

COMPULSORY PATENT LICENSING AND ACCESS TO
ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES
AFTER THE DOHA DECLARATION

by

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ABSTRACT

In 2001 the Declaration on the TRIPS Agreement and Public Health ('Doha Declaration'), affirmed the right of member states of the World Trade Organisation ('WTO') to interpret and implement the TRIPS Agreement as supportive of the protection of public health and, in particular, access to medicines. While initially well-received, consternation soon arose over the interpretation of a specific paragraph in the Doha Declaration dealing with compulsory licensing. After a further two years of deliberation, the WTO Decision on the Interpretation of Paragraph 6 ('Paragraph-6 Decision') was announced in August 2003 specifying when countries can import drugs produced elsewhere under compulsory licence.

With one third of the world's population is still denied access to essential medicines - a figure which rises to over 50 per cent in Asia and Africa - the problems facing the public health community are two-fold. The first is the capacity of developing countries ('DCs') actually to use the flexibilities afforded under the TRIPS Agreement, the Doha Declaration, and the Paragraph-6 Decision amid stark inequalities in health resources and the world trading system as a whole. These include provisions for compulsory licensing, parallel importation, and addressing imbalances in research and development ('R&D'). The pending ratification of the Paragraph-6 Decision, from an interim solution to a permanent amendment, is accompanied by considerable uncertainty: will the protections be accessible under the system currently proposed?

The second problem concerns the undermining of the above hard-won flexibilities by provisions adopted under various bilateral and regional trade agreements. Known as 'TRIPS-plus'- or 'WTO-plus'- measures, the level of intellectual property rights ('IPRs') rights protection being negotiated and even adopted under other trade agreements are more restrictive as regards public health protection. These two sources of concern have led to an increase in rather than a lessening of tensions between the public health and trade policy communities.

The thesis opens with a brief analysis of the interplay between patents and medicines. This includes an overview of the human rights framework and the right of access to medicines as a manifestation of human rights. The historical development of the TRIPS Agreement, its

legitimacy, and the effect of the introduction of patents for pharmaceuticals are critically analysed. The terms of the Doha Declaration as it relates to public health, the Paragraph-6 Decision and its system, the December 2005 Amendment, and the progress made to date on the public health protections available under the TRIPS Agreement are reviewed and discussed in detail. The thesis describes how, despite these important clarifications, concerns as to the capacity of DCs to implement specific measures persist.

This thesis further addresses the development of compulsory licensing in India and South Africa, and the legal framework for compulsory licensing in these countries. The role of competition law and constraints faced by DCs in implementing the flexibilities offered by the TRIPS Agreement and Doha Declaration are considered before turning to the threat posed by TRIPS-plus measures and calls for their critical reassessment. The thesis considers the role of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), the WHO Commission on IPRs, Innovation and Public Health (CIPIH), Patent Pools, and international and multilateral donors in access to medicines. The thesis concludes by reviewing potential ways forward to ensure that access to medicines by the poor living in DCs is secured in all trade agreements.

KEY TERMS

Access to medicines, Bolar provisions, Compulsory Licensing, Developing Countries ('DCs'), Essential medicines, Evergreening, Intellectual Property, Least Developed Countries ('LDCs'), Low and Middle Income Countries ('LMICs'), Pharmaceutical Products, Sub-Saharan Africa, TRIPS-plus measures, TRIPS flexibilities

ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ALP	AIDS Law Project
API	Active pharmaceutical ingredient
ARIPO	African Regional Intellectual Property Organisation
ARV	Antiretroviral
AU	African Union
BI	Boehringer Ingelheim
BMS	Bristol Myers Squibb
CAFTA	Central American Free Trade Agreement
CIPIH	WHO Commission on IPRs, Innovation and Public Health
CIPR	United Kingdom Commission on Intellectual Property Rights
CPTech	Consumer Project on Technology
DCs	Developing Countries
DDC	Drug Development Corporation
DNDi	Drugs for Neglected Diseases initiative
Doha Declaration	WTO Declaration on TRIPS and Public Health
DSB	WTO Dispute Settlement Body
DSU	Dispute Settlement Understanding
EC	European Commission
ECOSOC	Economic and Social Council
EU	European Union
FTA	Free Trade Agreement

GAO	United States Government Accountability Office
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product
GFATM	Global Fund for AIDS, Tuberculosis, and Malaria
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPO	Government Pharmaceutical Organisation (Thailand)
GSK	GlaxoSmithKline
GSP	Generalized System of Preferences
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation, and IP
HAART	Highly Active Antiretroviral Treatment
HAI	Health Action International
HIV	Human Immunodeficiency Virus
ICESCR	International Convention on Economic, Social and Cultural Rights
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
IP	Intellectual Property
IPRs	Intellectual Property Rights
IPAB	Intellectual Property Appellate Board (India)
IPRs	Intellectual Property Rights
KEI	Knowledge Ecology International (formerly CPTech)
LDC	Least-Developed Country
LMICs	Low and Middle-Income Countries
MFN	Most Favoured Nation Principle

MIDC	Middle Income Developing Countries
MPP	Medicines Patent Pool
MSF	<i>Médecins Sans Frontières</i> (Doctors Without Borders)
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organisation
NHS	National Health Service (United Kingdom)
OECD	Organisation for Economic Cooperation and Development
PCT	Patents Cooperation Treaty
PMA	Pharmaceutical Manufacturers Association
PEPFAR	President's Emergency Plan for AIDS Relief (United States)
R&D	Research and Development
RTA	Regional Trade Agreements
SADC	Southern Africa Development Community
SCP	Standing Committee on the Law of Patents
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
UNITAID	Organisation cooperating with WHO and others on the WHO millennium goals

US FDA	United States Food and Drug Administration
USAID	United States Agency for International Development
USTR	United States Trade Representative
VCLT	Vienna Convention on the Law of Treaties
WHA	World Health Assembly
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

*I declare that **COMPULSORY PATENTS LICENSING AND ACCESS TO ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES AFTER THE DOHA DECLARATION** is my own work and that all sources that I have used or **quoted have been indicated** and acknowledged by means of complete referencing.*

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CHAPTER 1

INTRODUCTION

1.1 Background and context

On 14 November 2001 the World Trade Organisation ('WTO') adopted the Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights and Public Health ('Doha Declaration'), as a joint declaration of the Ministerial Conference in Doha. The Doha Declaration aimed principally at addressing the conflict inherent in the epidemics ravaging the developing world and to act as an incentive for the development of new medicines. The Declaration has led to further debate as to the role the Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPS Agreement') can play in addressing the major health problems facing developing countries ('DCs') and least developed countries ('LDCs').

Paragraph 6 of the Doha Declaration acknowledges that 'no country should be prevented from taking measures for the protection of human, animal or plant life or health', while paragraph 17 of the TRIPS Agreement stresses that 'implementation and interpretation of the Agreement on Trade Related Aspects of Intellectual Property Rights should be in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines'.

The decision reached by the General Council of the WTO on 30 August 2003 (Paragraph-6 Decision) and the December 2005 amendment to the implementation of paragraph 6 of the Doha Declaration ('2005 Amendment'), create a foundation for future changes to the WTO rules and open the door to the possibility of granting compulsory licences for the manufacture of life-saving medicines in third world countries. These provisions pave the way for the export of generic medicines to countries unable to manufacture these for themselves.

The Paragraph-6 Decision constitutes a temporary waiver of the obligations imposed by article 31(f) of the TRIPS Agreement which provides that products manufactured under a compulsory licence must be 'predominantly for the domestic market'. Several WTO members have subsequently implemented the decision in their national legislation. Despite these important

clarifications, the actual implementation of these measures to improve access to medicines remains uncertain.

Based on experiences in certain DCs, the TRIPS Council's Paragraph-6 Decision appears to create more hurdles for, rather than solutions to, the Doha paragraph 6-problem. The problem of the implementation of the Doha Declaration and the implementation of the Paragraph-6 Decision on access to essential medicines in DCs provides the impetus for this study.

This thesis will examine and analyse how far the implementation of the compulsory licensing flexibility has facilitated access to essential medicines in DCs. The provisions for protecting public health provided by the Doha Declaration and the Paragraph-6 Decision are reviewed in terms of challenges facing implementation, along with measures to protect intellectual property rights ('IPRs') under regional and bilateral trade agreements. The so-called 'TRIPS-plus' measures, data exclusivity rules, and regulatory approval are undermining the ability of the poor to access affordable medicines. This thesis points out that there is a need to recognise that public health protection under the TRIPS Agreement must take precedence over measures subsequently adopted under other trade agreements.

The thesis also considers the efficacy of competition law in curtailing the monopoly power inherent in the patent system. The positive results of the competition law provisions used by activists and non-governmental organisations ('NGOs') in South Africa, the successful use of section 3(d) of the Indian Patents (Amendment) Act, and the effective use of compulsory licences and government-use orders by Thailand and Brazil, form the principal focus of the thesis.

The thesis posits that there is an urgent need to establish simplified procedures under the Doha Declaration and the Paragraph-6 Decision. Steps towards negotiations which will eventually make way for a practical implementation of these measures need to be initiated.

The thesis, therefore, makes appropriate law reform recommendations in respect of finding alternatives for research and development ('R&D'), compulsory licensing, and the elimination of

trade tariffs and counterfeit medicines. There is also an urgent need to fund research in neglected diseases, for regional partnerships, and for further support for patent pools.

The title of this thesis, ‘Compulsory Patent Licensing and Access to Essential Medicines in Developing Countries after the Doha Declaration’, is informed by two underlying considerations. The first is the parameters of the thesis as outlined above. The second consideration is the dearth of textbooks which address the issues of compulsory patent licensing and access to essential medicines from an holistic and legal perspective. Currently only one textbook deals with the politics of pharmaceutical monopoly. I seek to fill this void.

1.2 Definitions

This thesis is limited to intellectual property (‘IP’) considerations related to public health. Consequently, recurring concepts in the thesis integrate a number of fields from patent law, international trade law and public international law, to international human rights law and medicines policy. For the non-specialist the glossary below offers a comprehensive background to the terms most commonly used in the study.

Access to medicines: *Generally refers to the idea that health policies should foster the availability of drugs at affordable prices to all those who need them.*¹

Compulsory licence: *‘The authorisation given by a judicial or administrative authority to a third party for the use of a patented invention without the consent of the patentee, on various grounds of general interest’ such as absence of working, public health, anti-competitive practices, emergency, and national defence.*²

Intellectual property: *‘A category of public law that generally includes copy rights, patents, trademarks, geographical indications, industrial designs, utility models, plant breeders rights, integrated circuits and trade secrets.’*³

¹ German Velasquez & Pascale Boulet ‘Globalisation and access to drugs: Implications of WTO/TRIPS Agreement’ in ‘Globalisation and access to drugs-perspective on the WTO/TRIPS Agreement 2’ WHO doc. WHO/DAP/98.9 (1998). See also ‘United Nations Development Programme, Human Development Report 2001’ 3, estimating that some two billion people do not have access to low-cost essential drugs.

² See Carlos Correa *Intellectual Property Rights, the WTO and Developing Countries: The Trips Agreement and Policy Options* (2000) xiii.

³ Supra note 2 above.

Developing countries ('DCs'): 'A developing country is a nation with a low standard of living, undeveloped industrial base, and low human development index ('HDI') relative to other countries. These are countries which lack a significant degree of industrialisation relative to their population'.⁴

Low and middle-income Countries ('LMICs'): The World Bank classifies all low- and middle-income countries as developing countries but notes: 'The use of the term is convenient, it is not intended to imply that all economies in the group are experiencing similar development or that other economies have reached a preferred or final stage of development.' Classification by income does not necessarily reflect developmental status.⁵

Sub-Saharan Africa: 'The term used to describe those countries of Africa that are not part of North Africa. Sub-Saharan Africa is also known as Black Africa.'⁶

Essential medicines: 'Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.'⁷

Pharmaceutical product: 'Any patented product, or product manufactured through a patented process in the pharmaceutical sector, required to address the public health problems of a member country as recognised in paragraph 1 of the [Doha] Declaration.' It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use are included under the term.⁸

'TRIPS-plus' measures: Measures which involve the undermining of public health protection through bilateral and/or regional trade agreements.⁹

⁴ See Arthur Sullivan & Steven M Sheffrin *Economics: Principles in Action* (2003) 471.

⁵ See World Bank Classification Index (2010), available at http://data.worldbank.org/about/country_and_lending_groups.

⁶ Available online from the *WordIQ Dictionary* http://www.wordiq.com/definition/Sub-Saharan_Africa (accessed on 27 April, 2012).

⁷ See 'Report of the WHO Commission on Essential Medicines' (2008) available at http://www.who.int/topics/essential_medicines/en/index.html (accessed on 27 April 2012)..

⁸ See WTO 'August 30th Decision' WT/MIN(01)/DEC/1.

⁹ *Medecins Sans Frontiers* 'Access to medicines at risk across the globe: What to watch out for in the free trade agreements with the United States' <http://www.accessmed-msf.org/documents/ftabriefingenglish.pdf> (Date used 21 February 2014). Broadened IP rights beyond those negotiated in the WTO TRIPS Agreement are referred to as 'TRIPS-plus' measures.

TRIPS flexibilities: A measure that ‘allows governments to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right holder does not supply the invention, provided certain conditions are [fulfilled]’.¹⁰

Bolar provision: This provision, also known as ‘early working’, permits an invention, process and/or data protected by patent to be used without authorisation in order to facilitate regulatory approval of a generic product before the patent expires. This allows a generic product to enter the market faster and speeds up access to cheaper drugs.¹¹

Evergreening: The practice of making minor modifications to an existing patented drug to make it appear to be a new drug. It is a patent strategy aimed at extending the patent term on the same compound.¹²

1.3 Research problem

It is necessary to understand the problems and obstacles against providing access to essential medicines despite the compulsory licensing provisions that was passed specifically for that purpose: to help provide essential medicines to the poor people living in DCs who could not afford to pay the high prices for the medicines.

The Doha Declaration was in theory a breakthrough for DCs and for non governmental organisations (NGOs) who worked so very hard for low cost medicines in DCs. The declaration affirmed the right of all countries to protect public health and was important for drawing attention to and offering policy options for access problems related to IP. It has however been

¹⁰ See WTO Fact Sheet ‘TRIPS and pharmaceutical patents’: September 2006 available where?? Available at http://www.wto.org/English/tratop_e/trips_e/factsheet_pharm02_e.htm#importing (accessed 9 August, 2012)

¹¹ This exception is often referred to as the ‘Bolar exception’ because of the case *Roche Products v Bolar Pharmaceuticals* 733 F.2d. 858 (Fed. Cir.1984). In this case the USA Court of Appeals for the Federal Circuit (CAFC) ruled that the research exemption in the USA did not cover Bolar’s acts to carry out equivalent tests for the regulatory approval of the generic medicine before the expiry of the relevant patent owned by Roche. The USA legislators considered that it was inappropriate to prevent generic pharmaceutical manufacturers from starting to prepare and obtain regulatory approval for the generics, since it would delay the entry of generic medicines to the market for a substantial period, extending the effective protection period beyond the patent term.

¹² See ‘Report of the WHO Commission on Intellectual Property, Innovation and Health’ (2006) 148 available at <http://www.who.int/intellectualproperty/report/en/index.html> (Date of use 18 May, 2012.)

realised that the declaration has failed to live up to expectations of the developing world. The developed countries particularly the US and the EU have relentlessly applied TRIPS-plus¹³ and Data exclusivity measures, the only indication is that further strengthening of patent rules is about to take place.

The US and the EU have asserted in various forums, that the Doha Declaration is in fact limited to AIDS, infectious diseases or epidemics. These backtracking interpretations have always been strategic, when the US and the EU wanted to push back against a developing country's effort to use compulsory licensing of patents for anything other than drugs for AIDS.

The main motivation of the thesis is to analyse what developments have so far been made post Doha in making essential medicines more accessible to the poor people living in developing countries. The main focus of the study will be on Article 6 of the Doha Declaration concerning compulsory licensing and the analysis will include the Decision on implementing Article 6, taken on 30 August 2003.

The research question to be raised in this regard is: whether the developed countries have kept to their promises and obligations under the Doha Declaration, in the light of subsequent global pharmaceutical patenting practices and if so, what lies in the future for DCs in their quest to have access to the much needed essential medicines?.

1.4 Aims and objectives

This thesis will examine and analyse how far the implementation of the compulsory licensing flexibility has enabled access to essential medicines in developing countries. The provisions for protecting public health provided by the Doha Declaration and the paragraph 6 decision will be reviewed in terms of the challenges facing implementation, along with measures to protect intellectual property rights (IPRs). This thesis will also argue that there is urgent need for negotiations to establish simplified procedures under the Doha Declaration and paragraph 6 decision.

The study will show that there is need to recognise that public health protections under TRIPS

¹³ TRIPS-plus measures are being pushed onto developing countries, through north-south bilateral/plurilateral trade and investment agreements and IP enforcement initiatives pushed by developed countries and international organisations as well as patenting strategies by pharmaceutical companies aimed at delaying generic competition.

must take precedence over other measures subsequently adopted under other trade agreements (FTAs).

The thesis will also consider the effectiveness of competition law in curtailing the monopoly power inherent in the patent system.

The purpose of this thesis will therefore be to provide answers to the following three questions:

1. How far has the Doha Declaration, the WTO Paragraph-6 Decision of August,2003, and the 2005 Amendment, enabled DCs and LDCs to access medicines at affordable prices?
2. What constraints do DCs and LDCs face in their efforts to implement the Doha Declaration and the Paragraph-6 Decision?
3. Are there other more efficient ways by which to secure access to essential medicines and foster innovation in DCs and LDCs?

1.5 Research methodology

The analyses carried out in this thesis will be made from the view of the developing and least developed countries, as their problems and lack of access to essential medicines is the core of the study and communication from the African group¹⁴ laid the foundation for the discussions in Doha on TRIPS and public health.¹⁵

It is also necessary to comment on both the methodology and the materials used in this thesis. Recognising and taking into account the extensive literature related to the topic of the thesis, this research will be conducted entirely by way of document review and analysis. This will involve a critical assessment of the available literature on this topic. This literature includes published books, journals and newspaper articles, reported judgments of the law courts and legal instruments.

¹⁴ African group consists of 41 countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Congo (Democratic Republic), Cote d'Ivoire, Djibouti, Egypt, Gabon, The Gambia, Ghana, Guinea Bissau, Kenya, Lesotho, Madagascar, Malawi, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe.

¹⁵ The Doha Declaration was precipitated by a request made by the African Group in April 2001 for the WTO to hold a special session of the TRIPS Council to clarify the relationship between intellectual property and access to medicines.

The study also obtained some information through internet research. In this respect, the following online resources were used in getting information on patents on medicines and the use of TRIPS flexibilities such as compulsory licenses, government use orders and experiences in some Sub-saharan African countries : the listserv IP-health, WIPO Gold, WTO, WHO, UNICEF-UNAIDS , UNCTAD-ICTSD and ARIPO databases. Medicins Sans Frontiers : Reports and Publications “Access to Essential Medicines” Campaign. (The Website contains publications and news releases related to public health) Oxfam, Geneva South Center, TAC, Heinonline.Org,Managing Intellectual Property, Business Line of India websites and data bases.

The study will adopt a comparative approach of the position of compulsory patent licensing and competition law in some developed and developing countries. I shall also be using both primary and secondary sources of information. As stated above some of the primary sources shall include legal instruments, such as international legal instruments and domestic legislations, judicial decisions. Legislations on the South African patent system, the Indian Patents Act, the Brazilian Patents legislation and legislations from some othe sub-Saharan African countries will also be reviewed and analysed. For the secondary sources of information, I shall be relying on international treaties and declarations, published books, journals and published articles. The reliance on primary and secondary sources is informed by the analytical nature of this research and the availability of a pool of materials that are relevant to the topic.

