs are also covered by patent rents.⁸²

The lack of direct correlation between research expenditures and patent-based income has become more significant under TRIPS as R &D conducted in a single country can today be exploited by an effectively worldwide patent, so that income to the patent holder is generated from a far larger consumer base than was formerly possible.⁸³

These arguments attempt to evidence a bargain with society whereby the benefits to society generated by the extra innovation induced (for example, a lifesaving drug which might not exist but for the patent system) exceed the extra cost of the product. The problem with this concept however is that if the cost prohibits the public in the developing world from enjoying the benefit and if the innovation generated does not address diseases affecting the developing world then surely the preponderance of interests promoted by the conferment of the above rights in the context of our discussion rests squarely with the patent holding producers of pharmaceutical technology. Thus, to quote Kieth Maskus:⁸⁴

“...the preponderance of conclusions is pessimistic about the net effects of dug patents on the economic welfare of developing countries”⁸⁵

3.4 The Interests of Users: Striking a Balance

⁸² Marcia Angell, *The Truth About the Drug Companies: How They Deceive US and What to Do About It*, New England Journal of Medicine, (2004), quoted in Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, American Journal of International Law (2005) 99. 317-58.(Hereinafter, Abbott, The Medicines Decision)

⁸³ See, Abbott (2001), p 41

⁸⁴ Maskus is a world renowned economist, while Abbott and Correa are leaders as far as the legal aspects of IP/Public health are concerned; they rely heavily on Maskus for the economic analysis.

⁸⁵ Keith Maskus, *Intellectual Property Rights and the Global Economy*, Institute for International Economics (2000), p 160.

How then does the TRIPS Agreement attempt to reconcile the above monopoly rights conferred unto the producers of pharmaceutical technology with the public health interest of developing countries and LDCs? The answer lies in the TRIPS flexibilities.

3.4.1 *The Legal Derivatives of the TRIPS Flexibilities*

The TRIPS flexibilities result from the language of Article 1.1 of the TRIPS Agreement which provides that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”. WTO Members can thus exploit creative solutions to transpose into national law and practice those concepts that the TRIPS Agreement simply enunciates but does not define.⁸⁶

The flexibilities also result from the objectives and principles of the TRIPS Agreement enumerated in Article 7 and 8 which refer respectively to IPRs being enforced in a manner that contributes to “social and economic welfare, and to a balance of rights and obligations” as well as the ability of Members while formulating their laws to, “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”. The TRIPS Agreement must be interpreted in light of Articles 7 and 8 according to the international laws of Treaty interpretation.⁸⁷

The examples of those flexibilities to be discussed in this chapter include: transition periods, the patentability criteria and exemption from patentability; parallel importation;

⁸⁶ See, “Advice on Flexibilities under the TRIPS Agreement”. Available at: http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html

⁸⁷ Article 31(1) of the Vienna Convention on the Law of Treaties 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 object and purpose”.

as well as compulsory licenses and government use. These flexibilities were supplemented by the Doha Declaration and subsequent developments in the WTO.⁸⁸

From the perspective of developing countries attempting to promote their public health interests, the Doha Declaration was crucial in that it confirmed the right of Members to use the flexibility within TRIPS to interpret and implement their obligations in a manner consistent with those interests. To this end, the essence of the Doha Declaration is captured in paragraph 4 which reads as follows:

“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”.

3.4.2 *The Legal Status of the Doha Declaration*

The first two words of paragraph 4 are expressed in the form of an agreement (“we agree”). Since the statement was adopted by consensus of the Ministers and the operative language is in the form of an agreement, there is a consensus amongst the leading scholars that this constitutes a Decision under Article IX: 1 of the WTO Agreement. The Doha Declaration thus has legal effects on WTO Members and institutional bodies, particularly the Dispute Settlement Body (DSB) and the TRIPS Council.⁸⁹ This is evidenced by the fact that the TRIPS Council has taken actions, subsequently borne out by the General Council on the direct instructions of the Doha Declaration. Take for

⁸⁸ Council for Trade Related Aspects of Intellectual Property Rights “Implementation of Paragraph 6 of the Doha Declaration on Public Health”.IP/C/W/405 (Aug. 30, 2003), (hereinafter, August 30th 2003 Decision), and The Decision on the Amendment of the TRIPS Agreement, IP/C/41 (Dec. 6, 2005), (hereinafter, The 2005 Amendment Decision).

⁸⁹ See, Carlos M. Correa, “*Implications of the Doha Declaration on the TRIPS Agreement and Public Health*”, p 44, University of Buenos Aires, (2002), (hereinafter, Correa (2002)) and Abbott, “Lighting a Dark Corner”, p 491.

instance the negotiations and decisions taken to implement paragraph 6 and 7 of the Doha Declaration, both of which will be discussed below in subsequent sections of this chapter. These actions are also in accordance with the Final Act under which Members agreed to adopt Ministerial Declarations and Decisions.⁹⁰

The Doha Declaration is not strictly an authoritative interpretation in terms of Article IX.2 of the WTO Agreement; however, given the content and mode of approval of the Doha Declaration, it can be argued that it has the same effect as an authoritative interpretation.⁹¹

In addition, the Doha Declaration is part of the context of the TRIPS Agreement, which, according to the rules of treaty interpretation,⁹² has to be taken into account when interpreting the Agreement. Moreover, the Doha Declaration can be regarded as a “subsequent agreement” between the parties regarding the interpretation of a treaty or the application of its provisions, under Article 31.3 (a) of the Vienna Convention on the Law of the Treaties.

What can be concluded in practical terms about the Doha Declaration’s utility for Members wishing to rely on its provisions? In answer to this question it is appropriate to quote Professor Correa who opines *inter alia* as follows:

The confirmation [by the Doha Declaration] that the TRIPS Agreement has left room for flexibility at the national level has important political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement. In legal terms, it means that panels and the Appellate Body must interpret the Agreement and the laws and regulations adopted

⁹⁰ See, Article 2(b) of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations.

⁹¹ See, Article IX.1 of the WTO Agreement and Carlos M Correa, “*Implications of the Doha Declaration on the TRIPS Agreement and Public Health*”, p 44, University of Buenos Aires, (2002). (Hereinafter, Correa (2002)).

⁹² See Article 31(1) of the Vienna Convention on the Law of Treaties.

to implement it in light of the public health needs of individual Members.⁹³

3.5 The TRIPS Flexibilities: A Critical Analysis

The remainder of the chapter will be dedicated to a critique of selected flexibilities.⁹⁴ The critique will be undertaken with a view to ascertaining as the title of this paper mandates, whether or not the TRIPS flexibilities are sufficient to balance the interests of IP producers and users as envisaged in the objectives of the TRIPS Agreement. It looks specifically in the domain of public health.

3.5.1 Transition Periods

As mentioned in the previous chapter, a transition period can basically be defined as the period of time considered necessary and thus granted for a WTO member to bring itself into conformity with its obligations under a WTO agreement.

Transition periods were a new feature of the final package of agreements concluded at the Uruguay Round and are without parallel under the GATT 1947 regime. This has been attributed to the fact that the GATT was mainly about tariff reduction which has considerably less effect on a country's internal legal system than the minimum standards, border controls and enforcement procedures required by the TRIPS regime.⁹⁵

Transition periods were among the few concessions made by industrialized countries that sought to secure the interests of pharma at the Uruguay Round, TRIPS negotiations.⁹⁶ They were seen as necessary to bring on board developing countries whose assessment of

⁹³ See, Correa (2002), p vii.

⁹⁴ See, Chapter 2 above for a list of the flexibilities to be tackled.

⁹⁵ ICTSD Resource Book, p 706.

⁹⁶ See, Chapter 2 above, the section entitled, "The Incorporation of IP into the Multilateral Trading System".

the issue concluded that to standardize protection at advanced levels is to erroneously presume that each economy has in place a technological or creative infrastructure for which high protection would be beneficial.⁹⁷ These countries also considered that the GATT did not mandate uniform levels of trade protection and thus to do so in TRIPS would be inconsistent and excessive.⁹⁸ Furthermore, the concession was necessary because these countries had initially been vehemently opposed to the introduction of IP into the round and remained skeptical throughout.⁹⁹

The transition periods are a form of special and differential treatment (SDT). SDT in the GATT/WTO is based on the idea that developing countries are inherently disadvantaged in their participation in international trade for a variety of reasons such as institutional weakness, technological barriers, supply side constraints etc. It is for this reason the international community has agreed that, in principle, developing countries should be subject to somewhat different rules and disciplines in international trade than those that apply to developed countries; and that the latter will implement their obligations under the GATT and WTO in ways that would be favourable to development.¹⁰⁰

Of the transition periods agreed at the Uruguay Round, Article 66.1 which applies to LDCs will form the basis for the preponderant portion of this section. The reason being that it is one of only two transition periods that relate specifically to pharmaceutical product patent protection in developing countries and unlike its counterpart,¹⁰¹ the Article

⁹⁷ Keith Maskus, *Intellectual Property Rights and the Global Economy*, Institute for International Economics (2000), p6.

⁹⁸ Ibid.

⁹⁹ See, Chapter 2 above, the section entitled, "The Incorporation of IP into the Multilateral Trading System". See, also ICTSD Resource Book p 707.

¹⁰⁰ This principle was introduced into the GATT via the 1979 "Enabling Resolution" . See, Constantine Michalopoulos, *Special and Differential Treatment of Developing Countries in TRIPS*, Available at : [http://www.qiap.ca/documents/DT\(US\)1.pdf](http://www.qiap.ca/documents/DT(US)1.pdf) (Last Accessed on 23rd March 2007). (Hereinafter, Michalopoulos), p4.

¹⁰¹ The other provision in question is Article 65.4 which grants developing countries which had not previously provided pharmaceutical patent protection

66.1 transition period still applies. The transition period remains effective due to an extension adopted pursuant to paragraph 7 of the Doha Declaration.¹⁰²

Upon a reading of Article 66.1 in the context of SDT it is apparent that although financial and administrative constraints for the implementation of the TRIPS Agreement are a component of the rationale for Article 66.1, the particular requirements of LDCs and their need for flexibility to create a viable technological base clearly constitute the central objective of the provision. Article 66.1 aims to provide LDCs not merely with time to comply, but with time to develop their technological base (including pharmaceutical manufacturing capacity), national policies and economies to ensure that the eventual application of the patent protection provided for by the TRIPS Agreement will promote rather than undermine their socio - economic well-being.¹⁰³

The inclusion of an extension of the Article 66.1 transition period in the Doha Declaration on TRIPS and public health demonstrates the WTO Members' intention that the transition period should assist LDCs in their efforts to promote access to affordable medicines. Thus it is necessary in this section to consider whether this form of SDT can indeed assist LDCs to establish a viable technological base that can assist them to access affordable medicines.

The transition period and its' subsequent extension remove until 2016 any barriers that pharmaceutical product patents may impose on the ability of LDCs to produce, import and export medicines among themselves. Realistically however, the utilization of this

¹⁰² Decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 of 27 June 2002 and The Doha Ministerial Conference, "Declaration on the TRIPS Agreement and Public Health," 20 November 2001, WTO document WT/MIN(01)/DEC/2, paragraph 7 respectively. The extension relieves LDCs of the obligation to provide pharmaceutical patent or test data protection until 2016. The decision was adopted in accordance with the ministerial instruction to the TRIPS council in paragraph 7 of the Doha Declaration.

¹⁰³ South Centre – CIEL, IP quarterly Update First Quarter 2006, p2. Available at: http://www.ciel.org/Publications/IP_Update_1Q06.pdf (Last Accessed on 23rd March 2007).

opportunity can only occur if LDCs improve their technological base and develop capacity for the production of generic medicines.¹⁰⁴

Pursuant to Article 65.4 of the TRIPS Agreement, certain developing countries did not have the obligation to provide patent protection for pharmaceutical products until 2005. These countries, particularly India with its immense generic industry thus constituted a viable source of affordable generic medicines to LDCs wishing to import cheaper generic medicines. This is because as there was no obligation under the TRIPS Agreement to negotiate a voluntary license with the patent holder or to issue a compulsory license either on the export or the import side.

Thus the only off patent medicines currently available to LDCs from non LDC Members are those that have that status because the patent on them has expired. Medicines in this already limited category are further limited due to ever greening by brand pharmaceutical firms.¹⁰⁵

It should be noted that in any event, the option to import medicines on which the patent has expired is available to LDCs independently of the transition period assuming they are off patent on both the export and import side. Thus in the absence of LDCs finding means to utilize the transition period to develop a viable technological base and establish pharmaceutical manufacturing capacity, the effect of the transition period as it is on access to medicines will remain as is, insignificant.

In reality the Article 66.1 transition period is not a real concession but rather it is a form of second best SDT notwithstanding the 2002 extension and the 70.9 waiver.¹⁰⁶ Developed countries agreed to the transition period in large part because LDCs have limited purchasing power and thus do not constitute market for their products significant enough to warrant extensively protecting. In addition, LDCs generally have no

¹⁰⁴ Abbott, *Lighting a Dark Corner*, p503.

¹⁰⁵ See the section entitled "The Patentability Criteria and Exemption from Patentability" below for an explanation and discussion of ever greening.

¹⁰⁶ See, Michalopoulos. p14.

pharmaceutical manufacturing capacity hence the threat of generic industries in those countries emerging to rival brand pharmaceuticals is low.

It would be too categorical a criticism to describe the transition period as second best SDT without substantiation on its' demerits, therefore the reasons why it is so billed are explained below.

First, the transition period was chosen without any serious analysis of the time and resources required for establishing the necessary institutional capacity this is evidenced by the need to extend the LDC transition period from 2006 until 2016 with regard to pharmaceutical products and 2013 with regard to general obligations in 2002 and 2005 respectively.

Secondly, the problems faced by other small and low income countries in implementing TRIPS obligations are similar to those faced by LDCs. Those developing countries should at least have been included in the extension to 2016 provided to the LDCs.¹⁰⁷

A proposed solution to this anomaly is that GDP per capita should be used as a criteria to expand the list of countries that qualify for SDT.¹⁰⁸

Thirdly, a meaningful SDT provision should permit all developing countries, or at least the LDCs and other low income developing countries to decide which sectors of their economy to include for patenting and the length of the period for which patents would be provided as opposed to the current questionable transition period. This would be consistent with the development view that different levels and degrees of IPR protection are appropriate at different levels of development. Such an SDT provision would drastically change the meaning of the TRIPS regime and make it more development

¹⁰⁷ Ibid.

¹⁰⁸ A country like Bangladesh with DGP per capita of \$2,200 as of 2006 qualifies for the transition period whereas Zimbabwe with a lesser GDP per capita of \$2,000 as of the same year does not qualify under the current criteria,

See The Central Intelligence Agency (CIA)World Fact Book, Available at: <https://cia.gov/cia/publications/factbook/geos/gh.html> (Last Accessed on 25th March 2007).

friendly by meaningfully considering the interests of the world's poorest nations in the balancing act attempted by the TRIPS Agreement.¹⁰⁹

Given the time constraints and difficulties associated with the Doha mandate however, it will be extremely difficult to renegotiate the Agreement in this direction at present. Thus, it may be necessary for developing countries to resort to what in a sense are 'second best' SDT provisions that merely have the effect of delaying for as long as possible the obligation to fully implement the TRIPS Agreement.¹¹⁰

Moreover, the transition period does not address the real problem of access to medicines in LDCs which is lack of pharmaceutical manufacturing capacity exacerbated by a lack of ability to import expensive patented medicines. This problem is more acute in LDCs than even other developing countries.

If the transition period could incorporate a mechanism to assist LDCs to develop a viable technological base so as to allow them to create pharmaceutical manufacturing capacity,¹¹¹ then indeed the transition period could be regarded as genuinely assisting LDCs to facilitate access to medicines. The Integrated Framework for Trade-Related Technical Assistance to LDCs (IF),¹¹² is a possible avenue from which LDCs could pursue that end.¹¹³

¹⁰⁹ See, Michalopoulos, p13.

¹¹⁰ Ibid.

¹¹¹ This was requested by Zambia on behalf of LDCs when making their request for a fifteen year extension which resulted in the seven and a half year general TRIPS extension of 2005 which is due to expire in 2013 See, Transition Period for Least Developed Countries; Request for Extension, WTO document IP/C/W/457

¹¹² The IF is an international initiative through which the IMF, ITC, UNCTAD, UNDP, the World Bank and the WTO combine their efforts with those of LDCs, donors and other development partners to respond to the trade development needs of LDCs.

¹¹³ See, WTO Committee on Trade and Development, Technical Assistance and Training Plan 2007, WTO Document WT/COMTD/W/151.

The transition period is still of questionable benefit to LDCs in terms of the importation of generic medicines because on the exporter side, Article 31(f) exacerbated by recent Indian pharmaceutical product patent protection, inhibits LDCs' ability to import necessary drugs.¹¹⁴ Furthermore, as alluded to above, the availability of off patent medicines is independent of the transition period.

The real solution for access to medicines in LDCs is for those countries to develop pharmaceutical manufacturing capacity. In the absence thereof, they should mitigate the difficulties caused by lack of pharmaceutical manufacturing by making use of other TRIPS flexibilities. Otherwise LDCs run the risk of the transition period remaining no more than an extension of time as opposed to an instrument to facilitate achieving their development objectives within the IP system including greater access to affordable medicines.

3.5.2 *The Patentability Criteria and Exemption from Patentability*

The first portion of Article 27.1 of the TRIPS Agreement sets out the conditions which form the criteria for patentability. It is a good example of the uneasy balance that exists inherently within the TRIPS Agreement between the interests of producers and users. It explicitly creates enforceable rights for producers while leaving users (and producers) with considerable flexibility in terms of their interpretation and implementation.