The sources consulted are drawn from as wide a spectrum of publications as possible. . This is because this is a topic which invokes heated debate among commentators from different professional and academic backgrounds, often with agendas of their own which does not always ‘fit’ with a neutral academic assessment of the problems.

Finally, although there are a number of interesting works on the legal aspects of the TRIPS Agreement, the WTO, and the problems and politics surrounding pharmaceutical patents, very little has been written on recent developments in the WTO negotiations and the Doha Declaration. This is why I have, in the main, relied on articles in academic journals.

1.6 Theoretical framework

It is necessary to state and explain in brief certain theories that underlie this study. I shall in the following few paragraphs explain such theories as access to medicines, TRIPS flexibilities and

compulsory licensing. I hope this will to some extent help in clarifying the conceptual framework which is crucial to the understanding of the access to medicines debate.

1.6.1 Access to medicines

Today billions of people worldwide do not have access to medicines they need. In some of the lowest income countries particularly in Africa and Asia this figure rises to more than half of the population. The situation is getting worse despite significant scientific and technological breakthroughs and advances made by the humankind. Making medicines available and affordable to those in dire need in DCs remains a major challenge for the international community. For governments in DCs, availability and affordability of essential medicines are both key problems.

According to the WHO access to medicines should include access to therapeutic, physical and financial aspects i.e. cover priority health problems, be available within easy physical reach and affordable to all.¹⁶ Also, in 2006 the Report of WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH) (at pg. 196) made the following observation:

“Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. However, the fact that a patent can be obtained may contribute little or nothing to innovation if the market is too small or scientific or technological capability is inadequate. Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding.”¹⁷

The obstacles to access affordable medicines as stated above illustrates a disturbing aspect of the TRIPS agreement. The TRIPS agreement has facilitated anti-competitive behaviour and the flow of trade in products at prices that are influenced or determined by monopolistic elements. This monopolistic elements hinder trade at free-market prices which runs counter to the trade-

¹⁶ See “Access, Quality and Rational Use of Medicines and Essential Drugs”. Available at www.who.int/medicines/edm-concept.html.

¹⁷ A/HRC/11/12; available at www.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf.SCP/17/inf/3

liberalisation principle of the WTO.

Finding the right balance between protection of pharmaceutical patents and the supply of effective and affordable medicines and people's access to essential medicines has become a controversy between the DCs and industrialised countries. This conflict is both economical and moral. It is economic because it deals with the income of the patent holders and their incentive to innovate and create new medicines. It is also moral because the economic aspect makes it difficult for the poor people living in DCs to have access to the much needed medicines.

1.6.2 TRIPS flexibilities

Although the TRIPS agreement could in certain cases, lead to higher prices for patented medicines, it however obliges all WTO Members to formulate, amend laws, regulations and adopt measures to provide patent protection on pharmaceutical products, it also provides them with mechanisms to deal with potential conflicts that may arise from such protection.¹⁸

Firstly, the TRIPS Agreement provides governments with flexibilities such as compulsory licenses or government use, parallel imports,¹⁹ generic drug approvals, limited exceptions (i.e. early working also called Bolar exception, research exception), revocation of patents, test data protection and price controls to fine tune the protection granted in order to meet social goals. It authorises members to adopt appropriate measures to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

In other words, members may use any of the above mentioned flexibilities to prevent abuse of the exclusive rights conferred on the patent holder by the TRIPS Agreement.

Secondly, the TRIPS Agreement allows WTO Members to formulate, amend laws, regulations and adopt necessary measures for the protection of public health and nutrition. In addition, it encourages the 'promotion of the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the

¹⁸ But see transitional periods with respect to patent protection for LCDs at Articles 65 and 66 of the TRIPS Agreement.

¹⁹ TRIPS Agreement Article 6.

provisions contained in the TRIPS Agreement’.²⁰

The most important of all these flexibilities and the main focus of the thesis is compulsory licenses, which will be briefly discussed in the next paragraph of the thesis.

1.6.3 Compulsory licensing

A practical way of preventing the abuse of patent rights under the TRIPS agreement is compulsory licensing. It is compulsory because the patent holder does not have a choice. Under a compulsory license, the rightholder is forced to license his patented invention to a third party, who has been decided by the courts or the government. The patent owner in return obtains an adequate remuneration. Compulsory licenses may be used to protect the public interest, especially during public health emergencies, or to act as a safeguard against abuses that might arise from the monopoly rights conferred by patents.

Several research has shown that patented inventions are generally not licensed voluntarily for financial considerations. This is particularly the case in the pharmaceutical sector.²¹ Compulsory licenses are therefore an important asset for governments in DCs to make patented inventions available at more competitive prices. The existence of provisions on compulsory licenses in local legislation (as was the experience in Brazil and South Africa) is enough to trigger voluntary licensing of patented inventions. In other words the threat of compulsory licensing encourages parties to grant voluntary licenses.

There are no restrictions on the purpose for the grant of compulsory licenses or use by the government. However some of the important conditions are entirely dependent on the purposes and merits of such grant, as laid down in national laws. This gives considerable leeway to policy makers in DCs to construct the grounds such that the conditions do not become restrictions. For instance if the purpose is to lower prices, it can be tackled by making the sale of the patented invention on unreasonable terms a ground for compulsory licenses.²²

²⁰ See Article 8 (1) of the TRIPS Agreement

²¹ See, for instance, C.T Taylor and Z.A Silberston (1973) “The Economics of the Patent System: A study of the British Experience”, Cambridge University Press, pp. 180-186.

²² J. Watal ‘Access to essential medicines in developing countries: Does the WTO TRIPS Agreement hinder it?’ (2000). Science, Technology and Innovation Discussion Paper No.8, Center for International Development Harvard

Alternatively, an undertaking in the public or private sector could, in the public interest, be authorised by government to manufacture a patented pharmaceutical product for sale to the public through government hospitals or health centers on a non-commercial basis.

The TRIPS agreement does not set any explicit limitation of the permissible grounds for the issuance of compulsory licenses.²³ From the wording of Article 31 of the TRIPS Agreement, WTO members are free to determine various and diverse reasons for the grant of compulsory licenses for pharmaceutical patents. DCs are advised to incorporate this flexibility available in Article 31 of the TRIPS agreement into their patent laws.

1.7 Scope of the study

In order to create a foundation for a legal analyses of the topic of this research, only the problems related to section 5 of the TRIPS agreement; patent rights, more specifically the predicament with pharmaceutical patents, with the right to access to medicines on the one hand and the patent right granted in TRIPS on the other. Therefore only pharmaceutical patents will be considered although there are admittedly, many other patents in closely related areas in which similar questions arise. The entire TRIPS agreement will not be examined comprehensively. The thesis will also analyse the Doha Declaration, the decision of the General Council of the WTO (waiver decision) of 30th August 2003 and the 6th of December, 2005 amendment of the TRIPS agreement. There will be no clear distinction between developed countries DCs and least developing countries LDCs, as they will be acknowledged as one side of the conflict with developed countries on the other.

1.8 Literature review

A lot has been written in the past by many authors on the interplay between patents and access to essential medicines. I have reviewed literature related to pre-TRIPS scenario, TRIPS agreement and post-TRIPS scenario. There are various and divergent views on the relationship between patents and access to essential medicines due to the fact that the debate on this topic cuts across various fields and disciplines. The debate is at times inflamed and many authors and

University, Cambridge, MA, USA 3. Where the author estimates price reductions of over 90% in some medicines in India with the use of compulsory licensing.

²³ Except for semi-conductor technology where they can only be used for public non-commercial use or to remedy an anti-competitive practices.

commentators have their own agendas that do not necessarily correlate well with an academic and neutral study of the problem.

However, this study is distinct and novel in the sense that it is a specific research on how the Doha Declaration has had impact on and enabled access to essential medicines in DCs. The existing literatures have been extensively reviewed in order to lay a proper foundation for a critical assessment of the WTO TRIPS agreement and the Doha Declaration. This thesis agrees with the views espoused by some of the literature. It also disagrees with the points of views that others have posited. Arguments are given to justify the concurrence or divergence.

The first set of literature reviewed is of those authors who tend to explain the justification for patent protection. The second set of literature reviewed is of those authors who have dealt with the international framework. These authors have reviewed the WTO TRIPS agreement and other relevant instruments. Another set of authors have dealt with the relationship and interplay between patents protection and access to essential medicines. Whilst others have considered the various flexibilities and mechanisms that have been put in place to check the monopolistic power and abuse inherent in patent protection. These are the WTO-TRIPS flexibilities.

One may then ask the question, what is the reason and justification for patent protection?. John Locke and some of his followers like Hegel have espoused the notion that patent protection can be justified on the grounds that creators of an invention have a natural right to the fruits of their invention.²⁴ The common theme of the argument by Locke and Hegel is their focus on the natural rights of the owner of the invention or artistic work. This is the natural law theory.

There are also authors who justify patents protection as an incentive for further research and development .This is the incentive or utilitarian theory. Susan K Sell states that the rationale for intellectual property rights is that they provide incentives for the creation and dissemination of innovation. She argues that without the necessary compensation made possible by intellectual property rights protection (IPRs) public goods will be underprovided.²⁵ This view which is also shared by Carlos Correa and by Philip Cullet, is widely viewed as the most persuasive

²⁴ J.Locke The second teatise on government (1690); J.Hughes ‘The philosophy of intellectual property’.(1988-1989) 77 Georgetown Law Journal 287-330..

²⁵ S.K. Sell ‘TRIPS-plus free trade agreements and access to medicines’ (2007) 28 Liverpool Law Review 41-43.

philosophy of IPRs protection.²⁶

In this study I agree with these authors conclusions that patent protection acts not only as an incentive for research and development but I also share the view that a lot of medicines would not have been produced if there were no patent protection. If information is not protected through patent rights, important drugs may never be developed.

Feroz Ali Khalider a famous Indian author on pharmaceutical patents in his book ‘The law of patents with special focus on pharmaceutical patents’ stated as follows:

“Empirical studies have now established that in no other field of technology do patents play a more significant role as in the case of pharmaceuticals.....It is said that more than 30% of pharmaceutical inventions would not have been developed had it not been for patent”.²⁷

Alexander Watson also highlights the general controversy over TRIPS.²⁸ This controversy led to tension between DCs and developed countries. The DCs have criticised the TRIPS agreement for swinging the patent pendulum in favour of patent owners. DCs are of the view that the TRIPS agreement is too lenient in the protection of IPRs and considered TRIPS as imposing western values on them. Before the introduction of TRIPS agreement many countries did not have patent protection on product patents although they had protection on process patents. It is further argued in this thesis that the introduction of patents protection could if properly used be a boon for DCs (in view of reverse engineering which has made production of generic medicines easy) and a bane for developed countries (who bear the cost of research and development).

The use of compulsory licensing and the production of generic medicines will bring down the cost of drugs drastically in DCs.

There also exist two divergent views on the relationship between patents and access to medicines. Some authors like Ellen F.M T’ Hoen, Phillip Cullet and German Velasquez have

²⁶ P.Cullet ‘Patents and medicines: The relationship between TRIPS and the human right to health’ (2003) International Affairs 79-160.

²⁷ See Feroz Ali Khader, ‘The law of patents –with a special focus on pharmaceutical patents’ (2008) see Student Edition 2009 see preface to the book at page xii.

²⁸ See A.G Watson ‘International intellectual property rights: Do TRIPS’ flexibilities permit sufficient access to affordable HIV/AIDS medicines in developing countries?’ (2009) 32 Boston College of International and Comparative Law Review 143.

argued that patents increase the price of drugs thereby hindering access to the much needed essential medicines.²⁹ These authors have through their writings expressed the views that patents increase the cost of medicines and act as a constraint to access essential medicines in DCs. However, some authors have opposed this view and have argued that there is no empirical evidence to back up the argument that patent hinders access to essential medicines. Susan K Sell and Z.A Zanol et al among other authors have argued that there are many other non-patent factors that affect access to medicines.³⁰

Jayashree Watal also wrote that there are few reliable estimates of differences in prices of medicines in DCs, on account of patents alone.³¹ It is also argued that even drugs that are off-patent or ‘.....cheap generic drugs may not be affordable for people below the poverty line’.³² Frederick.M.Abbott wrote: “that it should be noted that low standards of patent protection reduces expected income streams and with it the incentive to invest. Consumers pay high prices for on-patent drugs, but this must be understood in the context that high prices are the mechanism for funding long-term research and development, thus yielding an offsetting social good”.³³

This thesis agrees with the arguments that the grant of exclusive patents right to the patent holder creates monopoly which leads to higher prices for drugs than the prices charged in a competitive market. The thesis also agrees with the view that patent protection has the potential of encouraging research and development but does not agree with the view that that charging high prices for drugs is the only way to encourage research and development and to ensure availability of medicines.³⁴

²⁹ T Hoen, E.F.M. 2009 The Global Politics of Pharmaceutical Monopoly Power (Drug patents,access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health) 2009.

³⁰ Z.A Zainol et al ‘Pharmaceutical patents and access to essential medicines sub-Saharan Africa’ (2011) 10 African Journal of Biotechnology 12376-12377.

³¹ J.Watal ‘Access to essential medicines in developing countries: Does the WTO TRIPS Agreement hinder it?’(2000) Science, Technology and Innovation Discussion paper No.8, Center for International Development Havard University, Cambridge, MA, USA 3.

³² P.Cullet ‘Patents and Medicines: The relationship between TRIPS and the human right to health’ (2003) International Affairs 79-160.

³³ Frederick.M. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a dark corner at the WTO. Journal of International Economic Law (2002) 469-505 at page 473.

³⁴ The protection of patent rights is considered to be a critical precondition for further investment in pharmaceutical research and in the development of new drugs. In other words patentability of pharmaceutical products provides an

Some writers also criticise the pharmaceutical companies for exaggerating their expenditure on research and development. Marcia Angell, former editor of New England Journal of Medicines, in her book 'The truth about drug companies' paints the pharmaceutical industry as corrupt and corrupting. According to her, pharmaceutical companies marketing expenditures far outweigh the cost of research and development.³⁵

The thesis will show that the current pharmaceutical innovation system largely depends too heavily on patent protection for financing and priority setting. The study will show that there is urgent need for a policy agenda to tackle the question of how to create incentives for research and development that does not create access barriers to medicines.

It is however not in dispute that generic medicines lead to lower prices of medicines because of increase in competition.³⁶

As already stated above the TRIPS agreement has in built mechanisms, the TRIPS flexibilities which states are obliged to use to strike a balance between patent protection and access to medicines. This thesis will critically review and access writings on policy tools like transition periods, patentability criteria, test data protection, compulsory licensing and parallel importation among others. Useful literatures in this regard will be F.M Abbott³⁷, Brook.K.Baker³⁸ and Reichman J.H and Hasenzahl³⁹. Also of note is 'T Hoen, E.F.M who critically analysed paragraph 6 of the Doha Declaration and questioned whether it could be a solution to the process of access to medicines in DCs. At page 36 of her book 'The Global Politics of Pharmaceutical Monopoly Power stated:

economic incentive for the pharmaceutical companies to invest and to engage in creative efforts, by ensuring that the creator can harvest financial reward from his effort.

³⁵ See Marcia Angell, 'The Truth About Drug Companies', N.Y. Rev. Books, July 15, 2004. (She is the former editor for New England Journal of Medicines).

³⁶ See J.Watal 'Access to essential medicines in developing countries: Does the WTO TRIPS Agreement hinder it?' (2000) Science, Technology and Innovation Discussion paper No.8, Center for international Development Harvard University, Cambridge, MA, USA 3, F.M Scherer 'The pharmaceutical industry' in Al Culyer & JP Newhouse (eds) 1, Handbook of health economics (2003) 1322-1324.

³⁷ Frederick .M. Abbott; The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the TRIPS provisions. Journal of International Economic Law (2007) 10 (4): 921-987.

³⁸ See Brook.K.Baker in Arthritic Flexibilities for Assessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on TRIPS Agreement And Public Health. Published in Indiana International Law and Comparative Law Review 613, 2004.

³⁹ See Reichman. J.H and Hasenzahl in "Non-voluntary Licensing of patented inventions'. The Canadian Experience". An online publication, UNCTAD-ICTSD issue No.5 Geneva 2003.

“However, the cooperative spirit of Doha quickly evaporated once negotiators were back in Geneva. It took the TRIPS Council nearly two years to reach an agreement to allow the export of medicines produced under a compulsory licence.”⁴⁰

In order to lay a proper foundation and to properly analyse the issues raised in the research problem it is necessary to consider an overview of the patent law system, the interplay between patents and medicines, and an over view of the human rights framework. It is also necessary to critically review and analyse some of the provisions of section 5 of the TRIPS agreement and paragraphs, 1,2,3,4,5,6, and 7 of the Doha Declaration. It is after these issues have been dealt with that the constraints to gain access to essential medicines in DCs will be identified and analysed. Finally, I shall make recommendations on the way forward.

1.9 Thesis overview

In this thesis I address two aspects of the TRIPS Agreement: patents protection; and access to essential medicines. This is approached in ten chapters.

The introduction (Chapter 1) sets out the research programme and is followed, in Chapter 2, by a background to patents law and access to medicines. The need for the protection of patent rights and the interaction between patents and access to medicines is highlighted in this chapter.

In Chapter 3 I discuss the human rights framework based on an overview of selected relevant human rights instruments and the international human rights framework. This is followed by an examination of the interplay and conflict between patents and medicines, and more specifically how this impacts on access to medicines. Section 27 of the Constitution of the Republic of South Africa, 1996 – the constitutional provision addressing access to medicines in South Africa -- is also briefly analysed.

Chapter 4 of the thesis addresses the TRIPS Agreement. The chapter opens with an overview of the historical development of the TRIPS Agreement in which I examine the circumstances surrounding its conclusion and its legitimacy, before considering its scope, objectives, and the general principles it establishes. The exemptions from and limitations available under the

⁴⁰ See The Global Politics of Pharmaceutical Monopoly Power: Drug Patent, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health (2009) at p. 36.

agreement are then considered alongside an analysis of the various categories of ‘flexibilities’ created by the TRIPS Agreement.

In Chapter 5 I consider how the Doha Declaration came to pass and analyse and review its content. The special Paragraph-6 (‘waiver’) Decision on production for export under a compulsory licence is considered in detail. The conditions and procedural requirements applying to the use of the new article-31(f) waiver are also set out in detail. The key elements and issues raised by the terms of the Paragraph-6 Decision are also briefly considered.

Chapter 6 traces the history and development of compulsory licensing and the rules which apply to the compulsory licensing of drugs under the TRIPS Agreement. The obstacles hindering the use of this mechanism in DCs and LDCs are briefly considered.

I then discuss how compulsory licensing has evolved in Canada, the United Kingdom, and the United States of America, and the use of the flexible provisions in selected DCs. Rwanda’s futile attempt to use the paragraph-6 system is briefly examined. The chapter also addresses the obstacles faced by DCs in their attempts to use the flexibility available under compulsory licensing.

Finally, the important issues of compensation for the patent owner under article 31(h) of the TRIPS Agreement and the adequacy of royalties are carefully analysed.

In Chapter 7 I discuss the introduction of product patents into India’s patent law for the first time in over four decades and how the country resisted the onslaught by *Novartis* and other lawsuits challenging section 3(d) of its Patents Act. The chapter also considers the problems India faced from pharmaceutical companies in its quest to develop and protect its generic manufacturing capacity. A selection of lawsuits instituted by pharmaceutical companies challenging India’s compliance with the TRIPS Agreement and the Doha Declaration are examined. The provisions of the Indian Patent Act,⁴¹ such as the limitations imposed on the patent rights and relevant exceptions to the right, are discussed in detail.