The portion of Article 27.1 relevant to the current discussion reads as follows:

‘... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...’

¹¹⁴ It is important to note that the August 30th 2003 Decision and the TRIPS Amendment adopted in pursuance thereof attempt to mitigate this problem. The extent to which that end is achieved will be the subject of detailed discussion in the section dealing with compulsory licensing below.

According to Article 27.1, the legal framework within a Member must grant patent protection upon application to any invention that is novel, involves an inventive step, and is capable of industrial application.

Footnote 5 to Article 27.1 allows for ‘inventive step’ and ‘industrial applicability’ to be interpreted as being synonymous with the lower benchmarks of non obvious and useful respectively.

The interpretation of the patentability criteria is left open to Members. Thus countries are free to interpret the various terms depending on their own national interests.

The US, Japan and a few Western European countries produce the majority of internationally marketable products and technologies and thus have commensurate IP laws aimed at protecting these inventions.¹¹⁵ The flexibility in Article 27.1 means that producer countries which have an interest that is pro protection can interpret the patentability criteria to allow the patenting of subject matter that in fact and science is not new, does not involve an inventive step or is not capable of industrial applicability.

In order to illustrate how the flexibility to adopt an inclusive, pro protection interpretation of Article 27.1 can and has been used, it is useful to examine certain pharmaceutical patents that have been the subject of scientific controversy yet are commonly granted in certain producer countries in relation to respective patentability criteria.

Novelty and Second Indications:

‘Second indications’ or new uses of known medicinal products are admitted in some countries such as the UK where:

¹¹⁵ Intellectual Property Rights in South Africa: An Economic Review of Policy and Impact, p3, Available online at: <http://www.iprsonline.org/resources/health.htm> (Last Accessed on 23rd February 2007)

'It is legitimate to allow claims directed to the use of a substance for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient'.¹¹⁶

Protecting new uses of known products including in particular, second indications, epitomizes an extremely expansive application of novelty because novelty requires that the information must not have been available to the public prior to the priority date.¹¹⁷

It is thus clearly abhorrent to logic to consider second indications to be novel as the medicament itself (product) and its method of manufacture (process) will be the same as that already used for the first pharmaceutical indication.

Inventive Step and Polymorphs:

Patents are frequently granted in the US for polymorphs, these are natural properties which are not created or invented; they are found and discovered normally as part of routine experimentation. Patents on polymorphs have become common and are often used to delay the entry of generic competition. Take for instance the patent granted in the US for a polymorph for ranitidine.¹¹⁸ The patent expiring in 2002 was granted for the polymorph whereas the main product patent expired in 1995.¹¹⁹ Polymorphs are discoveries not inventions; furthermore they are obvious to someone skilled in the art and

¹¹⁶ See, Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office (March 2004) First medical use, Section 2(6), Paragraph 64.

¹¹⁷ Carlos M. Correa, "Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge". Available at: <http://www.qiap.ca/pages/publications.html> (Last Accessed on 12th February 2007).

¹¹⁸ Ranitidine is a histamine that inhibits stomach acid production and is commonly used in the treatment of peptic ulcer disease (PUD) and gastroesophageal disease (GERD). It is currently marketed under the trade name of Zantac by GlaxoSmithKline.

¹¹⁹ Carlos M. Correa, "*Pharmaceutical Inventions: When is the Granting of a Patent Justified?*" Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006. (Hereinafter, Correa (2006)), p 18.

are therefore not capable of passing an evaluation of inventive step. Their patenting is thus an avenue for ‘ever greening’.¹²⁰

Industrial Applicability and Methods of treatment:

Article 27.3 (a) of The TRIPS Agreement explicitly allows member states to exclude methods of treatment from patentability. Even in the absence of such exclusion in domestic legislation however, methods of treatment are not capable of satisfying a requirement of industrial applicability since what is new in such method claims is an effect on the body, not the product as such or its method of manufacture. In the US however, a standard of ‘utility’ is applied allowing the patenting of methods of treatment including prevention, diagnosis and profilaxis.¹²¹

Moreover, the National Institute for Healthcare Management (NIHCM) compiled a report that characterizes the level of innovation of all the new branded medicines that entered the US market from 1989 to 2000.¹²² The report found that the great majority of patents are granted not for new therapeutic compounds, but relate to variations in production processes, new formulations or crystalline forms, new combinations of known products, and new uses of known drugs. In the period 1989-2000, a mere 153 of the 1035 new drug approvals by the US Food and Drug Administration (FDA) were reported to be for drugs that contained new active ingredients and offered significant clinical improvement.

The above examples illustrate the application of very expansive interpretations of the patentability criteria. A pro protection patent policy of this nature is not congruent with public health policies that facilitate access to medicines. Public health policies in the

¹²⁰ Professor Correa defines ‘ever greening’ as ‘the patent strategy consisting of acquiring patents on minor, often trivial, modifications of existing pharmaceutical products or processes in order to indirectly extend the period of patent protection over previously patented compounds’.

¹²¹ See, Correa (2006).

¹²² NIHCM (2002) “Changing Patterns of Pharmaceutical Innovation”, NIHCM, Washington DC. Available at: <http://www.nihcm.org/innovations.pdf> (Last Accessed on 10th February 2007)

developing world should be geared towards a larger public domain to facilitate access to medicines and thus exclude the sort of developments discussed above from patent protection.

The TRIPS Agreement can advance the public health needs of countries in the developing world in that it contains sufficient flexibility to allow those countries to adopt a non inclusive interpretation of Article 27.1 and thus avoid unduly restricting access to medicines under a patent system that protects incremental inventions.

Although the TRIPS Agreement obliges WTO Members (except LDCs) to grant patents on medicines, nothing obliges developing countries to replicate patent systems of industrialized countries. The Agreement allows each country to set its criteria of patentability and does not prevent countries from including measures preventing the grant of patents for known substances, i.e. trivial patents. Furthermore, the Doha Declaration states that “the TRIPS 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.”¹²³ Developing countries therefore have the right to design their patentability laws in a way that takes their public health needs into account.

Pro protection patent regimes allow the incremental inventions to be patented. Policymakers in producer countries argue that strong global protection akin to that found in their own jurisdictions would have beneficial spill-overs to poor countries and would stimulate innovation in these countries.¹²⁴ In contrast, renowned economist Keith Maskus is of the opinion that “The preponderance of conclusions is pessimistic about the net effects of dug patents on the economic welfare of developing countries”.¹²⁵

¹²³ See, Paragraph 4 of the Doha Declaration.

¹²⁴ See, Trade and Industrial Policy Secretariat (TIPS), South Africa, "Intellectual Property Rights in South Africa: An Economic Review of policy and impact", p3. Available at: <http://www.iprsonline.org/resources/health.htm> (Last Accessed on 14th March 2007).

¹²⁵ See, Keith Maskus, Intellectual Property Rights and the Global Economy, Institute for International Economics (2000) p 160.

The resolution of that debate is beyond the scope of the current discussion. What is clear however is that interpreting the patentability criteria as expansively as in the examples cited above produces at least three adverse effects to public health policies in the developing world. These adverse effects are as follows:

First, it delays the entry of generic competition by artificially extending monopoly rights to brand producers. Even when there is the possibility to have such patents revoked, strategic litigation can be used by brand producers to further inhibit generic competition.¹²⁶ Strategic litigation is effective because generic producers often do not have the resources to bring actions for revocation or defend against infringement claims.

Secondly, for countries that have been producing generic medicines by utilizing the flexibility within TRIPS in order to not grant pharmaceutical product patents,¹²⁷ an expansive interpretation of the patentability criteria would require a far greater amount of mailbox applications to be granted patent status and thus severely restrict the ability of those countries to continue to produce generic equivalents.

Finally, the expansive approach to patentability discussed above can inhibit innovation by impeding research by non patent holders.

In light of the above, defining ‘inventive step’ is thus one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent and the corresponding limitation on competition. Since the TRIPS Agreement does not define this concept, developing countries are entitled to use this flexibility to ensure that they adopt systems that reward only substantial departures from prior art and render the myriad of incremental innovations, excluded from patentability.

¹²⁶ Strategic litigation is where brand producers allege infringement and request provisional injunctions/interdicts that block commercialization until a final decision is made.

¹²⁷ See the section on transition periods above.

From the perspective of public health in developing countries and LDCs, the application of a strict standard of inventiveness and a generally narrow interpretation of the patentability criteria is the best policy.¹²⁸ Such a policy promotes genuine innovations and prevents unwarranted limitations to competition and access to existing drugs.

3.5.3 *Parallel Importation*

As mentioned in the previous chapter, parallel importation is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent.¹²⁹

A patent holder may have the exclusive right to manufacture his product and to put it on the market; but once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the subsequent resale of that product since their rights over the product have been exhausted by the act of selling it.¹³⁰ This termination of control is critical to the functioning of any market economy because it permits the free transfer of goods and services. Without an exhaustion doctrine, the original IPR holder would perpetually exercise control over the sale, transfer or use of a good or service embodying an IPR, and would control economic life.¹³¹

During the Uruguay Round negotiations on TRIPS, there was fairly extensive discussion of the exhaustion issue, but governments did not come close to agreeing upon a single set of exhaustion rules for the new WTO. They instead agreed that each WTO Member would be entitled to adopt its own exhaustion policy and rules. This agreement was embodied in Article 6 of the TRIPS Agreement, which precludes anything in the

¹²⁸ World Bank (2001) *Global Economic Prospects and Developing Countries*, p 143.

¹²⁹ See, Musungu and Oh.

¹³⁰ *Ibid.*

¹³¹ ICTSD Resource Book, p 93.

Agreement from being used to address the exhaustion of rights in dispute settlement, subject to national and MFN treatment. Thus Article 6 of the TRIPS Agreement can be interpreted to permit parallel importation provided that Members use their flexibility to determine their own regime for exhaustion to incorporate the principle of international exhaustion.¹³²

The Doha Declaration has re-affirmed that each Member is “free to establish its own regime for such exhaustion without challenge”.¹³³ The clarification of this concept by the Doha Declaration is an added reassurance for Members wishing to adopt an international exhaustion principle that it is legitimate and consistent with the TRIPS Agreement..

This flexibility can be very useful in advancing access to affordable medicines. This is because, the fact that WTO Members are free to determine their own exhaustion regimes means that a Member wishing to import a medicine whether due to a lack of domestic availability or better prices abroad, could pursuant to an international exhaustion regime in domestic patent laws, determine a generic version of a patented medicine manufactured under compulsory license in the country of export to have been legitimately placed on the international market and thus import that medicine.

3.5.4 *Compulsory Licensing and Government Use*

Compulsory Licensing:

Compulsory licensing or non-voluntary use is regulated by Article 31 of the TRIPS Agreement. A compulsory license is an authorization by a government to a party other than the patent holder to use the subject matter of the patent without the consent of the patent holder.

¹³² The doctrine of international exhaustion is where a country chooses to recognize that exhaustion of an IPR occurs when a good or service is first sold or marketed anywhere in the world.

¹³³ See, Paragraph 5(d) of the Doha Declaration.

It is important to note that Article 31 maintains the utmost flexibility for Members in terms of the grounds for the issuing of such a license. While Article 31 sets out certain procedural requirements and conditions in the granting of a compulsory license, the provision does in no way limit the grounds upon which a compulsory license may be issued. This has been confirmed by paragraph 5(b) of the Doha Declaration.¹³⁴

Therefore domestic law can legitimately provide for a public interest ground (among any others) for non voluntary use of a patent. Such a ground could be used for the non voluntary use of pharmaceutical product patents by balancing the interests of the public to affordable medicines with the commercial interests of the patent holder and finding that the former should take precedence.¹³⁵

Compulsory licensing has long been recognized as the most important tool for addressing the adverse effects of patent rights on public welfare (particularly in the context of health).¹³⁶ This is because as noted above, the price of goods is a more significant determinant of market demand in low-income countries because consumers have fewer resources to allocate among goods. Compulsory licensing is thus an instrument for obtaining lower prices on goods protected by patent.

Compulsory licensing can be effective in making lower priced medicines available not only when a license is actually issued but also when there is a legitimate threat that such a license can be issued because it can serve as leverage in negotiating better terms for a

¹³⁴ It should be noted that although the conditions in Article 31 do not inhibit the grounds upon which a license may be issued, they can inhibit the commercial viability of exploiting them for local firms with such capacity. This is an idea that the author will expand upon below in this section.

¹³⁵ The public interest ground leaves domestic authorities with broad discretion wide enough to encompass public health needs through ensuring access to affordable medicines. As such it has been recommended that all developing countries incorporate a public interest or similar ground. See, Musungu and Oh (2006), p 32.

¹³⁶ Edith Tilton Pinrose, "The Economics of the International Patent System", Ch. XI 1951: Johns Hopkins Press.

voluntary license with the patent holder.¹³⁷ Non Voluntary use or the legitimate threat thereof can even cause patent holders to revise their prices.¹³⁸ A compulsory license can legitimately be exploited by local manufacture of the patented product or by import.¹³⁹

Despite inherent flexibility in the wording of the TRIPS Agreement as confirmed by the Doha Declaration and the presence of compulsory licensing legislation in most developing countries,¹⁴⁰ the actual usage of compulsory licensing by those countries has been relatively limited. Professor Abbott has identified three very pertinent factors contributing to this scarcity. The author in turn has identified an additional two factors.

The reasons put forth by Abbott are as follows:

First, although TRIPS compliant, the use of compulsory licenses for the manufacture of patented medicines has been opposed by developed country WTO Members and pharma. The only way to address this concern is a strong political commitment to act in the face of this opposition.¹⁴¹

¹³⁷ For example, following the case of *Hazel Tau & Others v. GlaxoSmithKline and Boehringer Ingelheim, Competition Commission of South Africa (2003)*, the two pharmaceutical giants cited were found guilty of excessive pricing. In a bid to avoid a damaging ruling by the Competition Tribunal that would have led to non voluntary use of the patented subject matter, they negotiated a deal with the complainants that made the medicines available on more affordable terms in the South African market. See also Bryan C. Mercurio, "Trips, Patents, and Access to Life-Saving Drugs in the Developing World" 8 Marq. Intell. Prop. L. Rev. 211, p 224.

"Use of the threat of compulsory licenses to negotiate favorable terms is not unique to the developing world; when fears of an anthrax attack mounted in the United States government, it used the threat of a compulsory license to entice Bayer to provide Cipro at a greatly reduced cost. This event was instrumental in the US arriving at a compromise on their compulsory licensing position that facilitated the Doha Declaration on TRIPS and Public Health".

¹³⁸ For instance, in the aftermath of the decision by the Thai government to issue a compulsory license for government production of an HIV/AIDS drug, the patent holder of the product, Merck Sharp & Dohme (Merck), proposed reducing the price by almost two-thirds, local sources. See IPWatch, "Thailand Compulsory License On AIDS Drug Prompts Policy Debate", Available at: <http://www.ip-watch.org/weblog/index.php?p=499&res=1024&print=0>, (Last Accessed on 1st April 2007).

¹³⁹ As mentioned above, paragraph 5(d) Of the Doha Declaration confirms the right of Members referred to in footnote 6 to Article 31 to determine when IPRs are deemed exhausted.

¹⁴⁰ Musungu and Oh (2006), p 56.

¹⁴¹ Compulsory licenses for pharmaceutical products have traditionally and contemporarily been subject of opposition by developed countries and their pharmaceutical industries. The most popular such case came

Secondly, some developing countries have expressed concern regarding a potential backlash from foreign direct investors. Abbot argues however that this concern should not deter Members from issuing compulsory licenses as commercial investors recognize the risks posed by public health threats such as the HIV/AIDS pandemic, and should not perceive a compulsory license granted to redress such a crisis as evidence of a risk to general commercial investment.¹⁴²

Finally, domestic administrative procedures for issuing compulsory licenses may be either non-existent or overly restrictive. Overcoming procedural or process obstacles requires governments to adopt legislation that makes the granting of a compulsory license to address public health crises fast and inexpensive, technical cooperation from relevant UN organizations may be necessary in this regard.¹⁴³

The two additional obstacles identified by the author are as follows:



when South Africa adopted the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 which gave the Health Minister wide powers with regard to compulsory licenses/government use of pharmaceutical products. As a consequence, the South African government was subjected to a multi-pronged attack from the United States Trade Representative (USTR), the European Commission and 39 pharmaceutical companies. The US only backed away after NGO protests threatened to derail the political campaign of then US Vice President, Al Gore. The pharmaceutical companies persisted until NGO protests threatened a massive public relations disaster. See, Abbott, *Lighting a Dark Corner*, p 471.

In November 2006, the Thai government announced the decision to issue compulsory licenses for Merck patented antiretroviral drug, Efavirenz right before World AIDS' Day in 2006. The Doha Declaration and subsequent did little to dissuade the US from applying pressure on the Thai Government to revise the decision when shortly after the announcement, Ambassador Karan Bhatia, the Deputy USTR, called the Thai Embassy in Washington to deliver a message described as "bullying" by Thai government officials. Due in no small part to NGO pressure however, the Thai government did not back down and the compulsory license is due to remain effective until 2011. See, James Love, "Merck, USTR ask Thailand to Reconsider Compulsory License on AIDS Drug". Available at: http://www.huffingtonpost.com/james-love/merck-ustr-ask-thailand-b_36643.html (Last Accessed on 3rd April 2007)

¹⁴² Frederick M. Abbott, "*Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after The Doha Declaration on Public Health*". Available at: <http://quino.org/geneva/pdf/economic/Occasional/Compulsory-Licensing.pdf>. (Hereinafter, Abbott, *Compulsory Licensing for Public Health Needs*).

¹⁴³ Ibid.

First, while not affecting the legitimacy of pursuing such an enterprise, certain conditions in Article 31 have the potential to make the manufacture of drugs for which a compulsory license has been issued, commercially unviable for generic producers. Take for instance the requirement of Article 31(e) that a compulsory license be non assignable. The provision prevents the creation of a market in compulsory licenses as instruments with independent value. The creation of such a market would enhance the value of compulsory licenses and encourage parties to seek them.¹⁴⁴

Secondly, the grounds for granting compulsory licenses in the domestic legislation of developing countries can be unnecessarily restrictive. For instance, the Bangui Agreement of 1977 which established the African Intellectual Property Organization (OAPI) and was revised in 1999 contains rather restrictive grounds for compulsory licensing, for instance it does not contain a public interest ground.¹⁴⁵ Countries should maintain as much flexibility as permitted under TRIPS concerning the grounds for compulsory licensing and should exhibit a strong political will to service the health needs of their public in the face of adversity. Countries like South Africa and Thailand have shown that this can be done.

While some compulsory licensing safeguards in Article 31 can be described as being too focused on protecting the interests of pharmaceutical patent holders at the cost of restricting the pursuit of public health interests of the poor,¹⁴⁶ Article 31 does contain

¹⁴⁴ ICTSD Resource Book, p 473.

¹⁴⁵ Bangui 1999 has been more generally criticized as applying higher standards of patent protection than necessary under TRIPS to the detriment of access to affordable medicines in its member states. For instance, Bangui '99 allows parallel importing only among Member States, this is a severe restriction on access to affordable medicines as lower priced versions can often be found at lower prices outside the OAPI region. For instance a one-pill combination of the two antiretrovirals AZT and 3TC, costs US\$1.96 in Togo and US\$0.94 in Senegal (lowest price within OAPI region), but only US\$0.65 in India. Moreover, twelve of seventeen OAPI members are LDCs and are thus not obliged by TRIPS to protect pharmaceutical product patents, however they are so obliged under Bangui '99. See, Conference Report: Implementation of the Doha Declaration on the TRIPS Agreement and Public Health Technical Assistance - How to Get it Right." March 2002. Available at: <http://www.accessmed-msf.org/prod/publications.asp?scentid=26420021519443&contenttype=PARA#top> (Last Accessed on 22nd March 2007).

¹⁴⁶ As discussed in the commentary on Article 31(e) above.

options to alleviate and counter balance such restrictions. One such option is known as the Government Use flexibility.

Government Use:

According to the Government Use flexibility, the obligation, in Article 31(b) for a compulsory license applicant to undertake prior negotiations with the patent holder preceeding the non voluntary use of the subject matter is waived in cases of “public non-commercial use”.

This flexibility is particularly significant because the prior negotiation obligation contained in Article 31(b) can be used as a delaying tactic by a patent holder that doesn't want to issue a license or see a compulsory license issued to generic industry producers. The ‘public non commercial use’ waiver can thus be used by governments (or commercial entities acting for non commercial purposes), to effect non voluntary use of a patented medicine without undue delay.

This ‘Government Use option is crucial to patients in advanced stages of terminal illnesses such as AIDS who are in need of life saving medicines as quickly as possible, Thailand used this provision to great effect in November 2006 despite assertions by Merck that the government was obliged to negotiate with them before issuing the compulsory license.¹⁴⁷

3.6 The Article 31(f) Problem

Despite attempts by the drafters to mitigate potential difficulties caused by various compulsory licensing terms in the TRIPS Agreement, some problems remain, most

¹⁴⁷ See, James Love, “Merck, USTR ask Thailand to Reconsider Compulsory License on AIDS Drug”, available at: http://www.huffingtonpost.com/james-love/merck-ustr-ask-thailand-_b_36643.html (Last Accessed on 3rd April 2007).

notably those resulting from paragraph (f) of Article 31 in terms of its effect on countries without pharmaceutical manufacturing capacity.

Such countries are unable to exploit compulsory licenses for essential medicines by domestic manufacture and thus have a particularly acute problem; they have to meet their national demand for cheaper generic drugs by importation. The ability to do so is highly dependent on export side capacity to provide adequate amounts to meet the importing country's needs. Article 31(f) is a tremendous barrier to this ability because the said provision provides that licenses should be issued "predominantly for the supply of the domestic market" of the member granting them, thereby restricting exports to the non predominant portion.

Prior to 2005, Article 31(f) was in practice, unlikely to have a serious effect on countries depending on compulsory licensing by import because India, a thriving generic producer and exporter did not grant pharmaceutical product patent protection and was thus not bound by Article 31(f). Indian measures adopted to comply with the TRIPS Agreement such as its' executive ordinance of 2004 coupled with its' Patent Act amendment of 1999 result in a loss of unencumbered access to Indian generics produced post 1st January 2005 and generic versions of medicines for which there are applications in India's mailbox that meet the country's patentability requirements.¹⁴⁸

Article 31(f) frustrates access to affordable medicines on the import side because it makes it an infringement to issue a compulsory license for the manufacture of generic medicines for the sole purpose of export to a foreign country in need of those medicines. According to the said provision, a compulsory license must be issued to supply local demand in the predominant part, only the residual portion can be exported. The provision thus leads to a tragic paradox in that the WTO Members that are able to take advantage of compulsory licensing to supply essential medicines are the countries with capacity to

¹⁴⁸See, Abbott, The Medicines Decision, p 320.

manufacture those medicines.¹⁴⁹ Therefore the countries most in need of generic substitutes produced under compulsory license are the countries that are restricted from accessing such medicines.

The Council of Ministers recognized this problem and that the ability of a compulsory license to satisfy a domestic market by importation was dependant on some legal mechanism under which the rights of patent holders in exporting countries would not be infringed. The TRIPS Council was thus mandated by paragraph 6 of the Doha Declaration to propound such a mechanism, the August 30th 2003 Decision was the outcome.

3.7 The August 30th 2003 Decision

While 30th August 2003 Decision is not a TRIPS flexibility in the strict sense, it is an attempt by WTO Members to address the problem of those countries unable to effectively utilize the flexibility afforded by compulsory licensing. The decision attempts this through the use of three substantive waivers with regard to Article 31(f) restriction.

The substantive waivers:

The first waiver pertains to the obligations of an exporting Member under Article 31(f) of the TRIPS Agreement with respect to the grant by that member of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)".¹⁵⁰

The second waiver seeks to do away with double remuneration of the patent holder by providing that "adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid to the exporting Member taking into account the economic value to the

¹⁴⁹ See, Abbott 2001.

¹⁵⁰ Paragraph 2 of the August Decision

importing Member of the use that has been authorized in the exporting Member”, “...the obligation of the importing Member under Article 31(h) shall be waived in respect of those products for which remuneration is paid in the exporting Member”.¹⁵¹

While the third and final waiver pertains to the obligations under Article 31(f) of a developing country or LDC which is in a regional trade agreement (RTA). The said obligations are waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence to be exported to the markets of other developing country or LDC parties to a RTA that share the health problem in question.¹⁵² To legitimately use the said waivers, there are a number of terms that must be complied with by both importing and exporting members.

Obligations of Importing Members:

With the exception of LDCs, an eligible importing Member must make a prior notification to the TRIPS Council specifying the names and expected quantities of the product(s) needed,¹⁵³ confirming that the eligible importing Member in question “has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question,”¹⁵⁴ and confirming that, “where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (of August 30th 2003).”¹⁵⁵

¹⁵¹ Paragraph 3

¹⁵² Paragraph 6

¹⁵³ Paragraph 2(a)(i).

¹⁵⁴ Paragraph 2(a)(ii). The Annex to the decision sets out how the determination of insufficient manufacturing capacity should be made. Non LDC Members must establish either an overall lack of pharmaceutical manufacturing capacity or that following self assessment, the Member found that with the exclusion of the patent holder, it currently has insufficient pharmaceutical manufacturing capacity to meet its needs. The assessment of the sufficiency of manufacturing capacity is done on a product by product basis as opposed to sectorally. Should such capacity become sufficient to meet the members needs, then its authorization under the decision shall cease.

¹⁵⁵ Paragraph 2(a)(iii)

In addition, in order to ensure that the products imported under the August 30th 2003 Decision are used for the public health purposes underlying their importation, eligible importing Members are required to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.”¹⁵⁶

Obligations of Exporting Members:

Several obligations are imposed on exporting countries utilizing the system.

First, such an exporting country must have issued a compulsory license in accordance with Article 31 of the TRIPS Agreement.

Secondly, the compulsory license issued by the exporting Member must contain certain conditions. It must stipulate that “only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS.”¹⁵⁷ It must also stipulate that “products produced under the licence shall be clearly identified as being produced under the system set out in the August Decision through specific labelling or marking.”¹⁵⁸

Thirdly, the exporting country must also require that “suppliers ...distinguish such products through special packaging and/or special colouring/shaping of the products

¹⁵⁶ Paragraph 4

¹⁵⁷ Paragraph 2(b)(i)

¹⁵⁸ Paragraph 2(b)(ii)

themselves, provided that such distinction is feasible and does not have a significant impact on price.”¹⁵⁹

As per the fourth requirement, an exporting country must require that before shipment begins, the licensee shall post on a website “the quantities being supplied to each destination”,¹⁶⁰ and “the distinguishing features of the product(s).”¹⁶¹

The fifth requirement placed on an exporting country pertains to notification. An exporting Member is required to notify the TRIPS Council of the grant of the license and the conditions attached to it.¹⁶² The information provided in the notification shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b) (iii) which was mentioned above.¹⁶³

Finally, an exporting member who has granted a compulsory license under this system has an obligation to pay “adequate remuneration” to the patent holder pursuant to Article 31(h) of the TRIPS Agreement.¹⁶⁴

The August 30th 2003 Decision and the waivers contained therein were meant to provide a temporary solution to the Article 31(f) problem. The Decision mandated negotiations on the first permanent amendment to the TRIPS Agreement as a follow up to the August 2003 decision. The August 2003 Decision and the waivers granted by it terminate for

¹⁵⁹ *ibid*

¹⁶⁰ Paragraph 2(b)(iii).

¹⁶¹ *Ibid*.

¹⁶² Paragraph 2(c).

¹⁶³ *ibid*.

¹⁶⁴ Paragraph 3.

each Member on the date upon which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.¹⁶⁵

The Chairman's Statement:

To achieve a much needed consensus on the paragraph 6 question, it became necessary for the Chairperson of the General Council to adopt a statement to accompany the August 30th 2003 Decision.¹⁶⁶ The Chairman's Statement was issued essentially to placate the US and pharma and to ensure WTO Members that the decision would not be used for commercial purposes and thus undermine patent protection. This facilitated the countries arriving at a consensus before the biennial meeting of the WTO Ministerial Conference in 2003.

The Chairman's Statement has four important clauses: a 'good faith' clause,¹⁶⁷ an 'anti-diversion' clause,¹⁶⁸ a 'transparency' clause,¹⁶⁹ and a 'peaceful and expeditious settlement of dispute' clause. The Chairman's Statement also contains best practices used by companies such as GSK to minimise the diversion of their products.

The legal significance of the Chairperson's Statement is unclear. As a practical

¹⁶⁵ Paragraph 11.

¹⁶⁶ See, World Trade Organization, The General Council Chairperson's Statement, August 30, 2003, available at, http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm. (Hereinafter Chairman's Statement).

¹⁶⁷ Ibid. The clause states that WTO Members "recognize that the system that will be established by the Decision should be used in good faith to protect public health" and "not be an instrument to pursue industrial or commercial policy objectives."

¹⁶⁸ Ibid. In this clause, Members agree that "all reasonable measures should be taken to prevent ... diversion in accordance with the relevant paragraphs of the Decision."

¹⁶⁹ Ibid. The importance of notifications made under paragraph 2(a)(ii) of the Decision pertaining to eligibility of importing countries are underpinned by this clause as well as the instruction that such notifications should include information on how the Member in question established that it has insufficient or no manufacturing capacity in the pharmaceutical sector.

matter however, countries seeking to avail themselves of the August 30th 2003 Decision would be well-advised to make sure that their implementation of Decision is consistent with the Chairperson's Statement in order to avoid legal challenges.¹⁷⁰

The significance of the Chairman's Statement does not rest solely within its wording especially since its value as a legally binding document is unclear. The role played by the statement in facilitating an agreement in the August 30th 2003 Decision negotiations as well as its role as a factor dividing developing and developed countries in the subsequent negotiations on a permanent amendment are worth noting. This is because in the absence of the statement, the US would in all likelihood have not agreed to the August 30th 2003 Decision and with regard to the negotiations on the permanent amendment, so much attention was given to debating whether or not the statement should be included in the final amendment that little time was spent discussing and improving upon more substantive provisions.¹⁷¹ During the latter negotiations developing countries opposed the inclusion of the Chairman's Statement for fear that it would make it even more difficult to use the system while developed countries pushed for its inclusion as an assurance against *mela fide* use the waivers to the detriment of their pharmaceutical industries.

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3.8 The August 30th 2003 Decision: A Critical Analysis

The August 30th 2003 Decision and accompanying Chairman's Statement were hailed by the pharmaceutical industry as a welcome conclusion to the negotiations. In fact, Shannon Hertzfeld, the Senior Vice President of International Affairs of the Pharmaceutical Research and Manufacturers Association (PhRMA) issued the following statement on the day the negotiations were concluded:

¹⁷⁰ See, Frederick M. Abbott and Rudolf V. Van Puymbroeck, "Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of The Doha Declaration Paragraph 6 Decision. World Bank Working Paper No.61 (Hereinafter, Abbott and Van Puymbroeck).

¹⁷¹ See, Duncan Matthews, "From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries"? (2006) 10 Intellectual Property Quarterly 91-130. (Hereinafter Duncan Matthews (2006)).

“The two decisions that the General Council reached today will ensure that the system will not be abused. The additional clarifications contained in the Chairperson’s statement add strong provisions to prevent diversion, and increase the likelihood that the solution will benefit patients in the world’s poorest countries as envisioned in the Doha Declaration. Taken as a whole, this solution reaffirms the critical role of patents in the development of new medicines”.¹⁷²

Reading the decision from the perspective of stakeholders in the developing world, there are some very positive aspects to be drawn. For instance, the scope of the August 30th 2003 Decision is wide in terms of pharmaceutical products and diseases covered.

Pharmaceutical products are defined as any patented product or product manufactured with a patented process. Active Pharmaceutical Ingredients (APIs) are expressly included.¹⁷³ With regard to diseases covered, by not listing the diseases and through cross reference with the Doha Declaration, the decision is wide enough to cover all serious public health problems.¹⁷⁴

The Chairman’s statement suggests that the scope of the August 30th 2003 Decision goes beyond serious public health problems as it explicitly notes that some countries will only use the system for emergencies. It can thus be deduced that the system will normally apply to non emergencies (including routine public health care).

¹⁷² The Pharmaceutical Research and Manufacturers Association, Statement from Shannon Herzfeld, PhRMA’s Senior Vice President, International Affairs in reaction to the successful conclusion of the negotiations on TRIPS and Public Health. Available at: <http://www.phrma.org/mediaroom/press/releases/30.08.2003.841.cfm> (Last Accessed on April 10th 2007)

¹⁷³ Paragraph 1(a). The express inclusion of active pharmaceutical ingredients is significant because it broadens the scope of the decision to include a whole host of countries who may have significant innovative capacity in the pharmaceutical sector but not quite sophisticated enough to produce active ingredients. Thus the decision could be used by not only the very poorest developing countries with completely non existent manufacturing capacity but by any country experiencing public health problems and difficulties supplying affordable medication provided of course that the country has not opted out of using the decision as an importer.

¹⁷⁴ This was a significant victory for developing countries in the negotiations as the US had unsuccessfully attempted to restrict the application of the decision to HIV/AIDS, tuberculosis and malaria, the three diseases specifically mentioned in paragraph 1 of the Doha Declaration. See, paragraph 1(a) of the August 30th 2003 Decision, paragraph 1 of the Doha Declaration and Abbott, The Medicines Decision, p 328.

Another element of the decision favoring stakeholders in the developing world, particularly LDCs is that it contains a legal presumption in favor of LDCs' eligibility.¹⁷⁵ Other WTO Members may use the decision upon notification to the TRIPS Council.¹⁷⁶ Such notification is not determinative of the country's eligibility, it is merely intended to promote transparency.

Concern that the decision's wide scope in terms of eligible countries could see it benefit predominantly developed countries and high income developing countries as seen previously with compulsory licensing is allayed by the fact that most developed WTO Members have opted out of using the decision as importers.¹⁷⁷ These developed countries were joined by the 10 latest EU members.¹⁷⁸ Furthermore, high income developing countries have pledged to limit their importation under the mechanism to situations of national emergency or extreme urgency.¹⁷⁹

The definition of an exporting Member under the August 30th 2003 Decision is wide enough to encompass any WTO Member with the capacity to export the products in question to an eligible importing member.¹⁸⁰

¹⁷⁵ Paragraph 1(b) of the August decision. It should be noted that this is a significant degree of leeway as certain LDCs do have reproductive capabilities in terms of finished products from imported ingredients in the pharmaceutical sector; yet the presumption ensures that their ability to use the decision is not prejudiced. An example of such an LDC according is Zambia. See, Correa, (2002).