In Chapter 8, I consider the relationship between patents as IP and the right of access to

⁴¹ The Patents (Amendment) Act, 2005, No 15, Acts of Parliament, 2005, available at http://www.patentoffice.inc.in/ipr/patent/patent_2005.pdf

medicines. The constitutionality of patents is discussed together with the development of compulsory patent licensing in South Africa. I start by examining the legal framework for compulsory patents licensing before proceeding to evaluate South Africa's framework as an example for other DCs.

Competition law reform as one of the major policy options available to DCs like South Africa in accessing generic medicines, is considered through selected cases brought before the South African Competition Commission. Relevant sections of the South African Patents Act 57 of 1978, its Medicines and Related Substances Control Act (MRSCA) 101 of 1965, and its Competition Act 89 of 1998 are analysed in depth. Section 27 of the Constitution of the Republic of South Africa, 1996 and the constitutionality of access to medicines are also considered.

Chapter 9 describes how, despite important clarifications in the Doha Declaration, concerns persist in certain quarters as to the capacity of DCs to implement specific TRIPS flexibilities. This chapter discusses some of the shortcomings in the Doha Declaration and constraints faced by DCs in implementing the flexibilities offered by the Declaration. It further considers the threat posed by TRIPS-plus measures, data exclusivity, the need for national laws, and ambiguities in the Declaration that demand critical assessment.

In conclusion, in Chapter 10 I recommend that as the problem is a global one, it can only be resolved at the global level. I stress the need for a policy agenda which distinguishes between R&D and patent protection. I discuss the research being undertaken to formulate incentives for R&D that will not raise access barriers to medicines. I further emphasise that R&D must not lead to an increase in the price of essential drugs.

In my findings and conclusions I revisit the discussion of the Doha Declaration, compulsory licensing, parallel imports, counterfeit drugs, and access and innovation. I assess in detail the emerging role of CIPIH and the IGWG in resolving the research and development problem and changing how R&D can be prioritised and financed. I also consider the role of international donors in access to medicines, and the need to exempt discounted and donated pharmaceuticals from tariffs and taxes. Towards the end of the chapter, I make some important recommendations

for ensuring that access to essential medicines by the poor living in DCs can be secured. I conclude with suggestions for further research into this topic.

1.10 Assumptions

There is need to state some few words on the assumptions made in this thesis. This thesis proceeds on the basis of certain basic assumptions. First, for the sake of brevity, references to a “pharmaceutical drug” or to a “pharmaceutical product” should be read and construed as used interchangeably. Second, references to “pharmaceutical patents” or to “patents on medicines” should be read and construed as used interchangeably. Third, references to “developing countries” DCs should be read and construed as reference to both “developing countries” and “least developed countries” LDCs also.

Fourth, the words “plaintiff” or “applicant” are used interchangeably, and have the same meaning. The words are used basically to refer to a party who commences a patent proceedings or a patent opposition proceedings, while the word “defendant” or “respondent” have an obverse meaning unless otherwise specified. Fifth, the words “flexibilities” or “mechanisms” should be read and construed as synonymous. They are words used basically to refer to measures that allow governments to make exceptions to a patent holder’s right.

Lastly, the words “parallel trading” and “parallel imports” are used interchangeably, and have the same meaning. The words are basically used to refer to a practice whereby products produced under the protection of a patent, in one market are subsequently exported to a second market and sold there without the authorisation of the local owner of the patent.

CHAPTER 2

INTERFACE BETWEEN PATENTS AND ACCESS TO MEDICINES

2.1 Introduction

In this era of globalisation it is the goal of every business enterprise to maximise profits. Indeed globalisation affects every area of human endeavour including the area of intellectual property. Every developing country wants to take advantage of the benefits arising from globalisation, the incentives from developed countries such as foreign direct investment (FDI) and the introduction of technology into almost every sphere of life.⁴²

In the area of IP, the introduction of patents for pharmaceuticals has placed profit before human life. The TRIPS Agreement⁴³ was introduced in 1995. It introduced IP law into the international trading system for the first time and applies to all members of the WTO. Because it was recognised that the implementation of the TRIPS Agreement was set to have a major effect on generic drug production, the majority of DCs were allowed a ten-year transition period within which to comply with its provisions.⁴⁴ This means that DCs (India, for example) were able to continue developing generic drugs until 2005, whilst least-developed countries ('LDCs') now have until 2021 to do so.⁴⁵

The argument put forward by the drug manufacturers is that IP protection is essential for securing investment for research into new medicines⁴⁶ and that the patenting of medicines is not

⁴² See http://gupea.ub.gu.se/bitstream/2077/18240/1/gupea_2077_18240_1.pdf

⁴³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh, 15 April 1994, reproduced in (1994) 33 *International Legal Materials* 1197 ('TRIPS Agreement').

⁴⁴ See article 66.1 of the TRIPS Agreement. See also article 70.9 of the TRIPS Agreement which allowed LDCs until 2016, but which has now been extended to 2021.

⁴⁵ See World Trade Organisation [internet] Extension of the transition period under Article 66.1 for least developed country members: decision of the Council for TRIPS of 11 June 2013 (IP/C/64). Geneva: WTO; 2013 available at http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf (accessed on 29 May 2013).

⁴⁶ It is debatable for drug manufacturers to claim that their huge investments in R&D warrant the high prices for their products. A number of patented drugs were not discovered by the manufacturing companies. Public-funded institutions and universities were largely responsible for the initial R&D of several medicines. For instance, the National Institute of Health ('NIH') in the USA was instrumental in the discovery of a number of the AIDS medicines. In fact the NIH estimated that in 1995 its contribution to the overall USA health R&D accounted for 30 per cent of the total, whilst that of private industry amounted to 52 per cent (2001FULL REF REQUIRED?). Oxfam (2001) *Cut the cost, patent injustice: How World Trade Rules Threaten the Health of Poor People*, Oxfam GB. Available at <http://www.latp.org/files/cut-the-cost-patent-injustice-How-World-Trade.htm>. And yet it is the pharmaceutical industry that reaps most of the profit.

an impediment to accessing medicines in DCs.⁴⁷ This chapter opens with an overview of the patent system and discusses the history and genesis of the introduction of product patents for pharmaceuticals, and the justification for its introduction.

2.2 Overview of the patent law system

Intellectual property rights ('IPRs') usually refer to the 'property rights recognised on distinct types of creations of the mind'.⁴⁸

In IP law certain rights are given to owners to enable them distribute inventions, to enter different markets and to initiate legal proceedings to challenge infringed rights. These various types of exclusive intellectual property rights include patents, trademarks, trade secrets and industrial designs.⁴⁹

A patent is defined as 'the right granted to an inventor by a state, or by a regional office acting for several states, which allows the inventor to exclude anyone else from commercially exploiting his or her invention for a limited period, generally twenty (20) years'.⁵⁰ This definition covers 'any invention, whether product or processes in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application'.⁵¹ This implies that the new product or processes described in the patent application must be something that has not previously been disclosed anywhere in the world ÷ something that would not be obvious to a person of ordinary skill in the field involved: and something that has a functional utility for commercialisation.'⁵² Other procedural requirements include public disclosure and maintenance fees.

As of 30 April 2012 it was reported by the Global Health Technologies Coalition and Policy Cures, that the USA NIH contributed 45 per cent total investment in research. See Global Health Technologies Coalition and policy

⁴⁷ A common view in respect of the patent system is that it is intended to promote innovation by encouraging investment in innovative activities with the prospect of economic returns through the grant of a limited exclusive right. According to such a model, the consequences of excluding certain types of subject matter from receiving patent protection could be that there may be less incentive for inventors to invest in excluded subject matter.

⁴⁸ R Raysman, EA Pisacreta & KA Adler *Intellectual Property Licensing: Forms and Analysis 1999-2008* (2008).

⁴⁹ See <http://en.wikipedia.org/wiki/intellectual-property>. See also W.R Cornish *Intellectual Property, Trademarks and Allied Rights* 4th edition (1999) at page 6 -10

⁵⁰ See Patents Act 57 of 1978 sec 46(1). See also T.D Burrells *South African Patent and Design Law 1999* at pages 1-3. See also TRIPS Agreement Article 33

⁵¹ TRIPS Agreement art 27.

⁵² See W. Cornish *Intellectual Property; Patents, Copyright, TradeMarks and Allied Rights* 4th edition (1999) at page 173

A patent application involves a request for the grant of the patent, an abstract which gives information about the invention, and a description of the invention also termed a 'specification'.⁵³ The specification 'is the part of the application that contains: (i) a description of the invention; (ii) the claim or claims as to what has been invented and what monopoly is sought; and (iii) drawings referred to in the description.'⁵⁴ Once a patent has been granted, the owners are empowered to prevent others from using the protected invention without their authorisation.⁵⁵ The scope of rights under patents further extends to the ability to prosecute third parties for damages or to seek injunctive relief in the event of infringement.⁵⁶ However, patent rights are not absolute in that they remain limited in space, time, and content.⁵⁷

Patent law is domestic in nature. The geographical limitation of patent protection implies that rights are enforceable only in the country or countries where protection has been granted.⁵⁸ A single filing of an international application with a receiving office is possible. In that case, the patent owner automatically designates contracting states where protection is sought. This filing procedure is known as 'international patent application'.⁵⁹ Even here, patent holders must seek enforcement of their rights in each designated country.⁶⁰ As for duration, patent rights last only for a specified period, the global standard being twenty years from the application filing date.⁶¹ This means that the protected subject matter falls into the public domain after that period and may be commercially exploited without the patentee's permission.⁶²

Patents are also limited in content as they protect only what is set out in the specifications. It follows that they can only be enforced to the extent that application has been made. .⁶³It must

⁵³ Patents Act 1977 s 15(2).

⁵⁴ H MacQueen, C Waelda & G Laurie *Contemporary Intellectual Property: Law and Policy* (2007) 396.

⁵⁵ TRIPS Agreement art 28(1).

⁵⁶ Patents Act 1977 s 60(1) and 60(2).

⁵⁷ See WR Cornish *Intellectual property: Patents, Copyright, Trade Marks and Allied Rights* 4 ed YEAR1999

⁵⁸ See W.Cornish note 12 above.

⁵⁹ See e.g the international application system under the Patents Cooperation Treaty (PCT)

www.wipo.int/pct/en/texts/articles/atoc.htm

⁶⁰ See W.Cornish note 12 above.

⁶¹ TRIPS Agreement art 33.

⁶² See TD Burrell *South African Patent and Design Law* 3 ed (1999) 1-4.

⁶³ See W.Cornish note 12 above.

also be noted that the patent law system reflects a difficult balance between access and innovation.⁶⁴

2.3 The need for the protection of patent rights

The essence of IPR and patents in particular, is to provide the incentives necessary for research and technological development.⁶⁵

The main justification for conferring patent on a patent holder is to compensate the inventor. The patent holder can then benefit from the right to commercialise the invented product and has the right to prevent others from doing so. This in essence runs against the principle of free trade because it is only the inventor who has the right to gain economic benefit from the invention. He also has the right to prevent others from using it without his consent.⁶⁶

There are two basic justifications for the need for intellectual property right protection. One involves the theory of fair compensation, while the other relates to incentives to encourage invention.⁶⁷ The theory of fair compensation asserts that one owns the fruits of one's labour.^{68 69} The second theory, supporting the need for the protection of IPRs, asserts that few incentives to innovate exist where people are allowed to be rewarded for their inventions at little or no cost. This is the so-called 'free rider' phenomenon.⁷⁰

2.4 The interface between patents and access to medicines

⁶⁴ Article 7 of the TRIPS Agreement aims to balance these two competing interests of promoting innovation of new drugs and providing access to these drugs. For example, nations with weak economies and public health crises want medications for their people, while innovative pharmaceutical companies want to protect their temporary exclusive rights in order to recoup their investment and maximise profits.

⁶⁵ See P Cullet, 'Patents and medicines: The relationship between TRIPS and Human Rights to health' (2003) 79 *International Affairs* 140.

⁶⁶ See www.ielrc.org/content/a0301.pdf . See also P.Cullet at page 40

⁶⁷ J Trelbilcock & R Howse *The Regulation of International Trade* 2 ed (1999) 32.

⁶⁸ RE Meiners & RJ Staaf 'Patents, copyrights and trademarks: Property or monopoly?' (1990) 13 *Harvard Journal of Law and Public Policy* 91, 95.

⁶⁹ See E Cameron, 'Patents and Public Health: Principles, Politics and Paradox' paper delivered at the Inaugural British Academy Law Lecture, University of Edinburgh 19 October 2004.

⁷⁰ See EC Hettinger 'Justifying intellectual property' (1989) 18 *Philosophy and Public Affairs* 31, 35.

As stated above, patents serve as an incentive for the development of the private sector pharmaceutical industry.⁷¹

The rationale for granting exclusive rights on patented medicines as stated in the preceding paragraph is that while the development of new drugs is a costly process, it is relatively easy to copy an existing drug. Despite the private industry's plea for patent protection, a number of developed and developing countries have traditionally imposed restrictions on the patenting of drugs on public policy grounds.⁷² While patents on drugs are now the norm in developed countries, even those with significant interests in the pharmaceutical sector such as Switzerland, have introduced product patents on drugs only relatively recently.⁷³ The Indian Patents Act of 1970, introduced restrictions on product patents for medicines to limit commercialisation in the health sector.⁷⁴ The adoption of the TRIPS Agreement forced countries like India which had patent restrictions to amend their patents laws fundamentally to comply with their WTO-related legal obligations.⁷⁵

Patents undoubtedly play a major role in the health sector. First, they are a precondition for private sector involvement in the development and production of new essential medicines.⁷⁶ Secondly, patents offer exclusive rights to patent holders who benefit from a monopoly situation in the market. This implies that companies selling patented drugs have an important say in determining their price. The result from the perspective of individual patients is that patented drugs are usually significantly more expensive than generic drugs (drugs not protected by patent). The central role of patents does not imply that they are the only determinant of patients' access to drugs. In fact, a host of other factors play vital roles in shaping people's access to medicines. These include issues linked to the distribution of drugs as well as legal and policy

⁷¹ See Lisa Anderson 'The conflict between intellectual property rights and the right to health of AIDS victim in South Africa' (2002) Global Politics Network available at www.globalpolitics.net/essays/Lisa_Anderson.pdf (accessed 31st April, 2012).

⁷² See Carlos Correa *Integrating Public Health concerns into Patent Legislation in Developing Countries* (2000) at page 8.

⁷³ See P. Cullet at page 141.

⁷⁴ See also Shri Justice N Rajagopala Ayyangar 'Report on the Revision of the Patents Law' (September 1959), at preface (on file at National Law School of India University, Bangalore) (reviewed by author at NLSIU Library on Nov. 18, 2005)

⁷⁵ The increasing scope of patentability in the health sector, codified in the TRIPS Agreement, constitutes one of the most significant changes in law for DCs that are members of the WTO. See also P. Cullet page 139.

⁷⁶ UNICEF – UNAIDS – WHO/HTP/MSF 'Sources and Prices of Selected Drugs and Diagnostics for people living with HIV/AIDS' (2001), available at www.unaids.org/sites/default/files/media..../jc645-sources-prices-en-1.pdf

instruments that a government can use to regulate prices, such as the Drug Price Control Order (DPCO of India 2013).

As far as innovation is concerned, it is clear that the existence of patents in developed countries has not led pharmaceutical companies to develop drugs for DC-specific diseases.⁷⁷

In 2001, a commission set up by the UK government on IP and development noted that:

‘For most developing countries any benefits in terms of the development of new treatments for diseases that afflict them will be, at best, long term, while the costs of implementing a patent system are both real and immediate.’⁷⁸

It then recommended a variety of measures that countries could consider adopting. These included that developed countries strengthen parallel importation, provide international exhaustion of rights, establish workable laws and procedures to give effect to compulsory licensing, apply the ‘early working’ exception to patent rights, and avoid granting data exclusivity.⁷⁹

Nearly ten years after its independence India had one of the highest prices for drugs but can now boast of one of the lowest price of drugs in the world.⁸⁰

Even though access to drugs is far from universal, the patents regime has also contributed to notable improvements in access to medicines.⁸¹ As indicated above, the cost of developing a new medicine has generally been put forward to justify pharmaceutical innovators’ rights to profits

⁷⁷ See WHO ‘Policy Perspectives’ World Health Organisation, Globalisation, TRIPS and Access to pharmaceuticals (WHO Policy Perspectives on Medicines No.3, 2001) Available at <http://apps.who.int/medicinedocs>. The WHO noted that of the 1 223 new chemical entities developed between 1975 and 1996, only eleven were for the treatment of tropical diseases.

⁷⁸ “Integrating Intellectual Property Rights and Development Policy. Commission on Intellectual Property Rights”, 2002, Available at www.iprcommission.org.

⁷⁹ Commission on Intellectual Property Rights ‘Integrating Intellectual Property Rights and Development Policy’ 2002 available at www.iprcommission.org. 39 (date used 13 April 2013).

⁸⁰ Shektar Choudri ‘The evolution of the Indian pharmaceutical industry in Greg Felker et al (eds) The pharmaceutical industry in India and Hungary – Policies, Institutions, and Technological Development (1997)

⁸¹ See ‘Business Line of India’ 30 April 2014 available at <http://www.thehindubusinessline.com/news/international/ip-leads-to-innovation-investment/article5963414>. (date used 15 May 2014). In an interview with the publication outfit Jasper Macslarraw, Executive Director of US Chamber of Commerce’s Global Intellectual Property Center, stated that ‘in the absence of IP rights, millions of people suffering from diseases around the world will not have access to cures because the capacity to pursue this kind of research will be disrupted.’ Source for interview <https://www.uschamber.com/jasper-macslarraw>.

through the exclusive use of their innovation.⁸² However, the problem with the current rewards system under patent monopoly is that it fails to specify clearly whether profits are limited to the recovery of production costs or extend to the net benefit of the social value of the innovation, and if the latter, under what conditions.⁸³

In March 2012, the Indian Controller of Patents in granting a compulsory licence against Bayer's patented drug *Sorafenib*, stated that:

'It did not help Bayer's case that worldwide sales of the drug had exceeded \$1.2 billion, thereby presumably offsetting or surpassing Bayer's research and development cost'.⁸⁴

The social value attached to pharmaceutical products and processes far exceeds that of other industries in that health products are intended to improve human health and save lives.⁸⁵ For these reasons the patent monopoly system would not appear ideally suited to the pharmaceutical industry.⁸⁶ Generating profits and increasing access to essential medicines are often incompatible goals.

In 2009, the UN Special Rapporteur on the Right to Health in his submission to the UN General Assembly concluded:

'The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality, to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect and fulfill the right to health.'⁸⁷

⁸² See P. Cullet Pages 140-143.

⁸³ Research indicates that industry estimates for R&D on each new drug ranges from US\$350-500 million, while independent estimates range from US\$30-160 million. Using either estimate, revenues from many life-saving drugs very easily exceed the cost of their R&D. For example, in 1996 the sales of Bayer's *ciproflaxin* totalled US\$1,63 billion and Pfizer's sale of *fluconazole* totalled US\$ 1 billion. See *Medicines Sans Frontiers* (MSF) Report 2001 (available where and when used?). Available at <http://www.msf.org/sites/msf.org/files/old-cms/source/access/2001/fatal/fatal.pdf> (date of use 19 June 2012).

⁸⁴ *Bayer v Natco decision of an Indian High Court in March, 2012* Suit No (CS/OS) 1090/2011.

⁸⁵ See, eg, John H Barton 'Differential pricing of patented products' Commission on Macroeconomics and Health Working Paper Series WG4: 2, 2001.

⁸⁶ Hollis A *An Efficient Reward System for Pharmaceutical Innovation* (2005) 4.

⁸⁷ A/HRC/11/12. See http://www.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf. SCP/17/INF/3 (date used 12 March 2013).

The Committee on the International Covenant on Economic Social and Cultural Rights ('ICESCR') noted in its General Comment 14 that the basic elements of the right to health include availability, accessibility, and quality.⁸⁸ Access to medicines requires the medicines to be both accessible and affordable. The Committee similarly noted that economic accessibility presupposes that health facilities, goods and services must be affordable for all. It notes further that payment for health-care services, as well as services related to underlying determinants of health (including drugs), must be based on principles of equity, which demand that 'poorer households should not be disproportionately burdened with health expenses as compared to richer households.'⁸⁹

2.5 Conclusion

In this chapter, I have looked at the patent law system, its procedure and the nature of an application for a patent. The need for the protection of patent rights and the interface between patents and access to medicines was briefly examined.

I also tried to show that other non-patent factors also play a role in denying access to medicines in DCs and that ensuring access to health facilities, especially for marginalised groups, constitutes one of the core obligations inherent in the right to health. States are therefore obliged to respect, protect and fulfill the right to health,⁹⁰ and when patents interfere with access to essential medicines, this equates with an abuse of human rights. And it is this concept which forms the subject of my next chapter.

⁸⁸See UN Committee on Economic, Social and Cultural Rights 'General Comment no 14: The Right to the Highest Attainable Standard of Health' UN Doc E/C 12/2000/4 (2000).

⁸⁹ Id para 12.

⁹⁰ See P. Cullet at page 148.

CHAPTER 3

AN OVERVIEW OF THE HUMAN RIGHTS FRAMEWORK

3.1 Introduction

The right of access to medicines is a human right. Human rights are those activities, conditions, and freedoms which all human beings are entitled to enjoy by virtue of their being human.⁹¹ They include civil, political, economic, social and cultural rights. Human rights are inherent, inalienable, interdependent, and indivisible, although they may be limited under specified circumstances. The enjoyment of one right affects the enjoyment of others, and they must all be respected.⁹²

This chapter of the thesis will show that, only governments (states) are in a position to put in place the laws and policies necessary for the protection of human rights and to regulate private and public practices that impact on individuals' enjoyment of those rights.⁹³

The conflict between patents and access to medicines will be analysed and the role of limitation clauses in restricting guaranteed rights in national constitutions will also be critically examined. Section 27 of the South African constitution which guarantees access to health facilities will also be examined and finally the courts approach to cases on access to health care services will also be reviewed and analysed.⁹⁴

3.2 Conflicts between patents and access to medicines

⁹¹ See eg Martha C Nussbaum 'Capabilities and Human Rights' (1997) 66 Fordham LR 273.

⁹² See art 1 of the 'Vienna Declaration and Programme of Action' (1993) UN Doc A/CONF 157/24 (Part 1), which states that '(h)uman rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of governments.'

⁹³ See Cullet n 35 above 149 where he states that 'states are to ensure that other international agreements to which they accede do not adversely impact on the right to health. These are indications that states must, for instance, cooperate in making drugs available at affordable prices.'

⁹⁴ *VillagranMarales et al v Gautemala*, Series C No 65 19 November 1999 para. 144. See also *The Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria* Communication 155/96, decided at the African Commission's Ordinary Session 1 to 27 October 2001; similarly see the Indian Supreme Court decision in *PachimBangaKhetMajoorSamity v State of West Bengal* (1996) AIR SC 2426.

An emerging debate in the international human rights arena involves the relationship between IPRs and states' obligations under human rights treaties.⁹⁵ The right to life is the most fundamental of all human rights and is sacrosanct,⁹⁶ yet a person's life may depend on a patent.

Regrettably, IPRs and human rights are often at odds especially where the pharmaceutical industry is concerned.⁹⁷ There will always be a certain level of tension between pharmaceutical companies that research and develop new drugs to combat the world's maladies, and the inability of third world countries to afford the patented versions of such drugs.⁹⁸ Due to the human rights implications of this tension, this polarising subject continues to surface in international fora and to spark heated debate among state governments, pharmaceutical companies, non-governmental organisations ('NGOs'), and human rights groups.⁹⁹ This is particularly important when one considers that IP rights are also recognised in human rights instruments.¹⁰⁰

Notable among these instruments are the Universal Declaration of Human Rights ('UDHR'), the ICESCR and the African Charter. Article 27(1) of the UDHR provides: 'Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or

⁹⁵ US Senate investigations into pharmaceuticals and anti-trust (1950s-1960s). Early debates at the World Health Assembly. The public health community first raised concerns about the consequences for drug access of globalising IP standards during the 1996 World Health Assembly (WHA). In 2001 the G8 paid unprecedented attention to health and the need for action to increase access to medicines. In December of that year, a 3 day G8 summit on infectious diseases took place in Okinawa, Japan. The summit also put an important emphasis on new approaches to R & D. Another important event in 2001 was the 13th International AIDS conference that took place in Durban, South Africa. It was the first time that this prestigious meeting was held on the continent most severely affected by the disease. This conference signalled a paradigm shift, with participants focusing on the fact that most of the 30 million people with HIV/AIDS lived in DCs and had no hope of receiving the lifesaving treatment that had become the norm in the west. See 'T Hoen, E.F.M 2009 The Global Politics of Pharmaceutical Monopoly Power at page 28.

⁹⁶ Human Rights Committee 'The Right to Life' UN GAOR 37th SessSupp No 40. WEBSITE?? Available at <http://books.google.co.za/books?isbn=1472436776>

⁹⁷ See *Medicins Sans Frontiers* 'A Matter of Life and Death: The Role of Patents in Access to Essential Medicines' (Nov 2001) available at http://www.doctorswithoutborders.org/publications/reports/2001/doha_11_2001.pdf, where it is stated that people in developing nations are dying because patents are interfering with access to life-saving medicines. See, too, Seth Shulman 'In Africa, Patents Kill' (2001) April TECH.REV available at <http://www.technologyreview.com/Biotech/12348/> where he discusses the negative impact of western drug patents on African AIDS patients.

⁹⁸ For a discussion of the growing tensions between human rights and intellectual property law, of which pharmaceutical patents are just one important example, see Lawrence R Helfer 'Towards a human rights framework for intellectual property' (2007) 40 *UC Davis L Rev* 971.

⁹⁹ See Hestermeyer.H. *Human Rights and the WTO: The case of Patents and Access to Medicines*; Oxford University Press. (2007)

¹⁰⁰ P. Cullet *supra* at page 152.

artistic production of which he is the author.’¹⁰¹ Article 12 of ICESCR likewise emphasises the state’s obligation to respect the right of access to medicines and the obligation to protect and fulfil it. A state is therefore entitled to take appropriate measures to work towards the provision of access to medicines, including through legislative, administrative, and budgetary measures.¹⁰² General Comment 3 of the ICESCR also provides that states are obliged, regardless of their level of economic development, to ensure respect for minimum subsistence rights for all.¹⁰³

Article 15 of the ICESCR also recognises the rights of everyone to take part in his or her cultural life, to enjoy the benefits of scientific progress and its application, and to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author.¹⁰⁴

Article 16 of the African Charter¹⁰⁵ guarantees every individual the right to enjoy the best attainable state of physical and mental health. State parties are required to take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are ill. The principles and guidelines on the implementation of economic, social and cultural rights in the African Charter¹⁰⁶ elaborate on the contents of this right by providing that state parties should adopt and implement policies that ensure that members of vulnerable and disadvantaged groups have access to medicines.

The guidelines provide that ‘appropriate legislation and international trade regulation and cooperation should be utilized towards the establishment of scientifically sound pharmaceutical industries in Africa with particular emphasis on local African production for self-reliance in drug

¹⁰¹ With regard to whether property rights should prevail over the right to health, the United Nations Sub-Commission on the Promotion and Protection of Human Rights has pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right ‘subject to public interest limitations’. See Resolution 2001/5 ‘Globalisation and its Impact on Human Rights’ E/CN.4/Sub.2/Res/2001/5.

¹⁰² Koch IE ‘Social rights as components in the civil right to personal liberty: Another step forward in the integrated human rights approach?’ (2002)20/1 *Netherlands Quarterly of Human Rights* 32.

¹⁰³ The South African government by recognising the right to health in the Constitution and ratifying human rights instruments shows its support for the existence of an international human right to health.

¹⁰⁴ Article 15.1(c) of the ICESCR.

¹⁰⁵ African Charter on Human and Peoples’ Rights OAU Doc CAB/LEG/67/3/Rev 5 adopted by the OAU on 27 June 1981 and entered into force 21 October 1986.

¹⁰⁶ In November 2010 at its 48th Session, the African Commission on Human and Peoples’ Rights adopted the ‘Principles and Guidelines on the interpretation of Economic, Social and Cultural Rights in the African Charter on Human and Peoples’ Rights’ available at www.achpr.org.

industries.’¹⁰⁷ They explicitly state that ‘this should include utilizing parallel importation and compulsory licensing for medicines where available and applicable, to ensure the availability of drugs and technologies at affordable prices for treatment, care, and prevention of epidemic, endemic, occupational and other diseases including malaria, HIV/AIDS tuberculosis and other infectious diseases.’¹⁰⁸

It appears from the first two provisions, that both the UDHR and the ICESCR seek to strike a balance between the interest of the public to benefit from technology and that of the inventor of the technology. This would obviously require a human-rights approach. Such an approach, as suggested by Chapman, should be ‘predicated on the centrality of protecting and nurturing human dignity and the common good.’¹⁰⁹ The goal is to improve human welfare and to maximise economic benefits.’¹¹⁰ In other words, from a human rights perspective, IP protection is understood more as a social tool with a social function, than -- at least not primarily -- as an economic relationship.

This observation is further supported by the drafting history of these three agreements. A critical examination of the events leading up to the eventual drafting of these articles in the three human rights instruments mentioned above, reveals that basic human rights documents never intended to recognise the interests of authors or inventors as fundamental human rights.¹¹¹

Since the UDHR, the ICESCR and the African Charter, recognise the right of everyone to benefit from cultural life and scientific development, it would seem that in the balancing of priorities the right of an individual author is secondary to that of society.¹¹²

The implication is that human rights place the emphasis on societal benefits. This approach is opposed to that of IPR instruments, which focus mainly on the rights of authors, inventors, and other legal entities to claim exclusive rights to an intellectual creation.¹¹³

¹⁰⁷ Available at Community.lawcentre.org.za/003/pdf/at-download/file.

¹⁰⁸ Paragraph 67 (xxix) of art 16 of the African Charter

¹⁰⁹ AR Chapman ‘The human rights implications of intellectual property protection’ (2002) 5 *Journal of International Economic Law* 861, 867.

¹¹⁰ Koch, I.E. (2002): Social Rights as Components in the Civil Right to Personal Liberty: Another Step Forward in the Integrated Human Rights Approach? *Netherlands Quarterly of Human Rights*, VOL. 20, NO.1 AT P. 32.

¹¹¹ UN Sub-Commission on the Promotion and Protection of Human Rights ‘Globalisation and Its Impact on the Full Enjoyment of All Human Rights’ Res 2001/5 (15 August 2001) UN Doc E/CN.4/Sub.2/Res/2001/5.

¹¹² P. Cullet at page 158.

It follows that neither the UDHR nor the ICESCR can be invoked by pharmaceutical companies to justify hindrance to access to life-saving medications in DCs. On the whole, a major difference exists between the IPRs granted by patents and access to medicines as a human right. While the former are temporary property rights granted by a state and subject to revocation by the state, the latter are inalienable and timeless.¹¹⁴

3.3 The international framework

International human rights instruments are treaties and other international documents relevant to international human rights law and the protection of human rights in general. They can be classified into two categories: declarations/resolutions adopted by bodies such as the United Nations General Assembly, which are not legally binding although they may be politically binding (as soft law); and conventions/treaties which are legally binding instruments concluded under international law.¹¹⁵

International human rights instruments can be divided further into universal instruments, to which any state in the world can be a party, and regional instruments which are restricted to states in a particular region of the world.

The United Nations set a common standard on human rights with the adoption of the UDHR in 1948. Although this declaration is not part of binding international law save to the extent that it has met the requirements for the establishment of customary international law, its acceptance by all countries around the world lends great moral weight to the fundamental principle that all human beings, rich and poor, strong and weak, male and female, of all races and religions, are to be treated equally and with respect for their natural worth as human beings.

¹¹³ Id 152.

¹¹⁴ See CESCR IP Statement, para 12.

¹¹⁵The name by which a document goes is not determinative of its nature. See art 2 (1) (a) of The Vienna Convention on The Law of Treaties 1969. Under this Convention, it is also provided that the determination of states' rights and obligations pursuant to their treaties are 'subject to Article 103 of the Charter of the United Nations' article?? In the Aerial landing over Lockerbie case, the ICJ confirmed that pursuant to Article 103 of the UN Charter States obligations under the Charter supersede any conflicting obligation under any other international agreement. Order of April 14, 1992 (regarding request for indication of provisional measures) [1992] ICJ Reports 3 at para 42.

The United Nations has since adopted many legally binding international human rights instruments. These treaties are used as a framework for discussing and applying human rights. Through these instruments, the principles and rights they outline become legal obligations on those states choosing to be bound by them. The framework also establishes legal and other mechanisms to hold governments accountable in the event that they violate human rights.

The instruments constituting the international human rights framework are the UDHR ¹¹⁶ and the six core human rights treaties: the International Covenant on Civil and Political Rights ('ICCPR'); the ICESCR¹¹⁷; the Convention on the Rights of the Child ('CRC') ; the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment; the International Convention on the Elimination of All Forms of Racial Discrimination; and the Convention on the Elimination of All Forms of Discrimination against Women ('CEDAW'). ¹¹⁸

Every country in the world has ratified at least one of these Conventions, and many have ratified most of them. These treaties are important tools for holding governments accountable for the respect for, protection of and realisation of the rights of individuals in their countries.

3.4 The constitutional framework

In South Africa the right to enjoy access to health care services is guaranteed in section 27(1) of the Constitution of the Republic of South Africa 1996. In terms of section 27(2), the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.

Section 27 of the South African Constitution 1996 provides that:

1. Everyone has the right to have access to-
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and

¹¹⁶Article 25 of the Universal Declaration of Human Rights GA Res 217 A (III), UN Doc A/810 (10 December 1948).

¹¹⁷International Covenant on Economic, Social and Cultural Rights adopted 16 December 1966 GA Res 2200 (XXI), UN Doc A/6316 (1966), 993 UNTS 3 (entered into force 3 January 1976). South Africa ratified this instrument on 12 March 2015.

¹¹⁸ Convention on Elimination of All Forms of Discrimination Against Women GA Res 54/180, UN GAOR 34th Session Supp No 46, UN Doc A/34/46 (1980).

social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
3. No one may be refused emergency medical treatment.

This section of the South African Constitution makes it compelling and necessary for the South African Government to provide its citizens with access to medical facilities and essential drugs for the treatment of diseases. This is more important in cases of endemic diseases such as malaria, tuberculosis and HIV/AIDS. The section protects the right to health care and medicines and requires the state to take all necessary steps and measures to realise this right.¹¹⁹

As a party to the TRIPS Agreement which regulates the international protection of pharmaceutical patents, South Africa is permitted to make use of certain flexibilities, such as compulsory licensing and parallel importation, which would allow for improved access to medicines in both the public and private sectors.

In the recent case *Sanofi Aventis v Cipla*,¹²⁰ the Treatment Action Campaign ('TAC') which joined the proceedings, argued that the Patents Act must be interpreted alongside the Constitution and that the courts must balance the rights of those who hold patents against the rights of those in need of access to affordable medicines. The TAC further stated that section 27 of the Constitution protects the right to health care and medicines and requires the state to take 'reasonable legislative measures' to realise this right.¹²¹

It would, however, have been helpful had the TAC opened a discussion in its submission on section 27(2) of the Constitution on the obligation of the state to '...take reasonable legislative and other measures, within its available resources, to achieve the progressive realization' of the

¹¹⁹ Section 27. Org.Za>archive>other>General

¹²⁰ *Sanofi Aventis and Others v CiplaMedpro (Pty) and Another*2000/6386 (20090 ZACCP 2 (8 Dec 2009).

¹²¹ Id paras44 ,45..

rights stated in section 27(1). In particular, does the obligation to take reasonable legislative measures include an obligation to incentivise the development of new medicines?¹²²

The case revolves around a Sanofi-Aventis cancer drug *Docetaxel*, an important drug used to treat many forms of cancer. It has the potential to save lives or improve the quality of life of cancer patients, but remains expensive as it is under patent. Although the product patent on the medicine has expired, a patent relating to ‘a composition of unpatented products, which when mixed – facilitate the intravenous administration of *Docetaxel*’¹²³ remains in force. The validity of this patent was at the centre of the dispute with Cipla alleging that it is invalid as it is unclear and what is patented is not new.

Sanofi Aventis sought an interim interdict from the Commissioner of Patents to prevent Cipla from selling the drug in South Africa. However, the Commissioner refused to grant the interdict, ruling in respect of Sanofi-Aventis’s claim that ‘their prospects of success at trial are so slender that interim relief must be refused’.¹²⁴

The effect of this case is that in any future dispute over patents in respect of medicines, South African courts will have to consider public interest and the constitutional right of access to health care services. The analysis of the courts’ approach to these aspects is discussed in paragraph 3.7 of this chapter.

3.5 Limitation clauses

Limitation clauses suspend or restrict guaranteed rights to which they apply and appear in numerous treaties and national constitutions.¹²⁵ They are distinct from derogation clauses in that they allow states to breach obligations to uphold certain rights for reasons unrelated to war or public emergency.¹²⁶

¹²² Coenraad Visser ‘Of liability for patent infringement, public interest, and effective patent terms: *Cipla Medpro v Aventis Pharma; Aventis Pharma SA v Cipla Life Sciences*’ (2012) 24 *SA MercLJ* 456-466 .

¹²³ *Aventis and Others v Cipla Medpro* paras 3 -12.

¹²⁴ *Id* paras 60-62.

¹²⁵ HKwasi Prempeh ‘Marbury in Africa: Judicial review and the challenge of constitutionality in Africa’ (2006) 80 *Tul L Rev* 1239.

¹²⁶ Sara Stapleton ‘Ensuring a fair trial in the International Criminal Court: Statutory interpretation and the impermissibility of derogation’ (1999) 31 *Winter/Spring NYU J. Int’l L & Pol* 535.

Limitation clauses usually state that the restriction of rights should be done by the making of a certain law which must be essential or justifiable and which would lead to the creation of certain specified public or social objectives.¹²⁷

3.5.1. Limitation clauses in national constitutions

Most governments restrict basic rights through general or specific limitation clauses in their constitutions. General limitation clauses are comprehensive or an all embracing expression of governments' potential to limit freedoms while specific limitation clauses connect to particular rights:

‘Whether general or specific, the limitation of fundamental rights for public and social reasons is an extension of the state’s responsibility to secure the liberty and freedom of all. Limitation clauses provide for potential government intervention in individual rights to benefit individuals, the community, or society at large.’¹²⁸

1 The rights of others

These include fundamental rights of other persons. It may also include rights which are not protected by fundamental rights. For example, while the right to own private property is not inevitably recognised as a fundamental right, the fact that property is privately owned may indeed impact on the fundamental right of free movement in that the owner may restrict access to his or her property.

2 Public order

Public order considerations can limit the right of assembly. This limitation justifies, for example, a provision which requires that anyone wishing to hold a demonstration may only do so under specified circumstances – including prior approval. However, this basis for limitation is often

¹²⁷ www.knchr.org/.../MAKING_THE_BILL_OF_RIGHTS_Operational.pdf

¹²⁸ cop.health-rights.org/files/2/.../235f6c838eef0eed5df064d54d41da83.do...

abused and serves many authoritarian regimes with a justification to undermine human rights protection.¹²⁹

3 National security considerations

In international human rights instruments, national security is an acceptable basis on which to limit certain fundamental rights,¹³⁰ such as freedom of movement¹³¹ and freedom of expression.¹³²

4 Public health

Public health legislation the world over now authorises a wide range of social distancing powers, including compulsory screening, examination and treatment measures to protect public health. In addition, public health law provides for the possibility of certain limited emergency measures.¹³³

5 Public morality

The protection of public morality is a limitation recognised in many human rights instruments.¹³⁴ The extent of this limitation is often controversial when it comes to freedom of expression.