¹⁷⁶ Paragraph 1(b) of the August decision.

¹⁷⁷ These members are listed in a footnote to paragraph 1(b), they are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

¹⁷⁸ Slovenia, Estonia, Lithuania, Latvia, Hungary, Slovakia, the Czech Republic, Poland, Malta and Cyprus.

¹⁷⁹ See, The Chairman's Statement. The said countries are listed as follows: Chinese Taipei, Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Turkey and the United Arab Emirates.

¹⁸⁰ Paragraph 1(c).

An important feature of the August 30th 2003 Decision is that the paragraph 6 waiver is of benefit to trade groupings in Africa. Specifically, the Southern African Development Community (SADC) and the Common Market for East and Southern Africa (COMESA) qualify to use the waiver, these are regions where the diseases necessitating access to affordable medicines are most severe.¹⁸¹

The waiver allows these regional blocs to make use of economies of scale by bulk procurement by one (or more) of the members. It also facilitates the importation of component materials, formulation into finished products, and export to countries of the RTA. In the event of re-exportation to members of the RTA, paragraph 6 of the August 30th 2003 Decision does not impose any obligation of notification to the WTO. As an additional flexibility, the regional organization may make the required notification to the WTO of actual importation on behalf of all the importing members of the RTA.¹⁸² Members of eligible RTA's will need to harmonize their IP legislation in order to take advantage of the opportunities created by paragraph 6.¹⁸³

There is however a potentially disabling limitation to the paragraph 6 waiver arising from the conditions for its utilization. The waiver requires that the exporting country have the status of developing country or LDC and that the RTA contain at least a fifty percent LDC membership. While these requirements ensure a system that directly benefits the regions most in need of access to essential medicines, it also results in a system that may not be sustainable, take for instance the case of SADC. The said regional bloc has a membership comprising of exactly fifty percent developing country and fifty percent LDC membership, therefore the graduation of any member would render the RTA ineligible for the paragraph 6 waiver.¹⁸⁴

¹⁸¹ See, Chapter 1 above, the section entitled, "The Significance of the Study".

¹⁸² See, Abbott and Van Puymbroek.

¹⁸³ See, Avafia, Berger and Hartzenberg.

¹⁸⁴ Madalitso M. Mmeta "Amendment to TRIPs Agreement: consensus or dissension"? Available at: <http://www.tralac.org/scripts/content.php?id=5393> (Last Accessed on 30th December 2006. (Hereinafter Mmeta (2006)).

Another very important merit of the August 30th 2003 Decision from the perspective of IP users in the developing world is the fact that paragraph 9 explicitly retains the flexibility that Members have under the TRIPS Agreement and reaffirmed by the Doha Declaration with regard to provisions other than Articles 31(f) and (h).

The most significant benefit of the mechanism is perhaps the most apparent, the fact that the production of pharmaceutical products for the sole purpose of exportation is allowed. This alone in theory makes medicines more accessible in countries lacking pharmaceutical manufacturing capacity.

In practice however, the positive effect of the mechanism on access to medicines in the countries targeted may be less clear as NGOs and commentators alike have pointed out. They have been very critical of the August 2003 decision. Some NGOs have labelled it a gift bound in red tape.¹⁸⁵

The statement by PhRMA on the August 30th 2003 Decision presupposes that the mechanism can and will actually be used by the world's poorest countries. That assumption is currently far from proven. To date, the August 30th Decision has never been used by any country and has thus not benefited a single patient in any poor country. In exploring why this has been the case, it is necessary to consider some of the difficulties posed by various aspects of the Decision.

¹⁸⁵ Joint NGO Statement on TRIPS and Public Health WTO Deals on Medicine: A “Gift” Bound in Red Tape (September 10, 2003). Available at: <http://www.cptech.org/ip/wto/p6/ngos09102003.html> (Hereinafter Joint NGO Statement(2003)). The statement was signed by the following organizations: ACT Up Paris; Consumer Project on Technology; Consumers International; Essential Action; European AIDS Treatment Group; Health Action International; Health GAP; International People's Health Council; Médecins Sans Frontières; OXFAM International; People's Health Movement; SEATINI; Third World Network; Women in Development; CPTech; HAI; HealthGAP; MSF; Oxfam; and Third World Network.

The fact that each and every condition must be fulfilled over and over again for each and every drug and for each and every country by whom and to whom the drug will be exported has been described as a procedural nightmare.¹⁸⁶

Procedural and administrative obstacles have traditionally been attributed as contributory factors in the relative scarcity of the use of compulsory licenses in developing countries.¹⁸⁷ If the use of the original Article 31 was hindered by administrative constraints, it is unclear how a system which brings forth additional and more cumbersome procedural requirements which must be satisfied every time the decision is used will not in fact exasperate that particular obstacle. The August 30th 2003 Decision does encourage technical cooperation from developed Members in case of difficulty in utilizing the system. The TRIPS regime however, has always encouraged developed countries to provide technical cooperation through Article 67 yet administrative obstacles to compulsory licensing have persisted regardless.

Under the August 30th 2003 Decision, generic manufacturers must differentiate pill size, shape, and color from brand-name products. These measures are to act as safeguards on re-importation. There is a legitimate fear however that the safeguards may prove too costly for developing countries and generic manufacturers alike and thus discourage the use of compulsory licensing.

The author is not at all suggesting that safeguards against diversion are not necessary, to the contrary it is imperative for public health in poor countries that medicines imported under the August 30th 2003 Decision would reach their intended recipients. What the author questions however is whether giving the TRIPS Council the authority to second guess and interfere with the terms of compulsory licenses by requiring them to

¹⁸⁶ Uche Ewelukwa, "Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics and Global Trade". Available at: <http://law.bepress.com/cgi/viewcontent.cgi?article=1558&context=expresso> (Last Accessed on 10th April 2007). (Hereinafter, Ewelukwa, Patent Wars).

¹⁸⁷ See, Abbott, The Medicines Decision.

incorporate specific terms is appropriate.¹⁸⁸ It is difficult to reconcile this requirement with paragraph 5 of the Doha Declaration which confirms the right of Members to determine their own compulsory licensing terms. It would thus be a better practice to allow the countries concerned to maintain their traditional right under the TRIPS Agreement as confirmed by the Doha Declaration to determine their own compulsory licensing terms including independently determined safeguards for preventing diversion.

Although double compensation has been eliminated by the waiver of Article 31(h) remuneration for the importer, paragraph 3 which provides the waiver contains no safeguard against the said remuneration being added to the price of the medicines which is paid by the importer.

The August 30th 2003 Decision still requires that compulsory licenses be issued on both import and export side, maintaining the obligation to grant two compulsory licenses can cause significant delays.

One may counter-argue that the requirement to attain two compulsory licenses can not be attributed to the August 2003 Decision as it was always present in the TRIPS Agreement. In fact it is also arguable that it would be easier for generic producers to gain voluntary licenses from brand producers in potential exporter countries because their fears of being undercut are allayed by the safeguards and restrictions imposed by the Decision. What such an argument fails to consider however is that the safeguards and restrictions in the Decision impose significant obligations on potential exporter generic producers which result in a lack of commercial viability and are thus likely to create disincentives for generic companies seek the compulsory licenses necessary to produce and export the medicines needed by poor countries.

Health GAP (an AIDS Activist Organization) has argued moreover that the solution crafted by the August 30th 2003 Decision “is a failure for people with AIDS, and people

¹⁸⁸ See, paragraph 2(a)(ii) August 30th 2003 Decision and The Best Practices Guidelines in the Chairman’s Statement.

everywhere dying of treatable diseases”. The argument is that even if a willing and capable generic producer in an amenable exporting country is identified, “in the time it would take a generic company and the countries concerned to comply with all the conditions set out by the August 2003 decision, a patent would likely expire anyway.”¹⁸⁹ The criticism appears to be harsh but when one considers that the steps that must be taken in order to legitimately use the decision, the critique is not frivolous. The said steps are:

(1) Where the compulsory license is by a country that has no capacity to manufacture the medicine locally and the country is not a LDC, such a country must assess its industry’s capacity to produce the medicine locally, notify the TRIPS Council of its determination that it has no or insufficient capacity, and explain and justify its decision regarding capacity.¹⁹⁰

(2) The importing country must identify and notify a willing exporter that has sufficient capacity to manufacture the needed medicine.

(3) The prospective exporter must seek a compulsory license from its own government. In granting the license, the prospective exporting country must ensure that the conditions stipulated in Article 31 of the TRIPS Agreement.

(4) If and when a license is granted, the exporter must take adequate measures as stipulated in the Decision to prevent diversion. In particular, the exporter must: (a) produce only the amount necessary to meet the needs of the eligible importing Member;

¹⁸⁹ Health GAP Global Access Project, “*Bush Administration, Big Pharma about to secure disastrous “solution” on access to medicines at the WTO in effort to boost failing pre-Cancun talks, countries are poised for sell-out on public health*”, Press Release (August 28, 2003) , available at: http://www.healthgap.org/press_releases/03/082803_HGAP_PS_WTO_para6_aug30text.html (Last Accessed on 10 April 2007).

¹⁹⁰ This assessment alone could take a substantial amount of time, particularly where the country does have some pharmaceutical manufacturing capacity but it must undertake a defensible assessment of the entire national pharmaceutical industry which concludes that the country lacks the capacity to produce a particular product. Such an assessment on its own is technology and resource intensive and thus poorer countries may lack capacity to undertake a scientifically cogent assessment to the same extent that they lack capacity to manufacture the relevant product in the first place.

(b) export the entirety of the production to the Member(s) which notified its needs to the Council for TRIPS; (c) clearly identify the products produced under the system through specific labeling or marking, special packaging and/or special coloring/shaping of the products themselves; (d) before shipment begins, post on a website, the quantities being supplied to each destination and the distinguishing features of the product(s).¹⁹¹

Once the steps required to legitimately use the decision are laid down in this sequence, the concerns of Health GAP seem legitimate.

One of the supposed benefits of the August 30th 2003 Decision is that it creates a climate of legal certainty for countries that they will not be challenged for using the system. This legal certainty is said to be provided by the moratorium in paragraph 10 of the August 30th 2003 Decision.

It is not clear however if Members who utilize the system are completely immune from lawsuits under the WTO dispute settlement procedure. The Decision provides that “Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision”. This provision on moratorium is unilateral and not legally binding. This is because the moratorium is only a promise not to bring a lawsuit and thus falls short of a legally binding statement of non justiciability which is a clear, multilateral determination that actions taken under the mechanism are non-justiciable.¹⁹²

This uncertainty coupled with the track record of industrialized countries and pharma on allowing developing countries to exercise their compulsory licensing rights render it unsurprising that Members concerned have been hesitant to use the mechanism created by the August 30th 2003 Decision.

¹⁹¹ See, Ewelukwa, Patent Wars.

¹⁹² Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002) 12 Fordham Intellectual Property, Media & Entertainment Law Journal 859, quoted in Ewelukwa, Patent Wars.

Some criticisms leveled by NGOs appear to be voiced for the sake of opposing. Among these is the criticism that the August 2003 Decision “contradicts the basic principles of the WTO and fair trade” by prohibiting the export of drugs manufactured under the system to rich countries.¹⁹³ This contention completely ignores the fact that the Decision is meant to benefit poor countries whose poverty renders Article 31(f) an obstacle to their use of compulsory licensing. The contention marks a notable departure from the very role of those NGOs as advocates for the need to balance free trade with the development objectives of the south.

Some commentators reserved criticism preferring rather to allow the actual effect that the August 30th 2003 Decision would have on access to medicines in countries without manufacturing capacity be the determinative factor on the success or failure of the same. One such commentator, Constantine Michalopoulos opined as follows:

“It is important that the agreement reached on means to operationalise the exception on the imports of low cost drugs by developing countries finally reached in August 2003 is shown to be an effective solution through its rapid use by those countries in need and, if not, that more effective measures with less constraints be introduced”.¹⁹⁴

The view of Michalopoulos is logical as a mechanism which does not fulfill its purpose should not be maintained. Therefore the fact that the August 30th 2003 Decision (contrary to the prediction of PhARMA) has not benefited a single patient, tends strongly towards vindication of the view of critics.

Paragraph 11 of the August 30th 2003 is thus problematic as it mandated negotiation on a permanent amendment of TRIPS based on the August 2003 decision regardless of whether or not the mechanism proved effective. Surely a permanent amendment based on

¹⁹³ Joint NGO Statement (2003).

¹⁹⁴ See, Michalopoulos, p 2.

the August 2003 decision could rationally only be introduced once the latter had been tested and shown to be effective.¹⁹⁵

There is currently a dissenting view emerging to the effect that the August 30th 2003 mechanism need not actually be used to lower the price of medicines because the mere existence creates the threat of compulsory licensing and thus the mechanism will serve as a bargaining tool for licensing negotiations with patent holders.¹⁹⁶

The author disputes this reasoning on the basis that as per Abbott, the threat of compulsory licensing can only be an effective bargaining tool where there is a real and legitimate threat of a compulsory licensing.¹⁹⁷ The conditions imposed by the mechanism coupled with the fact that it has never been used render the threat of compulsory licensing posed under the August 30th 2003 mechanism no more than theoretical.

3.9 The 2005 Amendment Decision

The reasoning of commentators like Michalopoulos however, did not prevail. December 6th 2005 saw agreement reached on the text of an amendment to the TRIPS Agreement based on the August 30th 2003 waiver as mandated by paragraph 11 of the decision. Sadly, most of the discussion in the 2005 Amendment Decision negotiations focused on if and how the Chairman's Statement should be included in the permanent amendment as

¹⁹⁵ WTO Members Should Reject Bad Deal on Medicines, Joint Statement by NGOs on TRIPS and Public Health, December 3 2005, (hereinafter NGO Statement (2005)). Available at: <http://www.cptech.org/ip/wto/p6/ngos12032005.html>

¹⁹⁶ See, Mmeta (2006), p8.

¹⁹⁷ F M. Abbott, "WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries", IPR Commission, Study Paper 2a. Available at: http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf (Last Accessed on 24th April 2007).

opposed to how to make the substantive provisions of the August 30th 2003 Decision more effective in promoting access to medicines in the intended recipient countries,¹⁹⁸

The 2005 Amendment Decision was designed to match the August 30th 2003 Decision as closely as possible except for one significant change to the list of Members which opted out of using the waiver as importing Members. The change is that reference to the EC no longer contains the names of the individual states, it now refers to the EC with the effect that all states that are members of the EC immediately adopt the opt out upon accession to the EU.

The 2005 Amendment Decision consists of a protocol amending the TRIPS Agreement, an annex to the protocol amending TRIPS Agreement, an Annex to the TRIPS Agreement and an appendix to the Annex to the TRIPS Agreement.¹⁹⁹

The amendment will come into effect once two thirds of WTO membership has adopted the same; the deadline for two thirds assent is set at 1 December 2007 but is renewable.

The substantive part of the amendment is contained in Article 31*bis* which is contained in the Annex to the Protocol amending the TRIPS Agreement and consists of five paragraphs, they provide the following:

An Article 31(f) waiver; an Article 31(h) import side waiver with a view to preventing double remuneration; a waiver of Article 31(f) to the extent necessary to allow regional exportation of pharmaceutical products imported under compulsory license, provided the importing Member is a Developing country or LDC and is part of an RTA, composition is at least 50% LDC; a moratorium on non violation complaints against measures taken in

¹⁹⁸ See, the minutes of the TRIPS Council Meetings of March 31 2005; June 14– 15, 2005; and October 25-26,2005. See also “TRIPS Council Still Divided on Public health Amendment”, Bridges Weekly Trade News Digest, Vol. 9, No.36. Available at: <http://www.ictsd.org/weekly/05-10-26/index.htm>

¹⁹⁹ Duncan Matthews (2006), p111.

conformity with the system; and the retention of all existing TRIPS flexibilities not pertaining to Articles 31(f) and (h).²⁰⁰

The terms of using the substantive waivers are contained in the new Annex to the TRIPS Agreement and like the substantive paragraphs discussed above, are based on the conditions set out in the August 30th 2003 Decision.²⁰¹

With regard to the Chairman's Statement, it is not expressly mentioned in the 2005 Amendment Decision although it is arguable that its effect remains due to the choreography adopted for the adoption of the amendment which included the reading of the chairman's statement by the Chairman of the General Council of the WTO.²⁰²

The 2005 Amendment Decision was heralded by WTO Director General Pascal Lamy as confirming "once again that Members are determined to ensure that the WTO trading system contributes to humanitarian goals". Other proponents of the 2005 Amendment Decision have argued that it improves the legal certainty of the waivers propounded by the August 30th 2003 Decision.

Conversely, NGOs are not convinced by the 2005 Amendment Decision., 31 NGOs issued a joint statement to that effect on Monday, 5th December 2005.²⁰³ The NGOs expressed alarm that such an important instrument was based on a mechanism that has

²⁰⁰ Ibid.

²⁰¹ Ibid, pg 113.

²⁰² See, "Choreography for the Adoption of the Decision on the Amendment," para 5. Available at: <http://lists.essential.org/pipermail/ip-health/2005-December/008774.html>, (Last Accessed on 18th April 2007). See also Duncan Matthews (2006), pg 112.

²⁰³The NGOs included Oxfam, Action Aid, Christian Aid, Health GAP, CPTech, Health Action International (Africa and Asia Pacific), Ecumenical Advocacy Alliance, Pharmaciens Sans Frontieres Comite International, Medecins sans Frontieres Access to Essential Medicines Campaign, Act Up Paris, Third World Network and scores of treatment access groups issued a public statement urging WTO delegates to reject a bad deal on medicines.

failed to improve access to medicines.²⁰⁴ Criticism of the Amendment was not restricted to NGOs though. Three members of the US Congress, Henry Waxman, Sherrond Brown and Thomas Allen, wrote an open letter to then USTR, Robert Portman requesting immediate clarification on the US governments position on compulsory licensing and by importation. The letter asked specifically why the US intended to make permanent a system that had been criticized as overly burdensome and had not yet been shown to be effective.²⁰⁵

The fact that the WTO Members from different ends of the TRIPS/Public Health debate could come to a compromise culminating in a landmark decision to amend the TRIPS Agreement . Yet as various NGOs have pointed out, it did not make much sense to base the 2005 Amendment Decision on a mechanism that has never been used and which contains time consuming, costly and cumbersome conditions that arguably make the mechanism unworkable These constraints tend to defeat the very purpose of the 2005 Amendment Decision, to make it easier for countries without pharmaceutical manufacturing capacity to import the medicines they need.

Therefore, delaying the 2005 Amendment Decision would have been a better option as it would have provided an opportunity for testing and improving the August 30th 2003 Decision. There was no necessity to conclude the negotiations on an amendment to the TRIPS Agreement in 2005 since the waivers of the August 30th 2003 Decision, according to paragraph 11 thereof would only terminate on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member, effectively rendering the 30th August 2003 waiver permanent.²⁰⁶

²⁰⁴ See MSF, Amendment to WTO TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak. Available at: <http://www.accessmed-msf.org/prod/publications.asp?scentid=71220051425522&contenttype=PARA> (Last Accessed on 14th April 2007).

²⁰⁵ The letter was sent the day before the 2005 Amendment Decision was adopted by the General Council but 6 days after the draft text was made available on 29th November 2005. See, “Text with footnotes of Waxman, Allen, Brown letter to USTR”. Available at: <http://lists.essential.org/pipermail/ip-health/2005-December/008776.html> (Last Accessed on 18th April 2007).

²⁰⁶ NGO Statement (2005).

It is also difficult to conclusively judge the August 2003 Decision and the subsequent 2005 Amendment Decision in the absence of testing by importing and exporting Members. It is however clear that the conditions imposed on Members wishing to use the mechanism are highly complex and have the potential to render the mechanism unworkable.

3.10 An Alternative Solution to the Article 31(f) Problem

Article 31(k) of the TRIPS Agreement provides in relevant part as follows:

“Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases”.

A compulsory license issued in accordance with Article 31(k) is thus impervious to *inter alia*, the Article 31(f) restriction. The provision contains considerable flexibility as it is left to the Members concerned to define in their own domestic law what they consider to be anti competitive practice. To a large extent though, the effective utilization of this provision will be dependant on relevant countries’ capacity and legal infrastructure in the field of competition law.²⁰⁷

Thus, to conclude as to whether the above discussed flexibilities are sufficient to foster an equitable balance in the TRIPS patent regime, one can comment that the operational transition period currently offers limited benefits to the developing world but there are significant opportunities with regard to exemption from patentability, parallel importation and compulsory licensing.

Compulsory licensing however offers a very different extent of benefit for richer developing countries with pharmaceutical manufacturing capacity than for poorer

²⁰⁷ See, Avafia, Berger and Hartzenberg.

developing countries and LDCs. For the former, depending on their implementation, there are significant opportunities within the compulsory licensing provisions of the TRIPS Agreement to genuinely facilitate greater access to affordable medicines. As far as countries without pharmaceutical manufacturing capacity are concerned however, there are significant problems and it is rather doubtful whether the TRIPS Agreement and the subsequent developments on their own can offer much of a reprieve.

4. Chapter 4: Is Our Implementation Adequate?

4.1 Introduction

The TRIPS flexibilities are now well established. What is also well established is that whatever benefits that may accrue to countries from the TRIPS flexibilities do not arise automatically; they are dependant on implementation and utilization by nations. The WHO recognizes this reality and has accordingly urged WTO Members to “consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement”.²⁰⁸

Therefore, this chapter will examine the extent to which two potentially significant countries have implemented and utilized TRIPS flexibilities and in so doing, answer the second question posed by the title of this thesis, namely, “is our implementation adequate”? The reasons why these two countries in particular were chosen are explained in the introduction to each case study below.

4.2 India: A Brief Introduction

²⁰⁸ Fifty-Sixth World Health Assembly, Agenda item 14.9, WHA56.27, 28 May 2003

India's policy of not granting patents for medicines and their utilization of flexibility in the TRIPS Agreement to continue not granting such patents proved hugely important for the country's industrial development, meeting domestic public health needs and the public health needs of an un-estimated number of countries internationally. The specifics of why this is so will be discussed in full below. What is important for this brief introduction is to note that India's inclusion in the study is a consequence of the importance of the nation's patent laws and continued use of TRIPS flexibilities in terms of how it affects the ability of the country's pharmaceutical industry to supply generic medicines, not just for India but for many countries across the developing world.

4.3 Introduction to Relevant Aspects of Indian Patent Legislation

Patent law in India originated in colonial times with the Patents and Designs Act of 1911 which consolidated pre-existing colonial Patent rights. After colonialism, however it emerged that these laws were not suited to national objectives, this led to the formation of the Tek Chand Patents Enquiry Committee in 1948 and the more famous Ayyangar Committee in 1959. These committees employed an evidence based, analytical and transparent review of the domestic and international patent regimes. The result was the Indian Patent Act of 1970 (IPA'1970). The legislation was described by Justice Krishna Iyer (perhaps the most revered judge of the Indian Supreme Court) as follows:

“A well debated, development-oriented and patriotically processed statute of 1970, with a progressive perspective...passed after a thorough study, a tremendous national triumph”.²⁰⁹

Justice Iyer is not alone in his appreciation of IPA' 1970, the Act is widely regarded as a watershed in the Industrial development of India. It preserves the continuing interest of the inventor in his creation, the social interest in encouraging research, the consumers'

²⁰⁹ Dwijen Rangnekar, “*No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime*”. Available online at: <http://www2.warwick.ac.uk/fac/soc/csgr/research/workingpapers/2005/wp17605.pdf> (Last Accessed on 5th April 2007). (Hereinafter Rangnekar (2005)).

interest in enjoying the fruits of inventors' reasonable cost, and the creation of conditions for the acceleration and promotion of the economic development of the country.²¹⁰

Full compliance with the TRIPS Agreement necessitated the promulgation of three amendments to IPA 1970.

The first was enacted following a ruling in the DSB of the WTO that India had failed to implement its obligations with respect to Articles 70.8 and 70.9. Therefore, India enacted the first amendment, The Patents (Amendment) Act, 1999 (No. 17 of 1999), adding Chapter IVA titled 'exclusive marketing rights'.

The second amendment, Patents (Amendment) Act, 2002 (No. 38 of 2002) was enacted on 25 June, 2002.

The final patent-related obligation, product patents in exempt technologies,²¹¹ was to be enacted through the Patents (Amendment) Bill, 2003, but this lapsed with the dissolution of Parliament. The new government decided to introduce a marginally revised version of the same as the Patents (Amendment) Ordinance, 2004 (Ord. No. 7 of 2004) (hereinafter, the Ordinance) in light of the 1 January, 2005 deadline.

A final amendment was required to placate critics of the Ordinance which had raised protests from within India and all corners of the world including multilateral organisations such as the WHO and UNAIDS. These critics described the implications of the Ordinance as 'potentially devastating' to developing countries and LDCs who are dependent on Indian generic drugs. Responding to the widespread criticism, the government withdrew or re-drafted certain amendments to the Ordinance and Parliament gave its approval to the bill with those amendments on 23rd March 2005.

²¹⁰ Musungu and Oh (2006).

²¹¹ Namely, pharmaceutical and agrichemical products.

Thus in the final analysis, the Patents (Amendment) Act 2005 (hereinafter, 2005 Act) which received presidential assent is the instrument currently governing patent protection in India. Therefore the proceeding commentary on the implementation of TRIPS flexibilities in Indian patent law will be based predominantly on the 2005 Act.

4.4 Implementation of Flexibilities in India's New Patent Law

4.4.1 Transition Periods

India is a country with low cost human resources possessing specialist skills as well as a large domestic market for pharmaceuticals. The fulfillment of these preconditions made low cost pharmaceutical production economically viable in India.

The transition period applying to India was ended with the inception of the 2005 Act; this obviously necessitates discussion of the transition period applicable to India to being based on previous legislation.

IPA 1970 provided in Chapter II, Section 5 that inventions in the technological area of chemicals, food and drugs would be limited to claims regarding methods or processes of manufacture thus prohibiting product patents. As predicted by the Ayyangar committee, the country's process patent regime allowed their skilled scientists to develop alternative processes to manufacture equivalents of pharmaceutical products. This resulted in technological advancement and the development of a massive pharmaceutical industry able to provide low cost generic medicines not only domestically but to a huge range of international clientele.²¹²

The importance of India as an international supplier of generics is highlighted when you consider *inter alia* the following:

²¹² Rangnekar (2005).

80% of ARVs that Médecins Sans Frontières (MSF) uses for distribution in over 30 developing countries are purchased from India; over 50% of essential medicines that United Nations Children's Fund (UNICEF) distributes to in developing countries are purchased from India; and 75-80% of medicines distributed by the International Dispensary Association to developing countries are manufactured in India.²¹³

Excluding pharmaceutical product patents quite literally made India, the pharmacy of the poor.

Before the Ordinance, India utilized the Article 65.4 transition period to continue not granting patent protection for pharmaceutical products as mandated by Article 28 and the non discrimination clause of the TRIPS Agreement.

India's utilization of the transition period meant that applications for medicines already in India's mailbox did not have to be assessed until 2005 including medicines discovered between 2000 and 2005. This ensured from the entry into force of the TRIPS Agreement, at least 10 more years of virtually unfettered access to essential medicines for its own population including an estimated 5,700,000 Indians living with HIV/AIDS,²¹⁴ and even greater numbers of people across the developing world living with *inter alia* HIV/AIDS, tuberculosis and malaria.²¹⁵

One of the major areas of concern about India's full compliance with the TRIPS Agreement was the ability of generic pharmaceuticals to continue producing medicines which following examination, graduate from the mailbox to full patent protection. The ordinance was criticized for not addressing this issue. In response to the criticism, the

²¹³ See, Médecins Sans Frontières "Examples of the Importance of India as The Pharmacy for the Developing World". Available at: <http://www.accessmed-msf.org/documents/overview%20Jan%202007%20final.doc> (Last Accessed on 12 April 2007).

²¹⁴ UNAIDS/WHO 2006 Report on the global AIDS epidemic. Available on line at: http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp (Last Accessed on 27th April 2007)

²¹⁵ Ibid and Chapter 2 above.

government in revising the Ordinance introduced a new provision to Section 11A of the 2005 Act.²¹⁶

The newly inserted 3rd proviso to Section 11A, in paragraph seven thereof provides that generic production can continue on cumulatively meeting the following conditions: (1) substantial investment has been incurred, (2) production and marketing has commenced prior to and continues subsequent to 1 January 2005, and (3) a reasonable royalty rate is paid to the patentee. Accordingly, patentees cannot institute infringement proceedings against these said producers.²¹⁷

Section 11A (7) seeks to ensure the continued production of currently available generic medicines. There remain however a number of issues that still require clarification. These concern the definitions of “significant investment” and “reasonable royalty”. There is concern that the requirement of significant investment may be open to differing interpretations. Similarly, in the case of reasonable royalty, guidelines may be necessary to reduce uncertainty and thus reduce the potential for strategic litigation by patent holders.²¹⁸ In this regard, the practice in other countries may be instructive in terms of setting compensation or royalty rates for compulsory licenses. For example, the Japanese guidelines for royalty rates range between 2- 8%, and on average 4% and 5% rates are normally used in Canada and the United States.²¹⁹ It is also not certain whether this provision is TRIPS compliant which could potentially lead to litigation in the WTO's DSU.²²⁰

²¹⁶ See, FM Abbott, Amy Kapczynski and TN Srinivasan, “*The Draft Patent Law*”. Available at: www.hinduonnet.com/2005/03/12/stories/2005031201151000.htm (Last Accessed on 7 April 2007). (Hereinafter, Abbott, Kapczynski and Srinivasan).

²¹⁷ It is not certain whether this provision is in compliance with the Articles 70 and 28 of the TRIPS Agreement. It will thus be interesting to observe if it will be the subject of litigation in coming years.

²¹⁸ See, the section on patentability above for an explanation of “Strategic litigation”.

²¹⁹ Musungu and Oh (2006).

²²⁰ See, Lexorbis, Intellectual Property Practice, “*India’s Patents Bill, 2005 - Is It TRIPS Compliant?*” Available at: http://www.mondaq.com/i_article.asp_Q_articleid_E_31717 (Last Accessed on 12th March 2007).

4.4.2 *The Patentability Criteria and Exemption from Patentability*

"Ever greening" is a common phenomenon in the pharmaceutical industry for instance, details of the 7,000 applications in India's mailbox have recently been made public. An analysis by the Indian Pharmaceutical Alliance revealed that only 250 of the applications could relate to new chemical entities and associated new drugs that were developed outside India during the 10-year period of 1995-2005,²²¹ the other 6,750 therefore relate to, incremental inventions.²²²

There was thus a fear that full TRIPS compliance would result in Indian generic producers manufacturing drugs which were invented even before 1995 being blocked from the market as foreign producers might be granted Indian patents for older drugs based on later-filed patents on incremental inventions. Very few Indian generic producers have the financial means to fight protracted legal battles with the major multinational pharmaceutical companies over the thousands of patents on incremental inventions.²²³ These concerns underpin the importance of the Indian legislature utilizing the flexibility in Article 27.1 of the TRIPS Agreement to exclude incremental inventions from patentability. Let us now examine how this has been attempted.

Patentable subject matter in the field of pharmaceuticals and substances excluded from patentability are dealt with under Sections 2 and 3 of the 2005 Act. Three provisions in the 2005 Act stand out as utilizing the flexibility in Article 27.1 of the TRIPS Agreement by adopting a strict standard of patentability. They are the provisions dealing with (1) inventive step, (2) pharmaceutical substance and (3) exclusion from patentability.

Inventive step:

²²¹ (See National Institute for Health Care Management, "*Changing Patterns of Pharmaceutical Innovation*" (2002).

²²² Gopalkumar, KM and Tahir Amin, "Patents (Amendment) Bill 2005: A critique, *Economic and Political*". Available at www.epw.org.in (Last accessed on 15 April 2007). (Hereinafter Gopalkumar and Amin).

²²³ Ibid.

Section 2(j) of IPA 1970 defined an inventive step as “a feature that makes the invention not obvious to a person skilled in the art”. This definition has been replaced in the 2005 Act by Article 2(f) which defines an inventive step as “a feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art”.

The new provision has been criticized by Indian commentators such as Gopakumar and Amin, and internationally by the likes of Abbott and Musungu. These commentators are of the view that with the inclusion of the words, “or having economic significance”, the requirement of technical advancement is compromised and diluted by the fact that a patent could be granted on economic significance alone. According to these commentators, the IPA 1970 provision is thus broadened to the benefit of patent holders and to the detriment of generic producers and public health. Some commentators have recommended that the word “or” be removed from this phrase.²²⁴

Pharmaceutical substance:

For the purposes of patentability, a pharmaceutical substance is defined by Section 2(h) of the 2005 Act as “any new entity involving one or more inventive steps. This definition has been criticized as too broad, allowing all types of pharmaceutical substances to be patented. It has been submitted by Gopakumar that the term ‘chemical’ should have been inserted so that the definition would read “any new chemical entity”. According to proponents of an amended text, the present definition facilitates ever greening, is TRIPS plus and encompasses every type of pharmaceutical entity, including but not limited to, formulations, pharmaceutical salts, isomers, polymorphs and their combinations.²²⁵

The author supports the notion that a narrow scope of patentable pharmaceutical substance should be adopted so as to allow for a larger public domain and thus facilitate access to medicines; however, the fear expressed by Gopakumar concerning the scope of

²²⁴ See *inter alia* Musungu and Oh, p21, Rangekar, p4 and Gopakumar, p2.

²²⁵ See, Gopakumar and Amin.

entities falling within the scope of patentable under the Act is unfounded. This opinion is based on Article 3 of the 2005 Act.

Article 3 provides that, “the mere discovery of a new form of a known substance which does not result in the enhancement the known efficacy or the mere discovery of any new property or new use of such known process results in a new product or employs at least one new reactant”, would not be considered a patentable invention. The provision goes further in paragraph (d) stating, “ For the purposes of this clause, salts, esters, polymorphs, metabolise, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of know substances shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy”.

Thus, a reading of Article 3(d) reveals that the very entities which Gopalkumar fears patentable under the 2005 Act, are in fact, expressly excluded from patent protection. Section 3(d) was specifically targeted at preventing ever greening.

Section 2, dealing with novelty along with section 3 and pre-grant opposition provisions of the 2005 Act were used to great effect during the January 2006 denial of the patent application for an anti cancer drug beta crystals of Imatinib mesylate marketed as glivic by the Swiss pharma major Novartis, one of the pharma 39 complainants in the case against South Africa.²²⁶ Following the denial of the patent application by the Indian Patent office, Novartis sought to have the denial reversed in the Indian Courts. The application of Novartis was opposed by a cache of Indian generic producers including Cipla and Ranbaxy pursuant to the reinstated pre grant opposition procedures.²²⁷

The opposition was based on three arguments, (1) lack of inventive step/ obviousness and anticipation by Prior publication; (2) section 3(d) of the 2005 Act and (3) lack of priority

²²⁶ The pre-grant opposition provisions (which were reinstated following their removal by the Ordinance) can be found in Chapter V of the 2005 Act headed Representation and Opposition Proceedings.