Courts typically use a proportionality test and consider the necessity of state action in determining the constitutionality of restrictions.¹³⁵ In all cases, rights must be restricted by a specific law and this law ‘must apply generally and not solely to an individual case’, in essence it

¹²⁹ Article 19 of the International Convention on Civil and Political Rights (ICCPR) indicates that restrictions shall only be permissible if they are ‘necessary’ to achieve the objectives of the limitation.

¹³⁰ Article 19 (3) of the International Convention on Civil and Political Right specifies, the freedom of expression ‘carries with it special duties and responsibilities. Accordingly, it may be subjected to restrictions provided by law which are necessary for the respect of of the rights or reputations of others and/or for the protection of national security, or public order, public health, or public morality.

¹³¹ ICCPR art 12.

¹³² Id art 19.

¹³³ See R Martin ‘The role of law in pandemic influenza preparedness in Europe’ (2009) 123 *Public Health* 247-254.

¹³⁴ For example, article 12(3), 18(3), 19(3), 21 and 22 (2) of the International Convention on Civil and Political Rights refer the limitations on the exercise of human rights that are necessary to protect “public.....morals”. The Universal Declaration of Human Rights refers to limitations on the exercise of human rights to meet the “just requirements of morality” in Article 29(2).

¹³⁵ See *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC). Here the court considered the reasonableness of governmental measures in relation to medical care.

must not be discriminatory.¹³⁶ In most cases, courts will require that any move to restrict rights is necessary, minimally restrictive, non-discriminatory, and proportionate when viewed in relation to clear state objectives. Some drafters choose to be more specific than others in the limitation of rights and freedoms.¹³⁷

The South African Constitution has a general limitations clause which provides that ‘the rights in the Bill of Rights¹³⁸ may be limited by a law of general application which is reasonable and justifiable in an open and democratic society based on dignity, freedom, and equality.’ The provision then sets out the factors that must be taken into account during the balancing exercise. Though not exhaustive, they include the nature of the right that is infringed, its value in a democratic society, the public purpose served by the measure that has been challenged, the extent of the intrusion, the proportional relationship between the intrusion into the rights and the interest to be served, and the availability of less restrictive means to achieve the same objective.¹³⁹ The South African Constitution thus explicitly includes all the guarantees against the excessive limitations discussed above.

3.6 The impact of competing human and intellectual property rights on access to medicines

The link between medical patents and the human right to health has assumed central concern on the international level, as exemplified by the debates at the 2001 WTO Ministerial Conferences.¹⁴⁰

Intellectual property rights and human rights have largely evolved independently. The former, in particular, are deemed to provide the necessary incentives for research and technological development. Patents are time-bound monopoly rights. They constitute a derogation from the

¹³⁶ In *Minister of Health v Treatment Action Campaign* where the applicant claimed that ‘the policy restricting the provision of the drug infringed the right of everyone to have access to health care services.’

¹³⁷ See s 1, Chapter 2 Constitution of the Russian Federation (1993) in relation to arts 23 - 25.

¹³⁸ Section 7 (1) of the Constitution of Republic of South Africa 1996 states that: ‘The Bill of Rights enshrines the rights of all the people of South Africa and affirms the democratic values of human dignity, equality and freedom.’

¹³⁹ See Budlender AJ in *Residents of Bon Vista Mansions v Southern Metropolitan Council* 2002 (6) BCLR 625 (W) where it was stated that ‘the internal limitation in section 27(2) applies only to the State’s positive duties to promote and fulfil the rights conferred on everyone in section 27(1)’ para [XX].

¹⁴⁰ See WTO ‘Declaration on the TRIPS Agreement and Public Health’ WTO Doc WT/MIN (01)/dec/2 (2001) (‘the Doha Declaration’).

principle of free trade by offering exclusive rights to an inventor to exploit his or her invention and prevent others from using it without his or her consent. Human rights, on the other hand, protect the fundamental and inalienable rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being human.¹⁴¹ This is in direct contrast to property rights, which can always be ceded through voluntary transactions.¹⁴²

As codified in the two UN Covenants and other relevant instruments,¹⁴³ human rights constitute the basic framework guiding state action on both domestic and international levels.¹⁴⁴ Therefore, states must bear their human rights obligations in mind when they negotiate and implement international rules on IP rights and trade liberalisation.¹⁴⁵

The introduction of patents into medicines which is an essential and indispensable need, and some new occurrences in the health industry itself, the connection between these two fields is opening up and becoming more noticeable. This has led to debate for a further rethink of the relationship between the right to health and patents on essential medicines.¹⁴⁶

While human rights documents have given some consideration to the position of IP in relation to human rights, there has been no equivalent effort from the field of IP.¹⁴⁷ Despite the pharmaceutical industry's plea for patent protection, a number of countries traditionally restrict the patentability of drugs on public policy grounds.¹⁴⁸

As previously stated, access to medicines is a fundamental component of the human right to health.¹⁴⁹ Access to medicines has four key elements 'the adequate availability of medicines,

¹⁴¹See Martha C Nussbaum 'Capabilities and Human Rights, 66 Fordham L.Rev (1997) at page 273.

¹⁴²See eg Guido Calabresi & A Douglas Melamed 'Property rules, liability rules, and inalienability: One view of the cathedral' (1972) 85 *Harvard Law Review* 1089.

¹⁴³ICESCR; International Covenant on Civil and Political Rights (ICCPR) 16 Dec 1966, (1967) 6 *ILM* 368.

¹⁴⁴See preamble to the ICESCR.

¹⁴⁵See art 1 of the Vienna Declaration and Programme of Action 25 June 1993 UN Doc A/CONF 157/24 (Part 1) which provides that 'human rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of Governments.'

¹⁴⁶shodhganga.inflibnet.ac.in/bitstream/10603/7933/.../13_chapter%206.pdf at page 139.

¹⁴⁷Id 140.

¹⁴⁸See Carlos Correa, Integrating public health concerns into patent legislation in developing countries. (Geneva: South Center. 2000)

¹⁴⁹Commission on Human Rights Res 2001/33 'Access to medication in the context of pandemics such as HIV/AIDS' in Report on the 57th Session 19 March - 27 April 2001 UN Doc E/2001/23-E/CN 4/2001/167.

their universal accessibility, the acceptability of the treatment with respect to the culture and ethics of the individual and an appropriate quality of the available medication’.¹⁵⁰

The links between patents, the price of medicines, and access to drugs have been considered by various countries in developing their health sector legal and policy frameworks. India, regarded as the pharmacy of the developing world, offers a good example. The country adopted patent legislation prohibiting product patents for medicines, and this constituted one of the major incentives for the development of a vibrant pharmaceutical industry.¹⁵¹

The legal arguments surrounding the relationship between human and IP rights, and the practical debates on access to medicines in DCs both point to the existence of potential conflicts between the introduction of patents on drugs in DCs and the realisation of the right to health. While states must endeavour as far as possible to reconcile their various international obligations, there appear to be some cases where the implementation of the TRIPS Agreement implies a reduction in access to medicines and so represents a retrogressive step in the realisation of the right to health.¹⁵² This appears to be unacceptable under the ICESCR, and countries in this situation are expected to prefer their human rights obligations.¹⁵³

This solution, which accords primacy to human rights, is unlikely to meet with the approval of all states or to succeed in adjudication in a WTO context. It nevertheless appears adequate from a legal and ethical point of view.¹⁵⁴

3.7 Analysis of the courts’ approach to cases relevant to access to medicines in South Africa.

There are ‘internal modifiers’ in the South African Constitution which limit the extent to which socio-economic rights can be enforced. These ‘internal modifiers’ or internal limitations appear in sections 26(2), 27(2) and section 36 of the Constitution. For the purpose of this thesis I intend

¹⁵⁰General Comment No 14’para 12.

¹⁵¹Jean O Lanjouw ‘The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?’ NBER Paper 6366 (1999).

¹⁵²General Comment 14 n 115 above..

¹⁵³ICESCR IP Statement para 12, where it is specifically stated that ‘any intellectual property regime that makes it more difficult for a state party to comply with its core obligations in relation to health, food, education or any other right set out in the Covenant, is inconsistent with the legally binding obligation of the state party.’

¹⁵⁴Cullet n 35b above 139-160.

to show that the courts have been reluctant to apply the general limitations in section 36 in most of the cases that have come before them, relying instead on the internal modifiers in sections 26(2) and 27(2).

In Khosa v Minister of Social Development,¹⁵⁵ the court among several primary issues had to make a decision on the ‘reasonableness’ government actions as part of the investigation into the internal limitation in section 27(2). Alternatively, the court had to decide if the investigation should rotate around section 36 – the general limitation clause which governs the limitation of rights under the Constitution. The court was of the view that since there were no arguments on this issue, it refused to decide the issue. The majority, held that if an assumption could be made on the approach of reasonableness as is required under section 36 differs from that in sections 26 and 27, they were still not convinced that the exclusion of permanent residents from the programme was ‘neither reasonable nor justified within the meaning of section 36.’¹⁵⁶

Consequently it remains unclear whether the section 27 and section 36 ‘reasonableness’ tests are identical and how exactly section 36 operates in relation to socio-economic rights under the Constitution.

In *Minister of Health v Treatment Action Campaign* 2002 SA 721 (CC), the court considered the reasonableness of government’s measures in realising socio-economic rights in relation to medical care. The case arose from government’s failure to provide the antiretroviral drug, *Nevirapine*, to all HIV positive mothers in government hospitals. In delivering its judgment the court stated that:

‘This court has had to consider claims for the enforcement of socio-economic rights on two occasions. On both occasions it was recognised that the state is under a constitutional duty to comply with the positive obligations imposed on it by sections 26 and 27 of the Constitution. It was stressed, however that the obligations are subject to the qualifications expressed in sections 26(2) and 27(2). On the first occasion, in *Soobramoney*,¹⁵⁷ the claim was dismissed because the applicant failed to establish that the state was in breach

¹⁵⁵2004 (6) SA 505 (CC).

¹⁵⁶www.escr-net.org > Caselaw Database para 136 of courts judgment.

¹⁵⁷*Soobramoney v Minister of Health, KwaZulu-Natal* (1997) ZACC 17; 1998(1) SA 765 (CC); 1997 (12) BCLR 1696 (CC).

of its obligations under section 26 in so far as the provision of renal dialysis to chronically ill patients was concerned. In *Grootboom*,¹⁵⁸ the claim was upheld because the state's housing policy in the area of the Cape Metropolitan Council failed to make reasonable provision within available resources for people in that area who had no access to land and roof over their heads and were living in intolerable condition.'¹⁵⁹

The court went on to point out that in both *Soobramoney* and *Grootboom* the socio-economic rights of the applicants and the corresponding obligations of the state were interpreted in their social and historical contexts.¹⁶⁰ In this light, the question in the *TAC* case was whether the applicants had shown that the measures adopted by the government to provide access to health care services for HIV-mothers and their newborn babies, fell short of its obligations under the Constitution.¹⁶¹

The court held that section 27(1) and (2) of the Constitution requires that within its available resources, the government devise and implement a comprehensive and coordinated programme progressively to realise the rights of pregnant women and their newborn infants to access to health services to combat the mother-to-child transmission of HIV.¹⁶²

The court further held: 'Government is ordered without delay to ... remove the restrictions that prevent Nevirapine being made for the purpose of reducing the risk of mother to child transmission of HIV at public hospitals and clinics that are not research and training sites.'¹⁶³

In accordance with the provisions of sections 26(2) and 27(2), the state must take reasonable, legislative and other measures, within its available resources, to achieve the progressive realisation of the socio-economic rights enshrined in the Constitution. The general limitation clause in section 36, however, allows for the limitation of the rights in the Bill of Rights provided that the limitation is, inter alia, 'reasonable and justifiable in an open and democratic society'.

¹⁵⁸*Government of the Republic of South Africa & others v Grootboom & others* (2000) ZACC 19; 2001 (1) SA 46 (22); 2000 (11) BCLR 1169 (CC).

¹⁵⁹*Minister of Health v Treatment Action Campaign* 2002 SA 721 (CC) para 23.

¹⁶⁰*Id* para 24.

¹⁶¹*Id* para 25.

¹⁶²*Id* para 135 2(a).

¹⁶³*Id* para 135 3(a).

It is necessary to examine the form and content of the ‘reasonableness assessment’ under section 27(2), and then under the section 36 enquiry.

First, the court is required to interpret the scope and content of the right in order to establish whether it has been infringed. If there has been no infringement the inquiry ends. However, if the court finds that the right in question has been infringed, it must embark upon a ‘limitation analysis’. At this stage the court applies the factors listed in section 36 to determine whether the limitation of the right in question is constitutionally justifiable.

There are two general requirements that the limitation must meet in order to satisfy section 36: it must qualify as a law of general application, and it must be ‘reasonable and justifiable’ in an open and democratic society based on human dignity, equality and freedom.

Although, the Constitutional Court has not outlined the criteria for what would qualify as a law of general application, it has indicated that original and delegated legislation, the common law, and exercises in executive rule-making can all constitute ‘a law of general application’ provided that they are ‘accessible and precise’.¹⁶⁴ Administrative action taken under the authority of legislation, does not satisfy this requirement, and legislation conferring ‘unconstrained discretionary power’¹⁶⁵ on administrators has likewise been found not to qualify as a law of general application.¹⁶⁶

This requirement is necessary to prevent arbitrary limitations on rights and to enable citizens to understand exactly when their rights may be limited. The consequence of a finding that the contested conduct does not qualify as a law of general application is that it simply cannot justifiably limit rights. As the limiting measures do not constitute a law of general application, they will be declared unconstitutional.

However, if it is confirmed that the infringement is effected through a law of general application, the courts are required to conduct an enquiry to determine whether it ‘[took] place for a reason that is accepted as a justification for infringing rights in an open and democratic

¹⁶⁴Ian Currie & Johan de Waal *The Bill of Rights Handbook* 5 ed (2005) 171. What is the case/s in which this was held – refer to original sources where possible??*Khosa v Minister of Social Development* 2004 (6) 505 (CC).*Residents of Bon Vista Mansions v Southern Metropolitan Local Council*’ (2003) 120 SALJ 41.

¹⁶⁵*Id* 175.

¹⁶⁶*Dawood v Minister of Home Affairs* 2000(3) SA 936 (CC).

society based on human dignity, equality and freedom'.¹⁶⁷ If it does, the infringement will be constitutional. Currie and de Waal¹⁶⁸ explain that the purpose of the inquiry is to ensure that rights are not limited more than is required, and that the limitation serves a constitutionally acceptable purpose. This is in accordance with the constitutional imperative of justification and ensuring that actors are accountable for their actions that infringe on constitutionally protected rights.¹⁶⁹

In *State v Makwanyane*,¹⁷⁰ the Constitutional Court held that the nature of the analysis required under section 36 is one of proportionality.¹⁷¹ The court is required to put the nature and importance of the right and the impact that the limiting legislation would have on that right on one side, and the aim and importance of the legislation on the other. The court then weighs up these two considerations and determines whether the aim the limiting provision seeks to achieve is of greater import than the effect it has on the right in question.¹⁷²

The important thing to note, however, is that the emphasis must be on the justifiability of the limitation in an open and democratic society. Therefore, the democratic values of human dignity, equality, and freedom are the guiding principles in the analysis. Accordingly, when respect for the right infringed is essential to ensure a society based on democratic values, there must be an especially compelling need for the limitation.¹⁷³

Justice Richard Goldstone, reflecting on judicial interpretation of limitation clauses, noted as follows:

'The result is that I earn my living doing a judicial balancing act. Perhaps three out of four of our cases involve balancing. When competing claims and interests are involved, we are compelled to engage in proportionality exercise against the background of the values that the constitution requires us to promote.'¹⁷⁴

3.8 Conclusion

¹⁶⁷Currie & de Waal *supra* page 164.

¹⁶⁸*Ibid.*

¹⁶⁹See M Pieterse 'Towards a useful role for section 36 of the Constitution in social rights cases? Residents of *Bon Vista Mansions v Southern Metropolitan Local Council*' (2003) 120 *SALJ* 41.

¹⁷⁰1995 (3) SA 391 (CC).

¹⁷¹*Id* para 352.

¹⁷²*Id* para 352.

¹⁷³*Id* paras 368 – 370.

¹⁷⁴See Richard J Goldstone 'The South African Bill of Rights' (1997) 32 *Texas International Law Journal* 451.

In this chapter of the thesis, I have tried to show that access to treatment forms an integral part of the right to health which is guaranteed in so many international human rights instruments. The inability of the poor people in DCs to have access to life-saving medications compromises their right to health. I have discussed the conflict between patents and access to medicines and why it is necessary for governments to restrict basic rights through limitation clauses. I have also argued that it is necessary for the courts in South Africa to undertake an analysis of section 36 in socio-economic right cases before them. This will ensure that the infringement of rights is examined in terms of the required standards and foundational values and ensure respect for the transformed society the Constitution aspires to achieve.

CHAPTER 4

THE TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY AGREEMENT

4.1 The historical development of the TRIPS Agreement

The WTO was established in 1995 in the wake of the Uruguay Round Agreement and is a direct descendant of the General Agreement on Tariffs and Trade ('GATT'). The GATT was concluded in 1947 after the Second World War as part of an effort to promote economic recovery by reducing tariffs and other international trade barriers in order to prevent the world falling back into protectionism.¹⁷⁵ The GATT was negotiated while negotiators were preparing a Charter for an International Trade Organisation ('ITO'). The ITO never saw the light of day as the United States Congress refused to approve it in the late 1940s. The GATT, however, entered into force in January 1948 with 23 contracting parties and remained the only multilateral instrument governing international trade policies between 1948 and 1995.¹⁷⁶

The GATT lacked a sound legal foundation and was not accorded independent status under international law as it was regarded as a treaty rather than an international organisation.¹⁷⁷ The GATT, as its name implies, was intended as a multilateral trade and tariff agreement which would depend for its organisational context and secretariat services on the ITO. Compounding the anomalies of that period, the GATT 1947 treaty instrument was applied only 'provisionally'. At the time of its adoption, it was contemplated that the GATT would be applied provisionally for a number of years until the ITO came into force, and would then fall under the umbrella of, and be brought into line with, the ITO Charter. However, as the ITO never materialised, the GATT gradually became the focus for international government cooperation on matters of

¹⁷⁵See <http://en.wikipedia.org/wiki/General_Agreement_on_Tariffs_andTrade>.

¹⁷⁶See *WTO Understanding the WTO* 5th ed, WTO/Cambridge University Press, 2007.15 available at http://www.wto.org/english/thewto_e/whatis_e/understanding_e.pdf (hereafter 'Understanding the WTO').

¹⁷⁷Id 3.

trade.¹⁷⁸ The success of the GATT in promoting and securing the liberalisation of much of world trade over 48 years is incontestable.¹⁷⁹

The WTO has 153¹⁸⁰ member states and its overall goal is to improve global welfare¹⁸¹ by assisting member states to secure maximum profit from involvement in the global economy.¹⁸² This is to be achieved through applying the following principles: trade without discrimination (through then most-favoured-nation principle ('MFN') and the principle of national treatment); freer trade; predictability; the promotion of fair competition; and encouraging development and economic reform.

However, the considerable differences, both economic and ideological, between member states has meant that it has been difficult to achieve consensus in the WTO as to the goals and how to achieve them. While the principal or dominant economies in the WTO are developed countries, around two-thirds of WTO member states are classified as DCs or LDCs.¹⁸³ This has created considerable tension between north and south (the so-called 'north/south dichotomy'). The economies differ, as does their influence on world economy and trade. This has meant that the principle of encouraging development and economic reform (for which the WTO strives) has become very complex to apply – not least because economic reform and development in a developed country on occasion has the reverse effect in DCsandLDCs.¹⁸⁴

¹⁷⁸See John H Jackson , World Trade and the law of GATT (1969).

¹⁷⁹See Understanding WTO n 141 above 17. During its 48 years the GATT achieved many advantages for the development of international trade and its legal principles. In 1995, the rules were extended, improved, and renamed as the rules of the World Trade Organisation but the key ideas and purposes of the WTO remained the same as they had been in GATT. See also Peter Gallagher 'Guidetodipute settlement' at p.7 available at www.hse.ru/data/2014/04/30/1322585507/guide%20to%20dispute_pdf

¹⁸⁰ WTO members and observers. (2008 July 23). Retrieved from http://www.wto.org/English/thewto_e/whatis_e/tif_e/org6_e.htm.

¹⁸¹ See http://www.wto.org/English/thewto_e/whatis_e/tif_e/fact_e.htm.

¹⁸²Peter Gallagher, Guide to dispute settlement at page 7 Available at www.hse.ru/data/2014/04/30/1322585507/guide%20to%20disputes_e.pdf

¹⁸³Understanding the WTO n 141 above 93.

¹⁸⁴This understanding is shared by John Hilary (HomiKatrak pp. 38-62) who believes that trade liberalisation offers genuine opportunities to the developed world, but not the DCs or LDCs. Moreover he believes that the free trade regime which forces the weak into direct competition with the strong will yield more negative than positive results. See HomiKatrak, Roger Strange eds in 'Trade liberalisation, poverty and the WTO: Assessing the realities' *The WTO and Developing Countries* (2004). Published by Palgrave Macmillan. Available at <http://www.palgrave.com/page/detail/the-wto-and-developing-countries--homi-katrak/>

The inclusion of IP in the international trade backdrop of growing concern over the differences and inadequate systems governing IPR systems was noticeable worldwide.¹⁸⁵ By the late 1970s and early 1980s criticism was most strident among DCs and LDCs.¹⁸⁶ As observed by Hestermeyer, DCs strongly objected to the negotiation of substantive IP standards in the GATT.¹⁸⁷ They further demanded a 'New International Economic Order' ('NIEO') which was to include greater access to technology under the auspices of the World Intellectual Property Organisation ('WIPO').¹⁸⁸

In contrast, industrialised countries, particularly the USA and Japan, sought to negotiate a comprehensive agreement on IP standards.¹⁸⁹ They argued that patent protection in all fields of technology – as now embodied in article 27 of the TRIPS Agreement – would result in increased foreign direct investment ('FDI') and promote the transfer of the much needed technology to DCs. They further argued that patent protection would lead to the promotion of local R&D. The pharmaceutical industry in the USA was one most active and vociferous lobbies arguing for the need to expand and strengthen patent protection.

There were a number of reasons why the USA chose to use the Uruguay Round to propel IP onto the world stage. First, USA corporations with large IP portfolios were concerned about the loss of profits as a result of their products being pirated.¹⁹⁰ Secondly, and an element which goes a long way in explaining Congressional support, was the widespread fears over the loss of USA competitiveness.¹⁹¹ The third reason was the belief in the USA that the country was losing power in the world. The fourth and final reason was that the USA could not realistically expect to reform international IP protection framework through the agency of WIPO, a forum in which it

¹⁸⁵United Nations Conference on Trade and Development (UNCTAD) 'Patents: Non-Voluntary Uses of Compulsory Licenses' P1: IBE (2004) Chapter 25.

¹⁸⁶ Ibid.

¹⁸⁷The GATT was established in 1947 after the World War II as part of an effort towards economic recovery with the aim of reducing tariffs and other international trade barriers in order to prevent the world from falling back into protectionism. See <http://en.wikipedia.org/wiki/General_Agreement_on_Tariffs_and_Trade>.

¹⁸⁸In 1967, the World Intellectual Property Organisation (WIPO) was established to regulate the production, distribution, and use of knowledge. The organisation continues to function under the umbrella of the United Nations.

¹⁸⁹H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007).

¹⁹⁰See P Drahos 'Global property rights in information. The story at GATT' (1995) 13/1 *Prometheus* 9.

¹⁹¹The causes of falling competitiveness were not, however, initially attributed to poor IP protection. See the discussion by H Ullrich 'GATT: Industrial Property Protection, Fair Trade and Development' in FK Beier & G Schrickler (eds) *GATT or WIPO? New Ways in the International Protection of Intellectual Property* (1989) 131-132.

had only one vote and where it could always be out-voted by the DCs.¹⁹² Some form of coercion was needed if a global protectionist paradigm for USA IP interests was to have any chance of becoming a reality.¹⁹³

It was largely argued that with the advent of the knowledge-based economy, the inclusion of IP protection in the international trading system was a prerequisite for mainstreaming the benefits negotiated under the GATT and the impending/anticipated WTO system. Negotiations within the WTO context presented DCs with an opportunity to negotiate trade concessions with developed countries in exchange for an agreement on IP protection. Concessions here included increased market access, special attention to DCs concerns -- most notably transitional arrangements, concessions on agricultural export subsidies from Europe, and undertakings that the USA would not impose unilateral measures.¹⁹⁴

In 1982, the negotiations broke down in the face of competing demands concerning compulsory licensing. The negotiating parties convinced 'industry interests that they would not succeed in solving what they regarded as the IP problem' under the auspices of WIPO.¹⁹⁵ This led to the focus of IP efforts shifting to the GATT.¹⁹⁶

The TRIPS is the result of seven years of negotiations, between September 1986 and December 1993, as part of the Uruguay Round of Multilateral Negotiations of the GATT. These negotiations were launched at Punta del Este, Uruguay and formally concluded in April at Marrakesh, Morocco, along with the other negotiations making up the Uruguay Round. The TRIPS Agreement negotiations were long, arduous and at times acrimonious.¹⁹⁷

¹⁹²See P. Drahos supra at p. 9.

¹⁹³ <https://www.anu.edu.au/fellows/pdrahos/.../1996globalawreform.pdf>

¹⁹⁴H. Hestermeyer Human Rights and the WTO: The case of Patents and Access to Medicines (2007) at 46-47. For further information on the concessions promised to DCs see Frederick M. Abbott and Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law* 10 (4), 920 -987. and Correa n 2 above who stresses the fact that no concessions were granted to DCs.

¹⁹⁵Obviously, the concessions highlighted above could not be under the auspices of WIPO as it was not empowered to deal with such issues.

¹⁹⁶H. Hestermeyer supra at page 47.

¹⁹⁷See Peter Drahos 'Four lessons for developing countries from trade negotiations over access to medicines' (2007) 28/1/April *Liverpool Law Review* 11-39, 15.

Before the Uruguay Round, some 50 countries did not grant patent protection for pharmaceutical products. Among these were developed countries such as Portugal and Spain, and many DCs including Brazil, India, Mexico, and Egypt.¹⁹⁸ Article 27 of the TRIPS Agreement, which provides that patents should be granted in all fields of technology without exclusion, therefore represented a significant change for the pharmaceutical industry. Suddenly, patenting of pharmaceutical products was virtually universal in that all WTO member states were obliged to grant it.¹⁹⁹

When the GATT members committed themselves to meet for the Uruguay Round their goal was to adopt a set of universal standards of protection. The negotiations came to an end on 15 April 1994 and the Marrakesh Agreement establishing the WTO, also known as the WTO Agreement, was signed. On 1 January 1995 the TRIPS Agreement and other WTO agreements entered into force. Of the eighteen WTO agreements, the TRIPS Agreement has been said to have had the greatest impact on pharmaceutical products and access to medicines.²⁰⁰ As the most important IP instrument, the TRIPS Agreement sets minimum standards for IP protection. The core basis for its adoption is that ‘the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social, and to a balance of rights and obligations’.²⁰¹

With respect to pharmaceuticals this means that IPRs must be balanced against public policy objectives such as the protection of public health, the establishment of an industrial base in the pharmaceutical sector, and the adoption of specific measures to address R&D for diseases that

¹⁹⁸See CCarlos .M. Correa Integrating Public Health Concerns into Patent Legislations in Developing Countries (Geneva South Center, 2000) at page 33.

¹⁹⁹See P. Cullet, ‘Patents and Medicines: The relationship between TRIPS and the Human Rights to Health, 79 International Affairs (2003) at page 144.

²⁰⁰The TRIPS Agreement has been described as ‘undoubtedly the most comprehensive international agreement on IP protection ever established.’ See Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* 2 ed (2005) 28. The TRIPS Agreement can be distinguished from previous international treaties on IP in two ways - id 28-29. Firstly, it covers both major classes of IP: Copy right and Industrial property (including patents). Traditionally, these two classes had been treated separately in the Berne Convention and Paris Convention respectively. Secondly, the TRIPS Agreement marks the shift from ‘soft’ to ‘hard’ law. The Berne and Paris Conventions contained general enforcement provisions. However, these were dependent on domestic law. See Carvalho above 40.

²⁰¹ The TRIPS Agreement art 7.

predominantly affect DCs.²⁰² In order to attain these goals, the TRIPS Agreement obliges all WTO members to provide patent protection for pharmaceutical products and provides them with mechanisms to deal with potential conflicts that may arise from such protection.²⁰³

First, the TRIPS Agreement allows WTO members to formulate and amend laws and regulations and adopt measures necessary for the protection of public health and nutrition. In addition, it encourages the ‘promotion of the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions contained in the agreement.’²⁰⁴

Secondly, the TRIPS creates flexibilities by which governments are able to fine-tune the protection granted in order to meet social goals.

It further authorises members to adopt ‘appropriate measures’ to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. Differently phrased, any member may, among several other public policy objectives, prevent abuse of the exclusive rights conferred by patents by using any of the flexibilities available and thereby improve its access to affordable medicines under patent. Compulsory licensing is one of the flexibilities available under the TRIPS Agreement.²⁰⁵

4.2 The legitimacy of the TRIPS Agreement²⁰⁶

The process leading up to the negotiation of the TRIPS Agreement must be analysed against the recognised modes and standards of international law-making. Under article 52 of the Vienna Convention on the Law of Treaties 1969 (‘VC’), ‘a treaty is void if its conclusion has been procured by the threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations’.²⁰⁷ As such, it may be said that where it is shown that an

²⁸ See SF Musungu ‘The TRIPS Agreement and Public Health’ in C Correa & A Yusuf (eds) *Intellectual Property and International Trade: The TRIPS Agreement* (2008) 429.

²⁰³ But see transitional periods with respect to patent protection for LDCs at arts 65 and 66 of the TRIPS Agreement.

²⁰⁴ TRIPS Agreement art 8(1)

²⁰⁵ Id art 31.

²⁰⁶ See Peter Drahos & John Braithwaite ‘Developing countries and international intellectual property standard-setting’ (2002) 5 *Journal of World Intellectual Property* 765-789.

²⁰⁷ Of course, given the reality of the conduct of international relations, conduct would have to reach a necessarily high threshold of coercion before it could be said to negate the consent of the aggrieved party. While V Lowe

agreement was procured through extreme economic or political pressure, it will be difficult to sustain the argument that such a text was made with adherence to the rules of international law.²⁰⁸

A brief narration of the different stages in the negotiations will enable one to determine if the minimum conditions for the conclusion of a valid treaty as set out in the VC were met.

On 13 July 1978, during the Tokyo Round, the European Economic Community, the USA, Japan, Switzerland, New Zealand, Canada, the Nordic countries, and Austria released a 'Framework of Understanding' setting out what they believed to be the principal elements of a deal²⁰⁹ on the recognition and protection of IP rights. Developing countries reacted angrily pointing out that they had been excluded from a process that was laying the foundations for a final agreement. In his report,^{210 211} the then Director-General of the GATT, Oliver Long, acknowledged the problem of exclusion, but defended this behavior as a practical necessity.

International Law (2001) 75 asks the question: 'But what of situations where one state makes it known that unless the other state signs a treaty, it will lose all manner of economic and political benefits in the gift of the first state? Is that coercion? Or is it just how the world is? See also J Klabbbers 'The validity and invalidity of treaties' in DB Hollis (ed) (2012) *Oxford guide to treaties* (2012) 551, 569-570 observes that a limited form of pressure is not only understandable but even legitimate. See also the decision of the Court of Arbitration in the *Dubai-Sharjah Border Arbitration* (1981) 91 ILR 543, 571. The court observed that pressure of some sort was usual in international negotiations and that 'mere influence and pressure cannot be equated with the concept of coercion as it is known in international law'.

²⁰⁸P. Drahos, in *Global Property Rights in information* at page 16 had this to say: 'In the case of TRIPS a basic and well established causal mechanism operated coercion. 'States coerce other States'. By far the most popular means of coercion has been war or its threat. Patterns of military coercion form such a settled part of the history of states because rulers of states have wanted to rule over others and their resources.'

²⁰⁹The deal was the negotiations towards finalising the terms of the new IP standards with which members of the WTO must adhere, ie the TRIPS Agreement. The 'deal' towards an expanded and enforceable IP standard.

²¹⁰GATT 'The Tokyo Round of Multilateral Trade Negotiations: Report by the Director General of GATT' 1979 .., *Foreign Affairs* Vol. 58 No. 1 (Fall, 1979) Available at <http://www.jstor.org/stable/20040366>. Accessed 6 May, 2014

²¹¹(1) The Report was on trade liberalism and expansion of world trade. Consequently with the provisions of the General Agreement relating to such negotiations, and observing the most favoured nation clause (MFN) treatment under GATT requires that tariff concessions negotiated between any two trading partners be extended unconditionally to all members of GATT. Towards these objectives, the Report underlines the 'need for maintaining and improving the Generalised System of Preferences (GSP)'. Under this system the developed countries grant tariff preferences on designated imports from DCs.

A GATT decision in 1979 reaffirmed that the GATT'S basic MFN obligations are not affected by the codes, meaning that, even though non-signatories have no rights under the codes themselves, their existing GATT rights – specifically their MFN rights under article 1 – entitled them to equally favourable treatment. See Robert E Hudec *Developing Countries in the GATT Legal System: Implementing the Tokyo Round Codes* (1987) 88.

(2) The Report was written primarily for DC consumption. It was written quickly (but very thoroughly) in order to pre-empt the kind of negative evaluation that UNCTAD experienced after the Kennedy Round negotiations. Because it was written for a DC audience, it naturally celebrated all the 'victories' achieved

The deeper problem in this process was that it involved a strategy in which a non-representational inner circle of consensus was expanded to create larger circles until the goals of those in the inner circle had been met. The TRIPS negotiations saw the use of circles of consensus reach new heights. The negotiators at the GATT had developed a system known as the 'Green Room' process. Through this process all the negotiators representing each of the countries involved faced one another across the table to negotiate. There are exchange of drafts and progress is taken note of by narrowing down the differences and taking away of brackets in successive drafts.²¹²

This Green Room process was, in the case of TRIPS, profoundly shaped by the consensus-building exercise that the private sector had undertaken outside of the Green Room. The European Commission was brought around to the USA's view on the importance of securing a code on IP. The Quad states (USA, EC, Japan and Canada) were all enlisted in support of the USA's business agenda, as were their business communities. Meetings of the 'Friends of Intellectual Property Group' followed in places like Washington where the USA circulated draft texts of a possible agreement.²¹³²¹⁴

After the commencement of negotiations on the detail of the TRIPS Agreement in 1990, and especially after the breakdown of the Uruguay Round talks in Brussels over agriculture in 1991,

by the Group of 77. And once again, a central element of the 'victories' was all the new legal freedoms DCs had won, especially those which involved discriminatory special and differential treatment. See Hudec above 90.

assets.cambridge.org/97811070/03293/.../9781107003293_excerpt.pdf

by JM Finger -

²¹²J Gorlin *An Analysis Of the Pharmaceutical-Related Provisions Of the WTO TRIPS (Intellectual Property) Agreement* (1999) 4. 12. <http://www.grain.org/article/entries/1993-negotiating-ipr-between-coercion-dialogue-part-one?c=true>

²¹³See P. Drahossupra at p. 771.

²¹⁴Ibid. During the TRIPS negotiations, the Green Room process was carefully structured into concentric 'circles of consensus' that ensured that the objectives of the strongest actors were reflected in the text of the final agreement. The EC had also been 'brought around' to the US view on the importance of securing a code on IP. Similarly, the 'Quad states' (that is to say, US, EU, Japan and Canada) had all been mobilised to sustain the US business agenda. See also M Liang 'Evolution of WTO decision-making process' (2005) 9 *Singapore Yearbook of International Law* 125; G Downes 'The TRIPS Agreement: A test of WTO's legitimacy?' (2010) University of Limerick, Department of Politics and Public Administration, Limerick Papers in Politics and Public Administration No 1 8-9.

further groups were created within the TRIPS negotiations to move the process towards a final deal. Most notable among these was the '10+10 Group' which consisted of a mix of developed and developing countries. In the actual negotiations DCs were not part of the informal groupings where much of the real negotiation took place and where consensus that mattered was achieved.²¹⁵

As the TRIPS negotiations became ever more informal, the '10+10' was contracted or expanded to '3+3', '5+5' or a group of 25 depending on the issue under consideration. A list of these groups (roughly) in their order of importance was:²¹⁶

- 1 USA and Europe
- 2 USA, Europe and Japan
- 3 USA, Europe, Japan, and Canada (Quad)
- 4 Quad 'plus' (membership depended on issue, but Switzerland and Australia were regulars in this group)
- 5 'Friends of Intellectual Property' (a larger group that included the Quad, Australia, and Switzerland)
- 6 '10+10' (and variants thereof such as '5+5' or '3+3'). The USA and the European Community were always part of any such group if the issue was important. Other active members were Japan, the Nordic countries, Canada, Argentina, Australia, Brazil, Hong Kong, India, Malaysia, Switzerland and Thailand.
- 7 Developing country groups (for example, the Andean Group - Bolivia, Colombia, Peru and Venezuela - Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, Nigeria, Peru, Tanzania and Uruguay) combined to submit a developing countries' draft text in 1990.
- 8 Group 11 (the entire TRIPS negotiating group - some 40 countries were active in this group)

Of all these groupings, the first three were all that controlled the negotiations in the TRIPS Agreement. By the use of the circles, the process of the negotiations towards the TRIPS Agreement was more of hierarchy and status rather than one of democratic bargaining. Countries in the inner circle of groups always knew ahead of time what the TRIPS Agreement would

²¹⁵See P Drahos 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue' In P Drahos&RuthMayne (eds) *Global Intellectual Property Rights: Knowledge Access and Development* (2002) 161.

²¹⁶Ibid.

eventually look like. They coerced all others in the outer circle until all the groups came into an agreement. Therefore, the TRIPS Agreement was a product of the first three in the inner circle than it was of the last five groups. In the actual negotiations developing countries were not part of informal groupings where much of the real negotiations was done and where the consensus and agreement that mattered was obtained.²¹⁷

It is clear from the list of groups that the USA and Europe could move in and between all the key groups. This allowed them access to more information on the overall negotiations than any of the other states. Whenever they needed higher levels of secrecy they could morph into a smaller negotiating globule. The TRIPS negotiations could be compared to a 'one way traffic' where all the vehicles faced one direction. The way and manner in which the groupings were done undoubtedly gave the US and the EC an undue advantage making it easy for them to form a consensus whenever they needed to do so. When there were certain issues pertaining to how royalties from collective licensing were to be divided, they resolved it by the use of bilaterals. Although, there were occasions that they had disagreements but their failure to agree on some issues did not distract their focus neither did it derail the process towards the TRIPS Agreement.