²²⁷ Médecins Sans Frontières Briefing Note (2006) “*The case of Novartis’s challenge against the Indian government and what it could mean for millions of people across the globe*”. Available online at: <http://www.accessmedmsf.org/documents/Novartis%20Briefing.doc> (Last Accessed on 28th April 2007).

due to Switzerland's non membership of the Paris Union.²²⁸ Only the first two grounds for opposition are relevant for the current discussion.

As regards the first ground, the opponents' contention was that imatinib mesylate is known from prior publication in the US patent no. 5521184, the subject matter of the application was thus anticipated by the US patent. The opponents argued that there is no ingenuity or human intervention or novelty and inventive step in the preparation of beta crystal salt of imatinib mesylate as that is only a new form of a known substance and not an invention under 2005 Act.

The applicants counter argued that the disclosure made in the US patent is of the free base, 'imatinib' and not its salt, imatinib mesylate, therefore the present invention involves a two-fold improvement over the prior art. (1) The imatinib free base is chemically changed into a salt form and (2) a particular crystal form, beta crystal form, of the salt is made through human intervention. Further that the US patent does not give any example for the preparation of imatinib mesylate nor are there any claims made for it; however they conceded that the US patent may embrace imatinib mesylate.

It was held that the subject of the patent application was disclosed by prior art as it did not differ sufficiently from the US patent. Thus the opponents succeeded in proving that the application of Novartis was obvious, did not involve an inventive step and was anticipated by prior publication, it was hence, not an invention.

Under the Second ground, as regards efficacy under Article 3(d), the opponents pointed out that the patent application itself states that wherever beta crystals are used, the imatinib freebase or other salts can be used equally in the treatment of diseases or in the preparation of pharmacological agents. Therefore, it was argued that, the present patent specification does not bring out any improvement in the efficacy of the beta crystals over the known substance.

²²⁸ For an explanation of the terms priority and Paris Union, see the section on mailbox protection in Chapter 3 above.

The applicant in countering the argument, first attacked section 3(d) itself stating that section 3(d) could not legitimately be used against the application. The reason being that the aspect of this section allowing a discovery to graduate into a patentable invention solely on the basis of efficiency defied logic and was therefore unable to stand legal scrutiny. It was further submitted that this aspect of section 3(d) in question was against the tenets of the 2005 Act as well as the established principals of jurisprudence. Finally, the applicant submitted that the beta crystal form of imatinib mesylate is an invention, a new substance and not a mere discovery.

The judge concluded on the basis of the above arguments that the opponents were correct in their assertion that the subject matter of this application was not patentable under section 3(d) of the Patents Act, 1970 as amended by the 2005 Act.²²⁹

The verdict in the glivic case is crucial as it upheld the right of a WTO Member to reward only true innovation which is the rationale of a patent to begin with. The verdict thereby ensured that patentability standards do not unnecessarily restrict the public domain and thus access to medicines. A verdict in favor of Novartis would have restricted the ability of an India to supply the developing world with low cost generic versions of drugs based on a host of previously disclosed pharmaceutical substances.

The glivic case is the first major decision on a patent application after India complied with the TRIPS regime and thus despite ongoing Novartis appeals, the case set a significant precedent in favor of access to medicines.

This landmark decision was followed up in the context of AIDS drugs in March 2006 when the Indian Network for People Living with HIV/AIDS (INP+) filed the an opposition to the patent claim for a fixed-dose combination (FDC) of zidovudine and lamivudine filed by GlaxoSmithKline (GSK). INP+ like the opponents in the glivic case based its opposition on Section 3(d) of the 2005 Act arguing that the patent claim in question was not for a new invention but simply for the combination of two existing

²²⁹ Manisha Singh Nair, “*India: Novartis Denied Patent for Gleevec*”. Available at: <http://www.mondaq.com/article.asp?articleid=40082> (Last Accessed on 26th April 2007)

drugs. Soon after its patent was opposed in India, GSK announced the withdrawal of all its patent applications for the FDC ²³⁰

4.4.3 *Compulsory Licensing*

Implementation of a pharmaceutical product patent regime in India means the ability of India to use compulsory licensing will be crucial for access to genuinely new medicines invented after 2005, both in India and abroad. Access to new medicines assumes particular importance when one considers that patients suffering from various diseases including HIV/AIDS inevitably develop a resistance to the medicines they are being treated with and will thus require newer second line medicines.²³¹

Compulsory Licensing in India is based on grounds almost as wide as public interest. The relevant standard is that “the reasonable requirements of the public with respect to the patented invention have not been satisfied” or “...the patented invention is not available to the public at a reasonable price”.²³²

The standard justifying compulsory licensing in India is thus wide enough to be useful in a wide range of circumstances. It directly seeks to ensure that the price of patented subject matter remains affordable to the public. The IPR Commission recommended that the grounds for compulsory licenses should be abundant, clear and unambiguous so as to facilitate their rapid and routine issuing,²³³ in this regard, Article 90 is important as it clearly defines "when reasonable requirements of the public [are] deemed not satisfied".

Another favorable aspect of India's compulsory licensing regime is that it implements the flexibility in the non voluntary use provisions of the TRIPS Agreement that allows

²³⁰ Médecins Sans Frontières Briefing Note (2006) “*The case of Novartis’s challenge against the Indian government and what it could mean for millions of people across the globe*”. Available online at: <http://www.accessmedmsf.org/documents/Novartis%20Briefing.doc> (Last Accessed on 28th April 2007).

²³¹ See, Avafia and Narasimahan.

²³² See, Section 84(1) of the 2005 Act.

²³³ IPR Commission, Final Report, p 44.

Members to grant compulsory licenses to remedy practices determined to be anti-competitive by a judicial or administrative authority.²³⁴

The compulsory licensing provisions of the Indian Act have however been criticized by some commentators as being TRIPS plus. Some of these criticisms are as follows:

The process of obtaining a compulsory license has been criticized as slow because with the exception of a national emergency, extreme emergency or public non-commercial use, a compulsory licence is available only after three years from the date of grant of the patent.

The 2005 Act attempts to quicken the process with an amendment to Section 84(6) (iv). This amendment clarifies that the “reasonable time” after which voluntary license negotiations with the patent holder can be deemed unsuccessful is six months. The clarification is therefore an attempt to eliminate the possibility for delay in the process caused by ambiguity in the construction of “reasonable time”.

This amendment has however been described as a cosmetic change on the basis that the real issue is the requirement which stipulates that only after the expiry of three years from the grant of a patent, can a person make an application to the controller for the grant of a compulsory licence.²³⁵ Hence, despite the amendment, a compulsory licence application does not have to be considered for at least three years and six months from the date of the grant of the relevant patent.

Section 90 of IPA 1970 which elaborates and defines ‘reasonable requirement of the public’, the central basis for granting compulsory licenses, was amended by removing the phrase ‘manufacture in India’. Thus, while local non-working continues as one of the basis for revocation section,²³⁶ it is no more the case that a compulsory license may be

²³⁴ See, Section 90 (1)(ix) of the 2005 Act.

²³⁵ See, Section 84 (1).

²³⁶ See, Section 89(1) of the 2nd Amendment.

issued if domestic demand is not met to an “adequate extent or on reasonable terms from manufacture in India”.²³⁷ As discussed in Chapter 3 above,²³⁸ there is a strong case in favour of the stance that local working requirements are consistent with the TRIPS Agreement as evidenced by *inter alia*, the withdrawal of the US from dispute settlement proceedings with Brazil in 2000. Removal of reference to local working requirements in compulsory licensing grounds may be justifiable as a means of India avoiding the possibility of being dragged into a WTO DSB dispute however this degree of caution was very unexpected considering that India was a third party in the *US - Brazil* consultations in the DSU.²³⁹

Section 90(vii) of India’s 2005 Act by cross reference with section 84 (7) (a)(iii) specifically provides that where a compulsory license is granted for the supply of India’s domestic market, the licensee can also export the product where it is shown that “a market for export of the patented article manufactured in India is not being supplied or developed. This provision explicitly utilizes the limited flexibility allowed by Article 31(f) of the TRIPS Agreement.²⁴⁰

Another interesting feature of India’s patent regime that could prove indispensable to the pursuit of access to essential medicines in countries without manufacturing capacity is the country’s utilization of Article 31(k) of the TRIPS Agreement. Section 90(ix) of the 2005 Act allows a compulsory licensee in India to export a patented product to a territory that grants a compulsory license to remedy an anti competitive practice. Therefore, provided that countries on the import side actually grant compulsory licenses of the sort envisaged by Article 31(k) of the TRIPS Agreement then they may have recourse to imports

²³⁷ See, Section 90(a) (ii) of the 2005 Act.

²³⁸ See, Chapter 3 above, the section entitled “Non Discrimination”.

²³⁹ Rangnekar (2005).

²⁴⁰ Sorcha O’ Carroll , “*Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya*”. Available at: <http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20ocarroll%20trips.doc> (Last Accessed on 1st April 2007). (Hereinafter, O’ Carroll).

unfettered by the Article 31(f) restriction, without the cumbersome procedures accompanying the 30th August 2003 mechanism and without the obligation to engage in prior negotiations with the patent holder.

4.4.4 *August 30th 2003 Decision*

As a potentially important exporter of medicines under the system established by the August 30th 2003 Decision, India's implementation of the mechanism may have important consequences for countries without pharmaceutical manufacturing capacity. The 2005 Act inserted section 92A which amends the requirement in the Ordinance that the exporters obtain a compulsory license from the importing country in addition to the license obtained from the Indian authorities. This provision had the potential to further complicate the utilization of an already complex mechanism in situations where there is no patent on a product in the importing country and thus no requirement or possibility of obtaining a compulsory license from that country. This would have resulted in a scenario whereby countries utilizing the LDC transition period pertaining to pharmaceutical products would not be able to import medicines from India despite meeting all the requirements of the August 30th 2003 decision.²⁴¹ The waiver which India was instrumental in negotiating at the multilateral level was thus ironically in danger of being rendered meaningless (to LDCs) by the domestic implementation of that very same country. Section 92A of the 2005 Act rectifies this anomaly by providing that a compulsory license shall be available for manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned products to address public health problems, provided a compulsory license has been granted by the importing country or that it has by notification or otherwise, allowed the importation of pharmaceutical products from India.

It is clear from the above that India's 2005 Act has made an effort to implement the country's TRIPS obligations as to its patent regime in a manner that facilitates access to medicines both domestically and abroad while also adopting a cautious approach so as to

²⁴¹ Duncan Matthews (2006), p 121.

avoid being hauled into DSU proceedings at the WTO. Yet there are some provisions that demonstrate an overemphasis on caution at the expense flexibility:

One such feature relates to the country's interpretation of the non-discrimination clause which results in deletion of reference to local non-working as a ground for the grant of compulsory licenses.²⁴²

Another feature that should be addressed is the existence of ambiguity within the Act for instance as to what constitutes reasonable compensation in regard to pre-existing generic manufacture provisions. These ambiguities may result in a string of strategic litigation that could hinder or at the very least delay access to generic medicines.

Perhaps the most difficult to defend in the context of facilitating access to low cost generic medicines of all the features of the 2005 Act are the aspects that result in the necessity of at least three and a half years from the granting of a patent elapsing before the controller of patents actually deals with a compulsory license application. Article 31 of the TRIPS Agreement contains no such requirement and it is thus unnecessary for the Indian law to do so. The country should thus consider shortening the period of time so as to avoid unnecessary delay in the production of life saving generic medicines under compulsory license.

4.5 Zambia: A Brief Introduction

Zambia is an LDC with a GDP per Capita of USD87 as of 2001 and was ranked a lowly 143 out of 162 countries in UNDP's Human Development Index (HDI) in 2001.²⁴³ Aside from the country's HIV/AIDS prevalence rate among pregnant adult women of 18-20%, there are approximately 3 million clinical cases of malaria every year resulting in 50 000 deaths annually.²⁴⁴ Zambia's inclusion is thus due to its large public health

²⁴² Padmashree Gehl Sampath, "*Economic Aspects of Access to Medicines After 2005*". Available at: www.who.int/entity/intellectualproperty/ (Last Accessed on 18 May 2007).

²⁴³ See, United Nations Development Programme.2001. Human Development Report. Lusaka, Zambia.

²⁴⁴ See, UNAIDS. 2005. Report on the Global Epidemic. Available at: <http://unaids.org/epi/2005/doc/EPIupdate2005.pdf> en/ Epi05_05_en.pdf

problem/needs, its status as an LDC and its membership in SADC. These factors make Zambia eligible to utilize a number of flexibilities in the pursuit of access to medicines for its people. Therefore the study will survey implementation of TRIPS flexibilities in Zambia from the vantage point of how access to medicines for domestic needs is enabled thereby.

4.6 Implementation of TRIPS Flexibilities: The Case of Zambia

4.6.1 Transition Periods

Zambia is an LDC and as such, is not obliged by the TRIPS Agreement to grant patent protection to pharmaceutical products due to the 2002 extension to the Article 66.1 transition period.

The country however does grant patent protection for pharmaceutical products under The Zambian Patent Act of 1958 (as amended in 1982) as well as the Harare Protocol which is the legal instrument governing ARIPO (African Regional Industrial Property Organization) of which Zambia is a member.²⁴⁵

As mentioned above, the transition period is of limited value for most LDC's in the absence of pharmaceutical manufacturing capacity. Zambia however, while not possessing the ability to manufacture APIs and despite being an LDC, is a country with some pharmaceutical reproductive manufacturing ability.²⁴⁶ In fact, health minister Dr Brian Chituwo disclosed that Zambia has started manufacturing ARVs with assistance from the Cuban government.²⁴⁷ Therefore if Zambia had utilized the LDC transition

²⁴⁵ See, Phil Thorpe, “*Study on the Implementation of the TRIPS Agreement by Developing Countries*”. Available at: http://www.iprcommission.org/papers/text/study_papers/sp7_thorpe_study.txt (Last Accessed on 9 May 2007).

²⁴⁶ See, Correa (2002).

²⁴⁷ See, Ngoju Morgan, “*Zambia and Patents*”. Available at: <http://lists.essential.org/pipermail/ip-health/2004-September/006901.html> (Last Accessed on 4th April 2007) and Correa (2002).

period and refrained from implementing a product patent regime for pharmaceuticals, it could manufacture generic versions of patented medicines free from the imposition of any encumbrance by the rights of patent holders and freely provide those same generics to other LDCs without pharmaceutical product patent regimes.

In this regard commentators have recommended that Zambia “roll back” patent protection.²⁴⁸ Certainly this option is legally possible as the pharmaceutical product patent transitional period extension for LDCs of 2002 does not contain a “no roll back” provision like that contained in the LDC transition period extension for general TRIPS obligations granted in 2005.

It is not certain however whether this option would be politically viable. As noted in the previous chapter, one of the major factors inhibiting compulsory licensing has been extra legal/political pressure from interested developed countries and pharma.²⁴⁹ Some may argue that LDCs rolling back pharmaceutical product patent protection would be deemed inconsequential because pharma companies are unconcerned about LDC markets due to their lack of per capita purchasing power however this view neglects to consider LDC markets such as Bangladesh with significant markets as well as Zambia which possesses potential to develop greater pharmaceutical manufacturing capacity sufficient to supply existing pharma markets.

Zambia experiencing benefits from rolling back patent protection could trigger a wave of such a roll back among larger LDC economies as well as those LDCs with potential to

²⁴⁸ The term roll back in this context refers to the suspension or revocation of patent protection. The Article 65.4 transition period was subject to a no roll back provision, under which countries utilizing the transition period were not entitled to fall back to a lesser degree of compliance with the TRIPS Agreement. The LDC transition period extension for general TRIPS obligations is also subject to a no roll back provision. The transition period extension pertaining to pharmaceutical product patents however is not subject to such a requirement.

See, South Centre – CIEL, IP quarterly Update. First Quarter, 2006, p2. Available at: http://www.ciel.org/Publications/IP_Update_1Q06.pdf (Last Accessed on 23rd March 2007) and O’ Carroll.

²⁴⁹ See, the section on compulsory licenses in chapter 3 above. See also Sisule, F Musungu, “Intellectual Property and Public Health: Will it be Peace or War?” (2004) 7(2) Journal of World Intellectual Property 249 at 251.

develop into larger markets for pharma. Certainly the potential of Zambia's roll back causing future financial losses to pharma would constitute incentive enough for the industry to rally industrialized country governments to impose political campaigns on countries who threaten their interests as seen in the past with Brazil, South Africa and very recently with Thailand.

Therefore the decision to roll back patent protection is not as simplistic as suggested by authors like O'Connell and certainly would require Zambia to carefully consider the implications of such action. A commission such as that initiated by Justice Ayyangar in India preceding the 1970 Act would be a suitable forum for such considerations.

Although Zambia has not utilized its flexibility to refrain from adopting a pharmaceutical product patent regime, the country has utilized flexibilities as to certain aspects of its TRIPS obligations pursuant to the 2005 LDC transition period extension for general TRIPS obligations;²⁵⁰ The term of patent protection available in Zambia is one such example.

Despite non utilization of the 2002 extension of the Article 66.1 transition period which applies to pharmaceutical products, Zambia only grants a minimum patent term of 16 years as opposed to the minimum of 20 years mandated by the TRIPS Agreement.²⁵¹ This is a significant utilization of the 2005 extension of the Article 66.1 LDC transition period because medicines patented in Zambia fall into the public domain 4 years earlier than they would under a regime that complied with the term of protection mandated by the TRIPS Agreement.