It is necessary to note all the countries were not aware of the effects that TRIPS was probably going to have on information market. It was never in doubt that the US would make trade gains, but all the countries most especially the DCs took little note of the effect that the extension of

²¹⁷The claim that the Doha Declaration was a negotiating success for a coalition of weak actors can only be understood by reference to the negotiations that had produced TRIPS. Susan Sell points out that some twelve US corporations were primarily responsible for the lobbying that brought TRIPS into being. See Susan Sell *Private Power, Public Law: The Globalisation of Intellectual Property Rights* (2003). Others have come to a similar conclusion'. See Peter Drahos & John Braithwaite *Information Feudalism: Who Owns the Knowledge Economy?* (2002). 'TRIPS was a stunning negotiating victory that was made possible because a small group of individuals saw in the 1980s the possibilities of networked governance, especially when those networks could capture and deploy a bigstick in the form of US trade threats. TRIPS was the product of politically powerful and linked networks deploying a regulatory pyramid with the threat of trade sanctions at its apex'. See P.Drahos, 'Four lessons for developing countries from the trade negotiations over access to medicines' *Liverpool Law Review* (2007) 28:11-39 at page 15 (For an explanation of how the theory of the regulatory pyramid applies to US trade regulation as well the theory of the nodally co-ordinated pyramid see Peter Drahos 'Intellectual property and pharmaceutical markets: A nodal governance approach' (2004) *77 Temple Law Review* 401. Within these intersecting networks there were pools of technical expertise upon which to draw for the purposes of producing a draft agreement, while other networks steered the draft through a multilateral trade negotiation involving more than one hundred states that lasted from 1986 to 1993. Important to this achievement were small number of business actors who created ever-widening circles of influence that enrolled more actors in networks that had TRIPS as their mission.

IPRs would have on barriers to enter into markets. Multinationals were better informed than most governments of the effect of constructive use of IP portfolios in different markets across the globe.²¹⁸

During the negotiations of the TRIPS Agreement, the US and EC used coercion to force other member countries to agree to the contents of the proposed agreement. The US through its section 301 of its 1974 Trade Act could impose duties on goods from foreign countries or could withdraw the incentives of trade agreements from countries who refuse to improve on their standards of IP protection. The US used section 301 to demonstrate its IP objectives and to threaten or retaliate with trade sanctions against countries on the basis of what they consider to be 'non-compliance with adequate standards of IP'.²¹⁹In 1988 the US introduced significant changes to its Trade Act of 1974 which later became known as the 'Special 301' or 'super 301' provisions. These made it compulsory for the United States Trade Representatives ('USTR') to investigate and punish foreign countries that fail to adequately and effectively protect IP or who deliberately refuse to give fair and equitable market access to US IP right holders.²²⁰

There were also some important changes to the system of Generalised Special Preferences ('GSPs') introduced by the 1984 Act. In considering if a DC's goods were to be given preferential treatment under the GSP-system, the president had to agree to give great and noticeable amount of protection to foreign IP rights.²²¹For quite a handful of DCs having access to closed and subsidized agricultural markets of developed countries was their main goal. The main purpose of the GSP system was to improve access. During a meeting of the GATT Committee on Trade and Development in November, 1985 representatives of quite a number of DCs suggested that the US was using its GSP system in a manner that was strange to the spirit and aim of the generalized system of trade preferences in favour of developing countries.^{222 223}

²¹⁸For example, the first attempt to measure the welfare losses of applying the TRIPS patent period of 20 years to patents in existence for a country was an Australian study after the TRIPS came into operation: See N Gruen, G Prior & I Bruce 'Extending Patent life: Is It In Australia's Economic Interests?' Industry Commission, Staff Information Paper, June 1996.

²¹⁹See Section 305 of the Trade and Tarriff Act 1984

²²⁰See 19 USC s 2242

²²¹See s 505 of the Trade and Tariff Act, 1984.

²²²'Report of Committee on Trade and Development' L/5913 (1984-1985). *Basic Instruments and Selected Documents, General Agreement on Tariffs and Trade* 32nd Supplement 21, 26, 14.

In the early 1980s, the DCs resisted the US lobby for the inclusion of IP in a new round of multilateral trade negotiations.²²⁴The DCs argued that the GATT was not the right forum as it was primarily designed to deal with trade in goods and not issues of personal rights to property in intangibles. They argued that such rights were under the auspices of WIPO and that it is empowered to deal with such issues.²²⁵Dcs that were opposed to this US agenda were India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia.²²⁶

Following the 1986 Ministerial Declaration these DCs pursued their desire for a stricter interpretation of the ministerial mandate on the negotiation of intellectual property protection. It was crucial for the US to defeat its adversaries for it to achieve the desired results. Early in 1989 the 'super 301'²²⁷ was therefore put into operation and five of the ten DCs countries that opposed the US interests were identified for bilateral attention. The two leaders India and Brazil were named on the 'Priority Foreign Countries' List which was the most serious category of Priority Watch List. Three other countries Argentina, Egypt and Yugoslavia were placed on the less serious category of Watch List.²²⁸

In the words of the USA trade negotiator at the time, Clayton Yeutter, the TRIPS was less a negotiation and more a 'convergence of processes'. Opposition to the USA's GATT agenda, was

²²³See s 505 of the Trade and Tariff Act, 1984.

²²⁴Susan Sell points out that some twelve US Corporations were primarily responsible for the lobbying that brought TRIPS into being. See Susan Sell, *Private Power, Public Law: The Globalisation of Intellectual Property Rights*, Cambridge University Press, Cambridge, 2003. See also P. Drahos 'Four Lessons for Developing Countries from the trade negotiations over access to medicines' *Liverpool Law Review* (2007) 28: 11-39 at page 15.

²²⁵Industries in the US convinced first the US Trade Representative, and then the EU and Japanese Trade Representatives, that the GATT was the forum within which IP protection should be pursued. See generally CIESIN Thematic Guides: General Agreement on Tariffs and Trade, available at <http://www.ciesin.org/TG/PI/TRADE/gatt.html> (DATE USED 14 September 2013.)

²²⁶J.A Bradley 'Intellectual property rights, investment, and trade in services in the Uruguay Round: Laying the foundations' (1987) 23 *Stanford Journal of International Law* 57, 81

²²⁷ Within the 301 process there are three important categories; priority foreign country, priority watch list and the watch list. A country that is put on the 'Watch List' is being sent a message that it has unsatisfactory practices when it comes to intellectual property and that the US Administration is paying special attention to those practices. The country knows that it has entered the 301 process and that it can expect to be in regular contact with the Office of the United States Trade Representative (USTR). See P.Drahos, *Global Property Rights in Information: The story of TRIPS at the GATT*. Prometheus, Vol 13, No. 1, June 1995 at page 10

²²⁸Frederick M Abbott 'Protecting First World assets In The Third World: Intellectual property negotiations in the GATT multilateral framework' (1989) 22 *Vanderbilt Journal of Transnational Law* 689, 708-709.

being diluted through the conclusion of bilaterals.²²⁹ Each bilateral treaty the USA concluded with a DC brought the DC that much closer to the TRIPS Agreement ‘so that accepting TRIPS was no big deal’.²³⁰

The negotiations on the TRIPS Agreement are often said to have started seriously either in the second half of 1989 when a number of countries made proposals, or in the first part of 1990 when five draft texts of an agreement were submitted to the negotiating group.²³¹ A more cynical view is that the negotiations were by then largely over. Developing countries had simply run out of options. If they did not negotiate multilaterally they would each have to face up to the USA alone. The USA used its ‘301 process’ to target the DCs that were resisting its IP agenda in the GATT bilaterally. In the GATT, DCs were not part of the circles of consensus which set the agendas.

Furthermore, if the DCs resisted the USA multilaterally, they could expect to be on the receiving end of a ‘301’ action. This was anything but an idle threat by the USA. In its 1988 Trade Act the USA made resisting it in a multilateral forum part of the conditions that could lead to a country being identified as a Priority Foreign Country and therefore the subject of a ‘Special 301’,²³² investigation.²³³ There could be no clearer articulation of a threat than to enact it as law. At least if DCs negotiated multilaterally there was the possibility that they would be able to obtain some

²²⁹The US usually enter into bilateral treaties when they want to deprive other member countries of the use of flexibilities such as compulsory licensing, parallel trading, and the scope of patentability. They also use bilateral treaties to compel member countries to adopt measures and standards exceeding their obligations under the TRIPS Agreement. In this context, the US entered into bilateralism to coerce individual countries to accept the TRIPS Agreement. See Peter Drahos & John Braithwaite ‘Commission on Intellectual Property Rights: Study Paper 8 Developing Countries and International Intellectual Property Standard Setting’ writing on bilateralism in IP post-TRIPS and on model bilateral arrangements stated that: ‘In Bilateral trade negotiations between states involving a strong and weak state generally speaking the strong state comes along with a prepared draft text which acts as starting point for the negotiations. Bilateral negotiations are complex and lengthy affairs, features which make them costly even for the strong states. In order to lower the transaction costs of bilateralism the U.S. has developed models or prototypes of the kind of bilateral treaties it wishes to have with other countries. Once a model treaty is ratified by the senate, U.S. trade negotiators know that if they stick to its terms in other negotiations there is a good chance the treaties flowing from these negotiations will also be approved. For the U.S. there are very strong incentives for a standardisation of bilateral treaty standards.’

²³⁰See Drahos & Braithwaite ‘IP Standard Setting’ 1994 interview, with US trade negotiator.

²³¹See, for example, Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* (1998) 15. See also Jacques J Gorlin, An analysis of the pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement, Intellectual Property Institute, London, 1999, 4. 12.

²³²Section 301 is a national trade enforcement tool that allows the US to withdraw the benefits of trade agreements or impose duties on goods from foreign countries.

²³³ See 19 USC 2242 (b)(1)(c).

limits on the use of '301' actions. This, at any rate, was what they were being told by DC negotiators and the GATT Secretariat.

The United States Trade Representative, Clayton Yeutter, stated publicly that the '301' investigation of South Korea in 1985 was intended to send a message to GATT members. Similarly, countries like Singapore and Hong Kong began in the 1980s to reform their intellectual property law knowing that if they did not they ran a risk of losing GSP benefits in the USA market. The risk of losing GSP benefits was real. Yeutter, for instance, had written to a USA senator stating that if Mexico did not make substantial changes on intellectual property: 'I will not hesitate to recommend a significant reduction in Mexico's future level of GSP benefits'.²³⁴ When Singapore was removed from the GSP program by the USA in 1989 because it no longer met the criteria, Singaporean officials expressed disappointment pointing out that in 1987 they had been given a GSP package because they had made improvements in IP protection.²³⁵

During the Uruguay Round there were suggestions that if the DCs agreed to the TRIPs Agreement the USA would ease off negotiating IP standards bilaterally. The TRIPs Agreement was concluded as part of the text of Final Act of Uruguay Round negotiations and came into force on 1 January 1995.

As can be observed from the above sequence of events, the TRIPs Agreement was concluded not on the basis of a consensual process of free deliberation, but rather in the context of extreme economic pressure that seriously taints the systemic validity of the Agreement and the norms it contains.²³⁶

Although, the agreement was formally concluded with all the appearance of the traditional process

²³⁴ See the report of Yeutter's speech in (1986) 32 *BNA Patent, Trademark and Copyright Journal* 737.

²³⁵ See AUTHOR?? P. Drahos, Commission on Intellectual Property Rights Paper 8: Developing Countries and International Intellectual Property Standards Setting (2002) at pages 15-16 Available at www.anu.au/fellows/.../2002devcountriesandipstandards.pdf.

²³⁶ See JT Gathi 'The legal status of the Doha Declaration on TRIPs and Public Health under the Vienna Convention of the Law of Treaties' (2002) 15 *Harvard Journal of Law and Technology* 294, where he notes that 'during the Uruguay Round, the United States unilaterally pressured developing countries opposed to its negotiating position, such as Brazil, Thailand and India, using the authority of the United States Trade Representative ("USTR") under super 301'. To him 'the Agreement was negotiated within a coercive bargaining context, despite the fact that developing countries won some concessions in return for signing the TRIPs Agreement'. See also AT Guzman 'Against consent' (2012) 52 *Virginia Journal of International Law* 757-758 where he observes that 'developing countries were forced to choose between capitulation on the IP issues and exclusion from the international trading system', a strategy akin to a thief offering a choice of "your money or your life".

for the conclusion of treaties, in reality the context and the formal process involved in its conclusion offended a basic rule regarding the conclusion of treaties -that they be entered into with full and free consent.

4.3 Concerns of the developing countries before and during the negotiation of the TRIPS Agreement

Developing countries were reluctant to extend patent protection to pharmaceuticals. They realised that pharmaceutical production was highly concentrated in developed countries.²³⁷

More importantly, innovation in the development of new chemical entities ('NCEs') was almost exclusively undertaken in industrialised countries.²³⁸ At that time, 96 per cent of R&D expenditure worldwide occurred in developed countries and only four per cent in all areas of science and technology, in DCs.²³⁹ This is perhaps the most dramatic asymmetry in contemporary north-south relations, since it relates to the ability to create and apply new scientific and technological knowledge.²⁴⁰

In addition, even before the adoption of the TRIPS, a number of economic studies²⁴¹ showed that patent protection for pharmaceuticals in DCs would lead to increased prices for medicines, increased royalty and profit payments abroad, and to a greater market penetration by foreign firms. Further, the experience of developed countries, such as Italy (which had only recently adopted patents for pharmaceuticals), raised further doubts about the benefits to be gained from extending patents to pharmaceuticals.²⁴²

For almost three years from 1986 until May 1989, DCs refused to negotiate an agreement on intellectual property. Eventually, however, it was no longer politically possible to avoid the

²³⁷Available at apps.who.int/medicinedocs/en/d/Jh1459e/5.3.html

²³⁸See WHO 'The TRIPs Agreement and Pharmaceuticals: II General Issues' (2000) available at <http://apps.who.int/medicinesdocs/en/d/jh1459e/5.3.html> (Date used 12 June 2013).

²³⁹There are about ten industrialised countries with a pharmaceutical industry and research base capable of developing new chemical entities or new medicines.

²⁴⁰See K Balasubramaniam 2001 'Access to Medicines: Patents, Prices, and Public Policy – Consumer Perspective' paper presented at Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement? Brussels, 20 March 2001. Available at apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf

²⁴¹For instance by the World Bank.

²⁴²See Balasubramaniam supra above.

discussion and the drafting of the agreement got underway.²⁴³ During the negotiation of the TRIPS Agreement international NGO's and African states were not significant players. Although India and Brazil did formulate counter proposals, these were evaluated by counsel from the USA industry who had years of experience in IP protection and licensing.²⁴⁴

For DCs there were two potential benefits in negotiating the TRIPS Agreement. First, trade-offs which raised the possibility that in other areas of the Uruguay Round negotiations, developing countries could obtain benefits, for example access to markets for their textiles and agricultural products. In this regard, unfortunately for most DCs, it seems there have been fewer benefits than anticipated.²⁴⁵

Secondly, a further trade-off sought by developing countries from the negotiation of the TRIPS Agreement was the establishment of a multilateral mechanism for dispute settlement that would avoid unilateral action by developed countries. As a result of this concern, one of the express aims of the agreement has been to reduce 'tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures.'²⁴⁶

After the entry into force of the TRIPS Agreement, any controversy should be subject to a multilateral procedure of dispute settlement, and only after the completion of the procedure may retaliatory measures be adopted.²⁴⁷

4.4 How the concerns of the developing countries were reflected in the TRIPS Agreement

²⁴³See The WHO (2000) 'The TRIPs Agreement and Pharmaceuticals: II General Issues' (2000) available at <http://apps.who.int/medicinedocs/en/d/jh1459e/5.3.html> (Date used 24 May, 2013.)

²⁴⁴See P.Draho's Global Property Rights in Information: The story at the GATT. Prometheus, vol 13, No. 1, June 1995 at page 7.

²⁴⁵See Carlos M Correa *The TRIPS Agreement and Policy Options* (2000) 11.

²⁴⁶Ibid.

²⁴⁷Thus, President Clinton's submission (15 December 1993) to the US Congress of the Final Act of the Uruguay Round states that 'if Members of the Dispute Settlement Understanding (DSU) do not comply with their obligations at the end of the dispute settlement process, trade actions under section 301 of the Trade Act of 1984 will be legitimised and there will be no risk of counter-retaliation'. Available at www.wto.org/english/thewto-/mimst-emin98-e/slide-e/ur1.htm

The DCs were concerned that the hard-won flexibility achieved on compulsory licences in that there is no restriction on the grounds for the grant of such licences, could, for instance, be lost by the introduction of non-violation complaints.²⁴⁸

All these positions and concerns are reflected to some extent in articles 7 and 8 of the TRIPS Agreement, in which its objectives and principles are set out. This is particularly true of article 7 which refers to the balance that must be considered/effectuated/struck?? when developing national legislation to implement the agreement municipally.²⁴⁹ The article provides:

‘The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer of 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’.

The reference to social and economic welfare and to a balance of rights and obligations could serve to justify exceptions to exclusive rights, where the right-holder has failed to participate in social and economic development or, in other words, has used his rights without performing his obligations.

Certain commentators have alluded to this argument with respect to pharmaceutical products claiming that protection of such products is not necessarily in the interest of DCs.²⁵⁰ In this light, any country wishing to establish a violation of the TRIPS or *a nullification or impairment*, would be well advised to include sufficient data to substantiate its claims in its submissions.

The drafting of this paragraph shows that the balance of rights and obligations should be assessed using well established principles of IP law. Indeed, the reference to ‘the promotion of technological innovation and to the transfer of technological knowledge’ is a summary of the

²⁴⁸See G Dutfield *Intellectual Property Rights and the life science industries: A Twentieth Century History* (2003).

²⁴⁹See The WHO ‘The TRIPs Agreement and Pharmaceuticals: II General Issues’ (2000) Available at <http://apps.who.int/medicinedocs/en/d/jh1459/5.3.html> (Date used 17 April, 2014.)

²⁵⁰Professor Tankoano argues forcefully that, while many African nations had patent laws superior to those of countries such as Korea and Turkey, more foreign investment went to those two countries than to any African nation. See Amadou Tankoano ‘L’ accord relative aux aspects des droits de propriété intellectuelle liés au commerce’ (1994) 20 *Droit et pratique du commerce international* 428, 467 ff; see also C Correa ‘The pharmaceutical industry and biotechnology: Opportunities and constraints for developing countries (1991) December *World Competition* 56.

most important of these principles.²⁵¹ For a number of DCs, patent documentation is viewed as an essential basis for transfer of technology and as a way to accelerate research and developmental efforts.²⁵²

During a meeting of the TRIPS negotiating group, a spokesperson for a group of fourteen DCs declared:²⁵³

‘... [We reaffirm] the vital importance to developing countries of the possibility of exclusion of certain products and processes from patentability on grounds of public interest, health or nutrition as provided in Article 28.... Article 30 on conditions and obligations of patent owners, should, in line with that text,²⁵⁴ clearly specify that working the patented invention in the country of grant was one of the obligations of a patentee. Such working was an essential element upon which the patent system was based, and was part of the balance between the interests of patent owners and those of the country undertaking to protect the inventions.’²⁵⁵

In contradistinction to article 7, article 8 specifically allows government measures necessary to protect public health and nutrition, or to promote the public interest in sectors of vital importance to the socio-economic and technological development of the member, provided that such measures are consistent with the provisions of the Agreement. Price controls on pharmaceuticals, or any equivalent measure which could otherwise give rise to a non-violation-type or situation-type dispute, could, if the need arises, be defended under article 8.²⁵⁶

²⁵¹See Michelle McGrath ‘The patent provisions in TRIPS: Protecting reasonable remuneration for services rendered or the latest development in Western colonialism?’ (1996) 7 *EIPR* 398.