4.6.2 *Patentability Criteria and Exemptions from Patentability*

²⁵⁰ Negotiation of which was initiated by Zambia in the TRIPS Council. See, Transition Period for Least Developed Countries; Request for Extension, WTO document IP/C/W/457.

²⁵¹ See, Section 29 of the Zambian Patent Act 1958.

Section 38 of the *Zambian Patent Act* excludes from patentability a variety of subject matter including any discovery, scientific theory or mathematical method.

The Act further gives the Registrar of Patents discretionary powers to refuse to patent any invention which claims as an invention a substance capable of use as food or medicine which is a mixture of known ingredients possessing only the aggregate of those ingredients' properties, or claims as an invention a process for producing such a substance by mere mixture.²⁵²

The *Zambian Patent* regime thus adopts a high standard of innovation which promotes a large public domain and is not conducive to ever greening in the field of medicines.

4.6.3 *Compulsory Licensing*

The most notable and effective example of Zambia implementing and utilizing TRIPS flexibilities is the way the country has dealt with compulsory licensing.

There are a number of broad grounds for the issuance of compulsory licenses contained in the *Zambian Patent Act*. For instance, any person who can show that he has been unable to obtain a voluntary license on reasonable terms may apply to the Registrar for a compulsory license on the basis that the reasonable requirements of the public for the invention are not being or will not be satisfied.²⁵³ This ground like the parallel provision in Indian patent law examined above (section 84(1)), can be interpreted in the context of public health to allow compulsory licensing where national demand for patented medicines is not being met by the patent holder due to unaffordable prices.

²⁵² See, Edward D. Zulu, Rosemary M. Makano and Anessie Banda “*National Experiences and Plans to Implement a Sui Generis System of Protection in Zambia*”. Available at: <http://www.grain.org/bio-ipr/?id=369> (Last Accessed on 12 March 2007).

²⁵³ See, Section 37 of the *Zambian Patent Act* 1958.

Interestingly, the Zambian Patent Act includes a failure of local working ground.²⁵⁴ Depending on one's interpretation of the compatibility of such provisions with the TRIPS Agreement, the ground's continued presence could be seen as either, utilization of the 2005 extension of the Article 66.1 LDC transition period or a perfectly TRIPS compliant provision.²⁵⁵ In this regard, it will be interesting to see if Zambia maintains its local working ground beyond 2013.

Zambia's patent regime allows compulsory licensing on the grounds of anti competitive behavior by the patentee. It also provides that it may not be necessary to pay compensation when a compulsory license is issued on these grounds. The operation of this provision is compliant with Article 31(k) of the TRIPS Agreement provided that the determination of anti competitive behavior is determined by a judicial or administrative authority and that the decision that no compensation be paid to the patentee is made pursuant the determination that no royalty being paid is necessary to remedy the anti-competitive practice concerned. Therefore while Zambia is well placed to benefit from section 90(ix) of India's 2005 Act as the recipient of imports under compulsory licenses of the sort envisaged by India's 2005 Act in accordance with Article 31(k) of the TRIPS Agreement.

While Zambia provides this ground for the issuance of a compulsory license in its legislation, it has never actually used the ground to justify issuing a compulsory license. The country may need to strengthen its competition law institutions and capacity before it can make use of this ground.²⁵⁶ In this context, Zambia can benefit from regional cooperation within SADC by drawing on the experiences of South Africa where there is already considerable experience in utilizing competition law as a tool for facilitating access to affordable medicines as seen in the cases of *Hazel Tau and others v*

²⁵⁴ Ibid.

²⁵⁵ See, the portion dealing with the compatibility of local working requirements with the non-discrimination clause in the section on the non-discrimination clause in chapter 3 above.

²⁵⁶ See, Avafia, Burger and Hartzenberg.

GlaxoSmithKline and Boehringer Ingelheim and Treatment Action Campaign v Bristol Myers-Squibb respectively.²⁵⁷

The Zambian Patent Act contains both the government use and state of emergency flexibilities permitted by Article 31(b) of the TRIPS Agreement in sections 40 and 41 respectively. The Section 40 government use provision provides for the use of patented inventions for the services of the state, it provides that “any government department or any person authorized in writing by the minister may make, use or exercise any invention”, in some cases without even having to pay royalties. Section 41 authorizes a minister of state to declare a period of emergency as a consequence of which the said minister is allowed to use any patented invention and enumerates a non-exclusive list of the purposes for which an invention may be used during a period of emergency. Possible purposes include *inter alia*, “...the maintenance of supplies and services essential to the life of the community” and “securing a sufficiency of supplies and services essential to the well-being of the community”.

These broad provisions allow the Zambian government to take whatever steps it considers necessary to deal with public health emergencies as determined by the government. This conforms to paragraph 5(c) of the Doha Declaration which provides as follows:

“Each Member has the flexibility 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”.

Crucially, Zambia used the flexibility created by Section 41 when the government issued a compulsory license for the local manufacture of ARVs.

²⁵⁷ For a comprehensive discussion of the two cases, consult the news letter of the Treatment Action Campaign (TAC) entitled, “*Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines*”, the document is available at: http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm

4.6.4 Zambia's Compulsory License

In more detail, the compulsory license was granted by the Zambian Ministry of Commerce, Trade and Industry through Statutory Instrument 83 of 2004 in September 2004 to a locally-incorporated company, Pharco Ltd. The compulsory license authorized the local company to produce a triple fixed dose combination (FDC) of lamivudine, stavudine and nevirapine under the brand names of *Normavir 30* and *Normavir* and prescribed a royalty cap of 2.5% for the originators, BI and BMS. The royalty will only become payable if the originators apply for and are granted compulsory licenses for the drugs concerned in Zambia which interestingly are currently not patented in the country.²⁵⁸

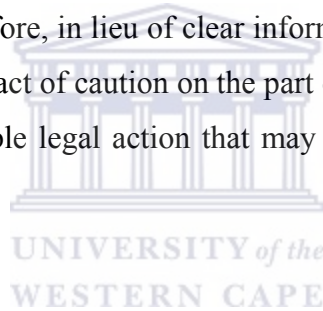
One aspect of the Zambian Compulsory license that could serve as an example to developing countries and LDCs grappling with access to medicines the world over is the direct reference to the Doha Declaration.

“On 14 November, 2001 the World Trade Organization, while recognizing Members=92 commitment to the TRIPS Agreement, declared the right of each Member State to take measures aimed at protecting public health and in particular to promote access to medicines for all, by utilizing to the full, the flexibilities in the TRIPS Agreement relating to among others, the granting of compulsory licenses, in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crises including those relating to HIV/AIDS, tuberculosis, malaria, or other epidemics which can represent a national emergency or other circumstances of extreme urgency”.

The inclusion of the above text in paragraph 4 of the Zambian Compulsory license evidences the huge political impact that the Doha Declaration can have with respect to the utilization of TRIPS flexibilities by WTO Member states. The express reference to the Doha Declaration as a basis for the issuance of the country's compulsory license and the fact that the measure remains unchallenged reflects the immense political importance that WTO Members attach to the instrument.

²⁵⁸ See, Avafia, Burger and Hartzenberg.

Some commentators have criticized Zambia for granting the compulsory license and issuing a state of emergency instead of directly going ahead with the manufacture of the FDC, commenting that the originator never applied for patents in Zambia and that the compulsory license was thus unnecessary.²⁵⁹ There is however a deficit of information on the patent status of the drugs concerned in Zambia. While it is true that no patent on the drugs was granted by Zambian authorities and that no patent application for any of the drugs was filed in the country, it is uncertain whether or not patents on the drugs were granted by ARIPO of which Zambia is a member. A patent granted by ARIPO will have effect in all its member countries, unless the patent is rejected by a member country within a 6 month time period. The lack of clarity on the status of patents indicates a common problem in many developing countries, where the patent offices are often not equipped to carry out comprehensive patent searches and inconsistencies are found in the information provided.²⁶⁰ Therefore, in lieu of clear information on the patent status of the drugs, it may have been a wise act of caution on the part of Zambia to grant a compulsory license thereby avoiding possible legal action that may have delayed availability of the FDC.



4.6.5 *Parallel Importation*

Zambian patent law has been criticized for unnecessarily restricting the possibility of parallel importation where drugs are sold for cheaper prices abroad than domestically by not including any provisions on exhaustion of IPRs.²⁶¹ This criticism can be illustrated by highlighting the opportunity provided by section 90(vii) of India's 2005 Act cross referenced with section 84 (7) (a)(iii) discussed in the section on India above. The inclusion of these provisions in India's 2005 Act mean that if the Zambian market for a particular medicine is not being supplied or developed and if India were to grant a

²⁵⁹ Ibid.

²⁶⁰ Cecelia Oh, "Compulsory Licences: Recent Experiences in Developing Countries" Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006, (hereinafter, Oh).

²⁶¹ Musungu and Oh (2006), Annex 1.

domestic compulsory license for the production of that pharmaceutical, the non-predominant portion of the drugs produced under the Indian license could be legitimately exported to Zambia.²⁶² In this situation, if the pharmaceutical is patented in Zambia, the incorporation of an exhaustion regime into Zambia's legislation (or alternatively but unlikely, a roll back of patent protection) would allow parallel importation without violating the any patent rights that may exist in Zambia.

Zambia does have some capacity to manufacture generic equivalents of patented medicines therefore; the country's patent regime not facilitating parallel importation can be mitigated through compulsory licensing for local manufacture of essential medicines. Such capacity however, is certainly not sufficient to deny the advantageous of the country incorporating an exhaustion regime to facilitate parallel importation.

Thus one can conclude on Zambian patent law that various TRIPS flexibilities are implemented and utilized, yet there are various criticisms that remain irrefutable:

Much like the Indian law, Zambia's compulsory licensing regime can be criticized for requiring a period of at least three years from the date the patent is granted or four years from the date of the patent application, which ever being the longest to elapse before a compulsory license can be applied for. Mandating such a long period to elapse causes unnecessary delay to access to generic medicines for the sick and the dying and can thus result in the needless loss of an un-estimated number of lives. Therefore the country should take advantage of the TRIPS Agreement's silence on the issue and reduce the time period required.

A major criticism is that Zambian Patent Law does not implement the August 30th 2003 mechanism and the various waivers provided therein. As an LDC, Zambia's limited manufacturing capacity in the pharmaceutical sector would in no way prejudice its ability to import medicines under either of the waivers to Article 31(f) of the TRIPS Agreement

²⁶² See, O' Carroll.

contained in the mechanism,²⁶³ while its membership in SADC, makes Zambia a prime candidate to benefit from the paragraph 6 waiver. Despite the country's eligibility however, none of the August 30th 2003 waivers have been utilized by Zambia.

The non utilization of the paragraph 2 waiver however, may be due in large part to the cumbersome nature of the procedural requirements attached and while the paragraph 6 waiver is less demanding in terms of notifications, its utilization requires a significant increase of regional coordination by SADC member states.

4.7 Bilateralism and its Potential to Undermine Multilateral Gains

The flexibilities contained within the TRIPS Agreement can be used to varying extents to assist developing countries and LDCs to meet their public health needs while still conforming to the minimum standards of protection mandated by the instrument. These flexibilities are supplemented by a powerful interpretive tool in the Doha Declaration. There is however a consensus among international IP experts that the benefits accruing from the flexibilities achieved and clarified at the multilateral level are under threat of being negated by a recent proliferation of bilateral and free trade agreements involving the US in particular which contain TRIPS plus provisions.²⁶⁴

The WTO has recognized the increasing amount Regional and Bilateral Free Trade Agreements (FTAs) involving the US and has referred to them as expanding preferential networks in a report by the Trade Policy Review Body (TPRB).²⁶⁵ This trend in US

²⁶³ See, paragraphs 1, 2 and 6 of the August 30th 2003 Decision.

²⁶⁴ According to Professor Drahos, a bilateral agreement that
(a) requires a Member to implement a more extensive standard; or
(b) which eliminates an option for a Member under a TRIPS standard,
is a TRIPS plus standard. The author agrees and will thus adopt that definition.
See, Peter Drahos and Herchel Smith, "Bilateralism in Intellectual Property". Available at:
<http://www.maketradefair.org/assets/english/bilateralism.pdf> (Last Accessed on 16th April 2007).
(Hereinafter, "Drahos, Bilateralism in IP").

²⁶⁵ Report by the WTO Secretariat, Trade Policy Review, United States, WT/TPR/S/126, 17 December 2003, at p.viii, para. 8.

Trade policy was previously identified by world trade expert John Jackson according to whom:

“...the US has moved away from its earlier support for multilateralism and most-favored-nation (MFN) to a more pragmatic [from a US perspective at least] – some might say ad hoc approach – of dealing with trading partners on a bilateral basis...”²⁶⁶

In order to illustrate how important flexibilities can be eroded by TRIPS plus provisions in Regional and Bilateral FTAs, it is necessary to examine relevant portions of various Agreements involving the US, namely, the Dominican Republic-Central America Free Trade Agreement (CAFTA-DR), US-Singapore, US-Jordan and US-Morocco.²⁶⁷

4.8 The Flexibilities Affected

4.8.1 *Term of Protection*

Article 15.9 of CAFTA-DR requires the establishment of a new, TRIPS plus standard for review of patent applications. Under the new standard established in the CAFTA-DR, a maximum of five years is allowed for the review of a patent application, after which the term of patent protection must be extended to compensate for the lack of patent protection during the period of review.²⁶⁸

When one considers that mailbox protection and EMRs are granted to the subject of patent applications and that these two forms of protection are certainly adequate compensation for the lack of patent protection during the period when a patent

²⁶⁶ J. Jackson, “*The World Trading System*”, MIT Press, Cambridge, Mass., London, 1997, 173.

²⁶⁷ The text of all FTAs involving the US are available at: http://ustr.gov/Trade_Agreements/Section_Index.html (Last Accessed on 20th April 2007)

²⁶⁸ See, Frederick M. Abbott, “*The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*”. Available at: www.quno.org (Last Accessed on 13th March 2007). (Hereinafter, Abbott, “Doha and Contradictory FTAs”)

application is being reviewed,²⁶⁹ it becomes apparent that CAFTA-DR unnecessarily extends the period of patent protection and will thus unduly delay patented medicines falling into the public domain.

4.8.2 *Compulsory Licensing*

Musungu and Oh have identified two ways that FTAs have restricted the ability of countries to execute compulsory licensing. The first is an indirect limitation and operates via the intersection of data protection and compulsory licensing while the second is a direct, express restriction of compulsory licensing grounds.²⁷⁰ Let us now turn examining these two instances of limitation.

The intersection of Data Protection and Compulsory Licensing:

Article 15:10(3)(a) of CAFTA-DR provides as follows:

“A third party (generic) producer, relying on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory”, must be prevented from obtaining marketing approval such as will allow that third party to market the product “during the term of that patent, unless by consent or acquiescence of the patent owner”.²⁷¹

If approval cannot be granted for marketing during the term of the patent without the consent or acquiescence of the patent owner, this will effectively preclude the possibility of government use or compulsory licensing. Even if a license on the patent is granted to a generic producer/importer, the patent owner will be able to prevent marketing of the equivalent medicine (because it will not consent or acquiesce to marketing). This, it will

²⁶⁹ See the section in Chapter 3 above on Mailbox and EMRs.

²⁷⁰ Musungu and Oh (2006), p 111.

²⁷¹ See, Abbott, “Doha and Contradictory FTAs”

not be permissible to put the generic product on the market regardless of the grant of a compulsory license.²⁷²

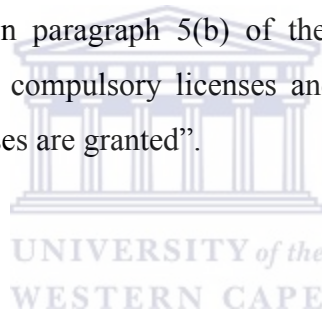
The Restriction of Compulsory Licensing Grounds:

A limited number of FTAs such as US- Singapore and US- Jordan, contain provisions which restrict the grounds on which compulsory licenses can be issued.

For instance, the US-Singapore FTA does not allow non-voluntary use of patented subject matter except in three situations, (1) to remedy practices deemed after judicial or administrative process to be anti competitive, (2) in cases of public, non-commercial use and (3) in the case of a national emergency or extreme urgency.²⁷³

This negates the recognition in paragraph 5(b) of the Doha Declaration that, “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”.

4.8.3 *Parallel Importation*



In Article 15.9(4), the Parties abandon their right under Article 6 of the TRIPS Agreement and express confirmation in Paragraph 5(d) of the Doha Declaration to determine their own policies with respect to exhaustion of rights and agree to prevent parallel importation of patented subject matter. Footnote 9 to this provision provides that the relinquishment may be limited to cases “where the patent owner has placed restrictions on import by contract or other means”, however, that does not mitigate the fact that the parties have mandated a limitation not contemplated in the TRIPS Agreement and of the sort that the Doha Declaration expressly attempts to prevent.

²⁷² Ibid.

²⁷³ See, Article 16.7(6) of the US-Singapore FTA.

4.8.4 *Exemptions from Patentability*

The US-Morocco FTA provides in relevant part that:

“patents shall be available for any new uses or methods of using known products, including new uses of known products for the treatment of humans and animals”.²⁷⁴

Therefore, Morocco is obliged to grant patent protection to products which exhibit a low standard of innovation and thus facilitate ever greening. As mentioned in the previous chapter,²⁷⁵ the practice of ever greening unduly delays generic competition and thus inhibits access to cheaper generic equivalents of brand medicines.

4.8.5 *The Dissenting View on Bilateralism in IP*

Despite the apparent contradiction between the Doha Declaration and the provisions discussed above, it is possible to argue that bilateralism in IP has not limited the flexibility of the parties concerned. This argument is based on two instruments, (1) non derogation clauses and (2) side letters with operative language.²⁷⁶ It is necessary to illustrate the argument by discussing examples of the two instruments.

Non Derogation Clauses:

An example of a non derogation clause can be found in CAFTA-DR, the clause reads as follows:

“Nothing in this Chapter shall be construed to derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual

²⁷⁴ See, Article 15.9 (2).

²⁷⁵ See the section in chapter 3 on exemptions fro patentability.

²⁷⁶ See, Abbott, “Doha and Contradictory FTAs”.

Property Organization and to which they are party”.²⁷⁷

Indeed, this provision might initially appear intended to preserve the flexibilities accorded to the parties under the TRIPS Agreement and the Doha Declaration. Yet despite the non derogation clause, it can be seen from the discussion above that various other provisions in the FTA’s IP Chapter very directly constrain the rights a WTO Member has under the TRIPS Agreement by effectively precluding the exercise of flexibilities.

Side Letters with Operative Language:

The US-Morocco FTA does not contain a non-derogation clause like CAFTA-DR. Instead, the Agreement attempts to ameliorate express derogation from rights under the TRIPS Agreement by means of a draft exchange of side letters with operative language. One such letter reads in relevant part as follows:

The implementation of the provisions of Chapter 15 of the Agreement [the IP Chapter] does not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all. This will concern, in particular, cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency.

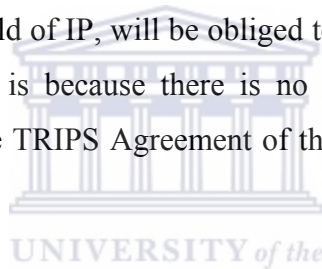
Much like what we saw in the discussion on the non derogation clause in CAFTA-DR, the exchange of letters does not diminish the fact that there are a number of provisions in the US-Morocco FTA that directly constrain the flexibility of Members contained in the TRIPS Agreement and affirmed by the Doha Declaration. Secondly, it is not clear what legal effect an exchange of letters between parties to a binding international instrument is expected to have in a legal dispute. Moreover, the letter incorporates limits not found in the Doha Declaration and which were specifically rejected during negotiations on the August 30th 2003 Decision such as (1) an apparent restriction on the scope of diseases and (2) a limitation to situations of emergency. Thus, while denying any intention to

²⁷⁷ See, Article 15.1.

affect public health, the parties are directly limiting the flexibilities of TRIPS Agreement and supplemented by the Doha Declaration and the August 30th 2003 Decision.

Therefore it is clear that the FTAs erode Members' TRIPS flexibilities. Hence we may conclude that should countries like Zambia with sizable public health problems except such restrictions to their ability to utilize TRIPS flexibilities, it would have negative implications for access to essential medicines needed to deal with the same. Worse still, if India, the global lynchpin in supplying affordable generic medicines to countries without manufacturing capacity was to accept such severe limitations to its patent regime, it would have disastrous effects for access to medicines in many countries that rely on Indian generic pharmaceuticals.

Furthermore, it is important to note that WTO Members which make bilateral concessions to the US in the field of IP, will be obliged to extend those concessions to all other WTO Members.²⁷⁸ This is because there is no exception to the Most Favored Nation (MFN) obligation in the TRIPS Agreement of the sort provided in the GATT by Article XXIV of the latter.²⁷⁹



4.8.6 *Why Do Developing Countries Accept TRIPS Plus Obligations in FTAs?*

In light of the consequences for access to medicines that can be brought about by the IP provisions in the FTAs discussed above, why are countries willing to accept such limitations to their flexibility? Three reasons have been identified by the author:

First, most developing countries are not in a position to expand export opportunities in the pharmaceutical sector or to protect a substantial domestic pharmaceutical sector. Hence because the domestic industry is not affected, substantial restrictions in FTAs on access to pharmaceutical products may be accepted within highly complex provisions

²⁷⁸ See, Article 4 of the TRIPS Agreement.

²⁷⁹ See, Drahos, "Bilateralism in IP".

with respect to patents and regulatory approval without close examination by public health officials.²⁸⁰

Secondly, the negotiations whether multilateral or bilateral are multi-sectoral and thus IP issues cannot be seen in isolation. Most developing countries rely on the agricultural sector for exports and thus have a huge interest in increasing agricultural market access to developed countries. This is often used by industrialized countries as leverage to gain concessions on IP for the benefit of pharma.²⁸¹

The final reason identified is the threat of trade sanctions under Section 301 of the US Trade Act. As discussed above,²⁸² Section 301 of the US Trade Act is the provision used by the USTR to address what are deemed unfair trading practices; this includes *inter alia* unfair practices concerning IPRs. An investigation under Section 301 may culminate in the imposition of trade sanctions by the US. Hence, a developing country may simply decide to adopt a 'TRIPS plus' measure in order to avoid action by the US under the 301 process.²⁸³ On the effectiveness of Section 301 in achieving US trade objectives, it is worth noting the following remark by a USTR official:

“One fascinating aspect of the Special 301 process occurs just before we make our annual determinations, when there is often a flurry of activity in those countries desiring not to be listed or to be moved to a lower list. IP laws are suddenly passed or amended, and enforcement activities increase significantly”.²⁸⁴

²⁸⁰ See, Abbott, “Doha and Contradictory FTAs”

²⁸¹ Ibid.

²⁸² See the section on the incorporation of TRIPS into the multilateral trading system in Chapter 2 above.

²⁸³ See, Drahos, “Bilateralism in IP”.

²⁸⁴ Technological Progress And American Rights: Trade Policy And Intellectual Property Protection’, Testimony of Ambassador Richard W. Fisher, Deputy U.S. Trade Representative, Subcommittee on International Economic Policy and Trade House Committee on International Relations, Washington DC, October 13th, 1999, 3.

Developing countries with public health problems should preserve their flexibility to deal with the same. To this end, they should as far as possible, refrain from undertaking TRIPS plus obligations in bilateral negotiations with the US and other trading partners. This is not as easy as it sounds considering the tremendous importance that most developing countries attach to agricultural market access to industrialized countries as well as the persuasive powers of Section 301. It may thus be necessary for the TRIPS Council to intervene on behalf of developing countries in this regard. Some authors have accordingly advocated that developing country WTO Members “form a coalition aimed at converting the TRIPS Council from a body that secures a platform to one that polices a ceiling”.²⁸⁵ This would entail a new agenda for the TRIPS Council in which rollback of TRIPS plus standards would be a central instrument.

One can conclude from the above discussion of the Indian and Zambian patent regimes that developing countries on both ends of the generic supplier/consumer spectrum have implemented a number of TRIPS flexibilities. Yet there is certainly room for these countries to take fuller advantage of TRIPS flexibilities and thus one would struggle to argue that their implementation has been adequate. These countries should seek to implement and utilize the full range of flexibilities contained in the TRIPS Agreement with a view to improving access to essential medicines both domestically and throughout all countries in need. FTAs with TRIPS plus provisions have the potential to paralyze the utilization of TRIPS flexibilities. Developing countries and LDCs should head the examples of this occurrence discussed above and take care not to fall into that trap.

5. Chapter 5: Conclusions and Recommendations

5.1 A Brief Overview

²⁸⁵ Peter Drahos and John Braithwaite have advocated the formation of such a coalition and reform of the TRIPS Council.

See, Drahos, “Bilateralism in IP”, p 16.

The TRIPS Agreement, the Doha Declaration and the August 30th 2003 Decision are currently the three major instruments laying the framework for the International IPR protection/public health debate. The instruments attempt to strike a balance between innovators of pharmaceutical technology and its developing country and LDC users in the arena of public health.

The Uruguay Round saw a massive victory for the interests of pharma, duly represented by developing countries. They were able to secure the most extensive package of IPRs for their products including the rights conferred unto a patentee; non discrimination; mailbox and EMRs; and enforcement related obligations. As a result of these provisions, their interests are secured to the extent of conferring a minimum twenty year monopoly (even longer through the operation of EMRs and where a national patent system allows ever greening through incremental inventions. At the conclusion of Uruguay Round, the preponderance of conclusions was certainly in favour of phama.

The TRIPS flexibilities including *inter alia* transition periods; patentability criteria and exemption from patentability; parallel importation; and compulsory licensing are the tools available to users of pharmaceutical technology to redress the imbalance perpetuated by IPRs conferred to innovators. The Doha Declaration is an important legal and political instrument confirming the right of countries to use TRIPS flexibilities.

Compulsory licensing is perhaps the most important of the TRIPS flexibilities. It is subject to a number of limitations imposed by the text of the TRIPS Agreement. Of particular importance for countries with limited to no manufacturing capacity in the pharmaceutical sector is Article 31(f). This provision limits the exploitation of compulsory licensing by importation. The August 30th 2003 waivers and the 2005 Amendment Decision on a not yet effective amendment of the TRIPS Agreement were thus propounded in the TRIPS Council to deal with the Article 31(f) restriction.

5.2 The TRIPS Flexibilities: Final Conclusions and Recommendations

As to the sufficiency of the TRIPS flexibilities analysed to tilt the balance created by the TRIPS Agreement in the direction of users and the adequacy of their implementation, the thesis concluded as follows:

5.2.1 *Transition Periods*

The Article 65.4 transition period which allowed developing countries that had excluded pharmaceutical products from patentability to continue this policy. The transition period expired in 2005 after becoming a lynchpin in the IPR/public health debate.

Pursuant to Article 66.1 of the TRIPS Agreement and a TRIPS Council Decision extending the transition period therein, LDC WTO Members are entitled to refrain from implementing product patent regimes. In theory the implementation of this flexibility removes until 2016 any barriers that pharmaceutical product patents may impose on the ability of LDCs to produce, import and export medicines among themselves. Realistically however, benefits can only be derived from this opportunity if LDCs improve their technological bases and develop capacity for the production of generic medicines.

Implementation:

India:

India's utilization of the Article 65.4 transition period until 2005 was crucial in sustaining the gains made from its decision to refrain from incorporating a product patent regime pursuant to the Ayyangar Committee.

Zambia:

Zambia is eligible to utilize the Article 66.1 transition period yet it has a product patent regime. This has prompted criticism by various commentators. Critics are of the view that Zambia should roll back pharmaceutical product protection. Conversely, some

commentators opine that the benefits offered by the transitional period are limited in the absence of a general increase of pharmaceutical manufacturing capacity in LDCs. This coupled with the threat of legal and political campaigns by pharma against the country may be contributory factors in Zambia's continued provision of patents for pharmaceutical products.

Recommendations:

The only real solution to the problem of access to medicines in countries with limited to no pharmaceutical manufacturing capacity is to remedy this lack of capacity.

As a means to attaining pharmaceutical self sufficiency, LDCs should encourage Indian generic drug companies to invest and set up in those LDCs. This would yield almost immediate benefits in terms of local manufacture of essential medicines as well as long term benefits as to the transfer of technology.

The major barrier that comes to mind is the lack of purchasing power and investment risks like infrastructure constraints, bureaucracy etc in the LDCs resulting in a lack of incentive for the generic companies.

In response to this barrier, any loss of profit incurred by investors could be offset by financial contributions investment guarantees from the LDC governments. Other investments risks could be mitigated by the Multilateral Investment Guarantee Agency (MIGA) of the World Bank Group.

This solution may be expensive to LDC governments in the short term but surely it would cost those countries more to suffer the strain on their health care systems caused by large numbers of patients and the losses to the economy caused by the incapacitation of the most economically active age group(a common feature of HIV/AIDS)?

5.2.2 *The Patentability Criteria and Exemption from Patentability*

Setting the standard of innovation necessary to derive patent protection is a crucial facet of any IP regime. The TRIPS Agreement gives Members considerable flexibility in this important exercise.

Implementation

India

The glivic case exemplifies the high standard of innovation required for a medicine to attain patent protection India.

Zambia

The *Zambian Patent* regime adopts a high standard of innovation which promotes a large public domain and specifically excludes ever greening in the field of medicines.



Recommendations:

Developing countries the world over can learn from the high patentability standards in India and Zambia. The two countries are clearly aware that the most effective way to prevent ever greening is to root out incremental patents.

5.2.3 *Parallel Importation*

Countries that incorporate an international exhaustion regime are eligible to meet their local demand for medicines by importing from cheaper overseas suppliers if they so wish as confirmed by paragraph 5(b) of the Doha Declaration.

Implementation:

India:

India's patent regime specifically provides that where a compulsory license is granted for the supply of India's domestic market, the licensee can also export the product where it is shown that "a market for export of the patented article manufactured in India is not being supplied or developed. Although this provision was dealt with under India's implementation of compulsory licensing, it represents a significant opportunity for countries whose need for affordable medicines is not being met domestically. These countries will however need to have in place, an international exhaustion regime wide enough to include products put on the market by compulsory licensing.

Zambia:

Zambia does not have an international exhaustion regime in place and thus importing drugs that are locally patented would infringe patentees' rights.

Recommendations:

Zambia and other countries should take advantage of the opportunity presented by India's compulsory licensing laws and incorporate an international exhaustion regime wide enough to allow the importation of drugs placed on the market by a compulsory license.

5.2.4 *Compulsory Licensing and Government Use*

This flexibility has been recognized by a number of authors as the most important tool for addressing the adverse effects of patent rights on public welfare and particularly in the context of health.

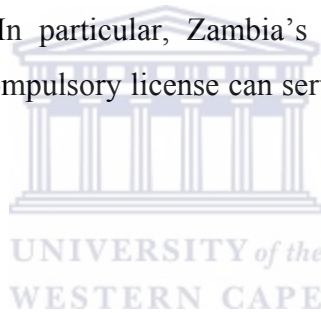
Implementation:

India:

The expiry in 2005 of the Article 65.4 transition period means that India's implementation of this flexibility is set to prove crucial for future access to affordable generic medicines within India and abroad. India's patent regime contains a number of compulsory licensing provisions that make use of various flexibilities in the wording of the TRIPS Agreement and that facilitate manufacture and exportation to countries in need of affordable medicines. There is however, room for improvement.

Zambia:

Similarly, Zambia has a vibrant compulsory licensing regime which makes use of various flexibilities in Article 31 of the TRIPS Agreement. The country successfully issued a compulsory license in 2004. In particular, Zambia's express reference to the Doha Declaration in the text of the compulsory license can serve as an example to all countries with public health problems.



Recommendations:

Both India and Zambia should speed up the process that must be followed for the issuance of a compulsory license by removing the minimum three year waiting period from the grant of a patent in their respective patent regimes.

5.2.5 *The August 30th 2003 Decision*

Some have hailed the Decision as resolving the Article 31(f) problem. Others have labelled it unworkable pointing to the numerous and complex administrative requirements attached. The resolution of that debate can only be resolved once the mechanism is tested by utilization. To date, however, the preponderance of conclusions does seem to agree with opponents of the Decision. The fact that not a single patient has yet benefited from medicines imported thereby is a telling factor.

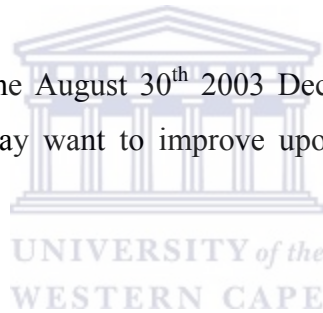
Implementation:

India:

India has implemented the August 30th 2003 Decision as a potential exporting Member. The relevant provision allows for compulsory licensing for manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned products to address public health problems. If the August 30th 2003 mechanism proves effective, India's implementation could prove crucial.

Zambia:

Zambia is yet to incorporate the August 30th 2003 Decision into its Patent legislation. This is an area the country may want to improve upon should the August 30th 2003 mechanism prove effective.



Recommendations:

With regard to the August 30th 2003 Decision, Zambia should study the benefits of implementing the paragraph 1 waiver and rally its SADC partners to undertake a uniform implementation of the paragraph 6 waiver.

Article 31(k) of the TRIPS Agreement does not require prior negotiations and is not subject to the Article 31(f) problem. In the limited circumstances where India were to manufacture drugs pursuant to the provision in its law that implements the Article 31(k) flexibility, the drugs could be exported to countries with limited to no manufacturing capacity free of the administrative, financial and time burdens associated with the August 30th 2003 Decision.

Regardless of the August 30th mechanism or any flexibilities in the wording of the TRIPS Agreement, the best solution is for countries with limited to no pharmaceutical manufacturing capacity to become self sufficient. In this regard, please refer to the recommendations made as to transition periods above.

5.3 Bilateralism: A Word of Caution

The gains made by developing countries and LDCs in securing the TRIPS flexibilities will come to naught if they allow bilateral Agreements such as FTAs to erode their policy space. In this regard, countries could reject TRIPS plus provisions in bilateral negotiations where possible. The TRIPS Council should be explored as a forum to curb bilateral negotiation difficulties of countries with limited bargaining power.



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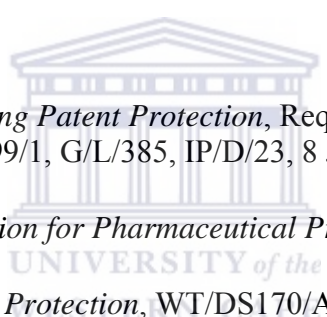
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