²⁵²See ShahidAlikhanthe author of the chapter on ‘Intellectual Property, the Developing Countries and Economic Development’ published by Rajiv Ghandi Institute for Contemporary Studies No. 14, 1994 at pages 14-15.

. This chapter has been published by WIPO. See Geneva, June 27, 2000 Press releases PR/2000/228 available at www.wipo.int/pressroom/en/prdocs/2000/wip_pr2000.228.html. The chapter was also published in the book ‘Intellectual Property rights/ed by BibekDebroy 1998 at pages 65-121. MrShahidAlikhan was formerly Deputy Director General of WIPO and Under Secretary General of the UN. The chapter highlights socio economic benefits of IP protection.

²⁵³See communications from Argentina, Chile, China, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe. See Appendix II to MusunguS.F . (2008). The TRIPS Agreement, and Public Health in C Correa & A. Yusuf (eds) Intellectual Property and International Trade: The TRIPS Agreement, 2nd Edition, Kluwer Law International, The Netherlands..

²⁵⁴Reference is made to DCs’ proposal for a TRIPS Agreement. See Doc.MTN.GNG/NG11/W/71.

²⁵⁵See Daniel J Gervais *The TRIPS Agreement: Drafting History and Analysis* 4 ed (2012).

²⁵⁶Violation-type complaints (WHATEVER THEY MAY BE??) may fail against price controls since the direct obligation is only to allow the patent owner the right to exclude third parties as provided for in art 28.

The negotiating history of article 8 shows that there was an attempt to change the wording from the December-1990 version which read ‘provided that PARTIES do not derogate from the obligations arising under this Agreement’, either by inserting the words ‘or impair the benefits’ after the word ‘obligations’, or by inserting the words ‘or otherwise undermine’ before the words ‘the obligations’. Given the opposition, none of these suggestions was included in the final text, which now contains the words ‘provided that such measures are consistent with the provisions of this Agreement’.²⁵⁷ A plausible interpretation, therefore, is that article 8 will provide a safeguard from certain of the non-violation complaints most relevant to DCs. If this were not the case, those proposing the amendments may have been less insistent during the negotiations on including the proposed words in order to accommodate non-violation complaints.

Article 8 is essentially a policy statement which explains the rationale for measures taken under articles 30, 31 and 40. Given the phrase added by negotiators, it would be difficult to justify an exception not foreseen under the agreement, unless it is an exception to a right not protected under other provisions of the TRIPS Agreement or those of other international instruments incorporated in the TRIPS Agreement.

4.5 The scope, objectives and general principles of the TRIPS Agreement

The TRIPS Agreement includes references to overall public interest and developmental objectives.²⁵⁸ Article 1 deals with the ‘scope’ of the agreement while articles 7 and 8 establish the ‘objectives’ and ‘principles’ of IPRs protection under the agreement.

Article 1 states that:

‘Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’

²⁵⁷See IP/C/W/124 dated 28 January 1999 6-7 available at www.wto.org. (Date used 16 April, 2013)

²⁵⁸See Ellen F.M ‘tHoen The Global Politics of Pharmaceutical Monopoly Power : Drug Patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health. (2009) at page 12.

Carlos Correa²⁵⁹ is of the view that article 1.1 of the TRIPS Agreement provides protection against demands for higher standards than the TRIPS Agreement requires, and is against unilateral sanctions such as section 301 of the USA Trade Act. The aim of article 1.1 is to provide some protection from ‘TRIPS-plus’ pressures.

Article 7 states that:

‘The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligation’s.

This objective was included in the TRIPs Agreement in response to the proposals made by DCs who were concerned about their ability to get western technologies under an IP system that ran ahead of their level of industrial development. Article 7 also made it clear that IP protection should be seen as a social-policy tool designed to benefit societal and economic welfare. The TRIPS objectives in article 7, together with article 1.1 give countries leeway on how the TRIPS Agreement can be interpreted and implemented.²⁶⁰

Article 8.1 states that:

‘Members ... may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.’²⁶¹

The concerns of the DCs were also at the root of article 8. In the context of public health and access to medicines, article 8.1 offers some scope for DCs to take necessary measures. However, the extent of its usefulness is limited by the phrase ‘provided that such measures are consistent with the provisions of this Agreement’ as it to a large extent negates the underlying premise of article 8 which is to allow DCs the flexibility of adopting policy measures for the public good.

4.6 Patents under the TRIPS Agreement

²⁵⁹Carlos .M. Correa, 2000 ‘The TRIPS Agreement and Policy Options’ atpage 8.

²⁶⁰See Ellen F.M ‘Hoen at page 13.

²⁶¹Id 14.

The TRIPS Agreement sets minimum standards in the field of IP protection which all member countries must respect. To achieve these standards, WTO members are required to modify their IP laws to bring them into line with the new WTO standards. For example, the TRIPS Agreement provides that all patents shall be valid for at least twenty years from the filing date, whereas before the TRIPS, the patent term varied considerably from country to country (ranging between 7, 10, 17 or 20 years). All WTO members must incorporate this twenty-year patent term in their national patent laws.

Before the Uruguay Round and the TRIPS Agreement, pharmaceutical patents and other intellectual property rights relating to drugs were widely recognised among major industrialised countries, but not in many DCs. As there were no international standards governing the scope of patent protection, countries had widely divergent provisions on IP protection depending on their individual needs. Within the pharmaceutical sector, in more than 40 countries patents were simply not available for pharmaceutical inventions. As a result, copies of medicines protected by patent in other countries were widely available, usually at a price under that charged for the original patented drug. The copies were either manufactured by local companies producing generics, or imported, without having to seek licences from the patent-holder.

Although the TRIPS Agreement imposed minimum standards, the agreement also contained provisions allowing a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. This means that countries have a certain measure of freedom in modifying their regulations, and that when formulating their national legislation, various options are open to them to ensure a proper balance between the goals of providing incentives for the future development of new drugs and providing affordable access to existing medicines.

Under the TRIPS Agreement, all WTO members are obliged to make patents available for pharmaceutical inventions in their countries.²⁶² A company that has invented a new pharmaceutical product or process has, since 1 January 1995, been able to apply for at least a twenty year patent protection in any WTO member country.

²⁶²Taking into account the transitional periods allowed to DCs and LDCs by the TRIPS Agreement.

As regards transitional periods, the TRIPS Agreement takes into consideration the different levels of economic development in its member countries. Developed countries were given until 1996 to comply with the TRIPS standards by modifying their patent law if necessary. Developing Countries had until 2000 - subsequently extended to 2005 - and LDCs had until 2006 - now extended to 2016 under the Doha Declaration. Developing and Least-Developed Countries were allowed these transition periods in order to give them sufficient time to implement the various TRIPS standards on IP rights at national level.

These standards reflect no more than the minimum standard of IP protection and member states may elect to provide greater protection than required under the TRIPS Agreement. For example, legislation within the EU and the USA provides that pharmaceutical patents may be extended (beyond twenty years) for up to five years to compensate for the long delays in securing marketing approval for a drug. As there is no international standard, this patent extension will vary from country to country depending on the date of market approval. However, a pharmaceutical patent cannot be extended by more than fifteen years from the date of marketing approval in the EC (20+15), and fourteen years in the USA (20+14).

4.6.1 Protection of data submitted for registration of pharmaceuticals under the TRIPS Agreement

As a condition for permitting the sale or marketing of a pharmaceutical product, drug regulatory authorities require pharmaceutical companies to submit data reflecting the safety, quality and efficacy of the product.²⁶³

The TRIPS Agreement requires that WTO members protect undisclosed test data submitted to drug regulatory authorities for the purposes of obtaining marketing approval, against unfair commercial use. As countries have a considerable discretion in defining 'unfair commercial use', I feel that countries can meet their obligations to protect test data by prohibiting 'dishonest' use

²⁶³ Available at www.who.int/medicines/areas/policy/wto_trips/en/

of data. Use by government authorities to assess the efficacy and toxicity of a pharmaceutical product would, therefore, not be affected.²⁶⁴

However, it is now argued that data exclusivity is a requirement under the TRIPS Agreement. The data-exclusivity approach grants the originator exclusive rights over its test data and prevents regulatory authorities relying on that data to register generic substitutes.²⁶⁵

Before the TRIPS Agreement came into force, most countries allowed reliance on the originator test data to approve generic products. Once test data had been submitted by the originator company, the regulatory authorities could rely on it to approve subsequent applications for similar products, or to rely on proof of prior approval of a similar product in another country.²⁶⁶

Generic manufacturers were required to prove only that their product was chemically identical to the brand-name or original product - and in certain countries that it was bioequivalent. This approach enabled the swift introduction of generics into the market without registration data-related costs.²⁶⁷

Within the data-exclusivity approach, once a company has submitted original test data, no competing manufacturer is allowed to rely on these data for a specified period. Data exclusivity could thus pose an obstacle to the effective use of compulsory licences, as the entry of the generic product would be delayed for the duration of the of the exclusivity period or for the time²⁶⁸ it takes to compile new test data.²⁶⁹ The public interest in limiting data protection is aimed at promoting competition and ensuring that data protection does not become the vehicle by

²⁶⁴See WHO /WTO AND THE TRIPS AGREEMENT available at http://www.who.int/medicines/areas/policy/wto_trips/en/index.html (Date used 16 April, 2013.)

²⁶⁵Available at www.who.int/medicines/areas/policy/wto_trips/en/

²⁶⁶See Carlos M Correa, 'Implications of bilateral free trade agreements on access to medicines' (2006) 84/5/May *Bulletin of the WHO* 401.

²⁶⁷See M Perez 'Intellectual Property and Pharmaceutical data exclusivity in the context of innovation and access to medicines' October 2004 available at <http://www.iprsonline.org/unctadictsd/Bellagio/docs/Pugatch.Bellagio3pdf> (date used 15 September 2013.)

²⁶⁸See <http://www.css-romande.ch/downloads/trips/TRIPS-CSSR.pdf>

²⁶⁹See Vanessa Bradford Kerry & Kelly Lee 'TRIPS the Doha Declaration and Paragraph 6 decision: What are the remaining steps for protecting access to medicines?' 2007 *Globalisation and Health* 4 available at <http://www.globalisationhealth.com/content/3/13> (Date used 21 April, 2013.)

which to block timely entrance of affordable generic medicines of public health importance into the market.²⁷⁰

4.6.2 Scope of patent protection

Patent protection is included in the TRIPS Agreement Part II section 5 and protects inventions of all kinds, both products and processes. The invention must, however, be new, involve an inventive step, and be capable of industrial application.

Article 27.1 of the TRIPS Agreement stipulates that ‘patents shall be available for any inventions, whether products or processes, in all fields of technology.’²⁷¹ While the TRIPS Agreement obliges WTO member countries to protect products and processes, it does not extend this protection to the use of a known product for pharmaceutical purposes.

These rules clearly indicate that the negotiators of the TRIPS Agreement, despite the strong differences existing on this issue, finally agreed to extend protection to all types of product and process,²⁷² thus foreclosing the possibility available under the Paris Convention of leaving certain matters outside of the ambit of protection. This possibility had been extensively exploited by developing (and some developed) countries, particularly when it comes to pharmaceutical products.²⁷³

While the aim of article 27.1 is clear, this provision does not mean that the TRIPS Agreement has introduced a uniform rule on patentability. Member countries of the WTO still have the option, within certain limits, to define the scope of patentability in relatively broad terms

²⁷⁰See M Pugatch ‘Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation’ Conference Proceedings ICTSD-UNCTAD ‘Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines 2004’ available at <http://www.icts.org>. Bellasio, ICTSD/UNCTAD (Date of use 21 April, 2013.)

²⁷¹Before the TRIPS Agreement some countries – eg India -- did not recognise patents on pharmaceutical products. Product patents are the cornerstone of complex patent portfolios that are built by large pharmaceutical companies around the basic compound they wish to protect. See Drahos n 162 above 16.

²⁷²In principle, all inventions, whether product or processes, in all fields of technology are patentable. See art 27 of the TRIPS Agreement.

²⁷³See Carlos M. Correa, Intellectual Property Rights, The WTO and Developing Countries: The TRIPS Agreement and Policy Options (2000) at page 50.

depending on each country's strengths and weaknesses in different areas, and on the impact that patentability may have on the access to or development of technology.²⁷⁴

The TRIPS Agreement does not cover a number of areas of IP, either because there was no consensus at the time the Agreement was negotiated, or because the areas in question had not yet emerged, or simply because the negotiators of the TRIPS Agreement did not consider that barriers to trade existed in those areas. Some of those areas are of particular interest to DCs. These included utility models, traditional knowledge, and handicrafts.

4.6.3 Exceptions and limitations to patent rights

In principle, patents confer exclusive rights for a limited period which prevent others from making, using, offering for sale, selling, or importing a patented invention without the patentee's consent. The grant of such rights is considered an incentive for investment in innovative activities and the production of knowledge. There are, however, a number of mechanisms in the patent system to counteract the potential inefficiencies in the market power arising from this type of exclusive right.²⁷⁵

'Generally speaking, there are two types of exception and limitation which allow states to fine-tune the different interests among stakeholders. First, provisions that exclude or allow for the exclusion of, certain types of use of patented inventions from being addressed in infringement proceedings are found in both national laws and in treaties. Patentees cannot enforce their rights against certain acts performed by third parties, although they would normally be considered as an infringement. In other words, third parties are free to perform those limited acts without having to anticipate infringement proceedings. The underlying consideration here is that under certain circumstances the public interest justifies, a denial of the enforcement of the exclusive rights granted to patentees.²⁷⁶

...

²⁷⁴Carlos .M. Correa Intellectual Property Rights, The WTO and Developing Countries, The TRIPS Agreement and Policy Options (2000). London/Penang:Zeng Books Ltd. & Third World Network. At page 50

²⁷⁵See Cullet n 35 above 145-146.

²⁷⁶Id 146 where he states that: 'This provision can thus be used by countries to pursue public health goals. Indeed, that is exactly what the objective clause of article 7 requires by calling for a balance of rights and obligations on the part of the patent holder.'

The second type of exception and limitation relates to situations where patentees cannot stop third parties from using the patented invention, but are nonetheless entitled to remuneration in respect of such use. In other words, although the possibility of obtaining injunctive relief may be significantly limited, a right to remuneration is maintained. Compulsory licences (or non-voluntary licences) represent one type of mechanism used to establish this type of limitation.^{277 278}

Article 30 of the TRIPS Agreement allows member states to provide limited exceptions to the exclusive rights conferred by a patent, provided that these exceptions do not unreasonably conflict with a normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, having regard to the legitimate interests of third parties. Article 30 establishes three conditions: (i) that the exceptions to the exclusive right must be ‘limited’; (ii) that the exceptions must not unreasonably conflict with a normal exploitation of the patent; and (iii) that the exceptions do not unreasonably prejudice the legitimate interests of the patent owner, having account to the legitimate interests of third parties.²⁷⁹

In conjunction with the *Canada-Patent Protection of Pharmaceutical Product case* (DS114),²⁸⁰ the Dispute Settlement Panel provided guidance on the above three conditions set by article 30.

First, the panel found that the three conditions apply cumulatively, and that ‘the exact scope of Article 30’s authority will depend on the specific meaning given to its limiting conditions.’²⁸¹

²⁷⁷See WIPO ‘Special Committee on the Law of Patents Report, Doc 2009 (WIPO) at page 19. Available at www.wipo.int/edocs/mdoc/scp_13/scp_13_7.pdf

²⁷⁸See P. Cullet supra at pages 146-147. This is confirmed by the Doha Declaration.

²⁷⁹Article 30 is sometimes used as follows:

- (i) “To authorize the manufacture, use, export and import of medicines used to prepare regulatory approval for medicines;
- (ii) To authorize more general research or experimental use (including reverse commercial engineering) of inventions; or
- (iii) To authorize personal or humanitarian uses of medicines. These uses are typically authorized without obligation to notify or compensate the patent owners. Whilst, the exceptions under Article 30 are “limited”, they can be economically important. For example, the “early working” exceptions permits generic drug manufacturers to reduce, by 18 to 24 months, the time needed to register generic alternatives”. See WTO ‘TRIPS Provisions on Remuneration for non-voluntary use of a Patent’ 10.

²⁸⁰Report of the Panel, WTO WT/DS114/R 17 March 2000. The dispute concerned the regulatory review provision and the stockpiling provision under the Canadian Patent Act which allowed generic pharmaceutical manufacturers to override the patent rights in certain situations. As regards compliance with art 30, the Panel found that, while the stockpiling provision did violate art 30 because it was not a ‘limited’ exception to the rights, the regulatory review provision was justified under art 30 as it met all criteria in that article. See http://www.wto.org/english/tratop_e/dispu_e/cases_e/eds114_e.htm).

When examining the wording of the conditions, ‘both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind, as well as other provisions of the TRIPS Agreement which indicate its objective and purposes.’²⁸²

Secondly, the panel held that the ‘limited’ character of an exception should be measured by the extent to which the exclusive rights of the patent owner have been curtailed.²⁸³

With respect to the expression ‘normal exploitation of the patent’, the panel considered that this was a reference to the ‘commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent.’²⁸⁴ The term ‘normal’ was interpreted by the panel to mean the combination of ‘an empirical conclusion about what is common within a relevant community’ and ‘a normative standard of entitlement.’²⁸⁵ Further, the panel’s decision stated that, while the specific forms of patent exploitation by the patent owner are not static, ‘protection of all normal exploitation practices is a key element reflected in all patent laws.’²⁸⁶

In the specific circumstances of the case, the panel concluded that the ‘additional period of de-facto market exclusivity created by using patent rights to preclude submissions for regulatory authorisation should not be considered “normal”’.²⁸⁷ It was not a ‘natural or normal consequence of enforcing patents rights’, but rather an ‘unintended consequences of the conjunction of the patent laws with product regulatory laws’²⁸⁸ that resulted in such additional period of market exclusivity.

As regards the third criteria, the panel concluded that the term ‘legitimate interest’ must be ‘defined in the way that it is often used in legal discourse- as a normative claim calling for protection of interests that are “justifiable” in the sense that they are supported by relevant public policies or other social norms.’²⁸⁹ In the specific circumstances of the case, the panel considered that the ‘interest claimed on behalf of patent owners whose effective period of market exclusivity

²⁸¹See para 7.49 and 7.50 of the Panel Report.

²⁸²Id para 7.26.

²⁸³Id para 7.44 and 7.45.

²⁸⁴Id para 7.51.

²⁸⁵Id para 7.54.

²⁸⁶Id para 7.55.

²⁸⁷Id para 7.57.

²⁸⁸Ibid.

²⁸⁹Id para 7.69.

had been reduced by delays in marketing approval was neither so compelling nor widely recognised that it could be regarded as a “legitimate interest” within the meaning of Article 30.²⁹⁰

Article 27.2 of the TRIPS Agreement allows states to restrict the patentability of inventions, for example, if they pose a threat to human life or health. However, this restriction on patentability is not acceptable if the law simply bans the exploitation of the invention. This would, for example, prohibit a blanket restriction on product patents on pharmaceuticals. The major difference between article 27.2 and article 30 is that the latter does not allow states to reject the patentability of a specific drug or other invention but only to regulate its use.²⁹¹

Article 31 of the TRIPS Agreement provides that a member may, under the conditions stipulated, allow use other than that permitted under article 30 without the authorisation of the rights-holder. These other uses are typically compulsory licences and government use without the authorisation of the right-holder. This is further discussed in the subsequent paragraphs.

4.7 Analysis of the TRIPS flexibilities

The TRIPS Agreement establishes minimum standards of protection that each government must accord the IP of fellow WTO members, thereby limiting the earlier scope of flexible national approaches. It incorporates certain ‘flexibilities’ aimed at allowing DCs and LDCs to use TRIPS-compatible norms in a way that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development.

The WIPO Secretariat, together with member states has identified four clusters of flexibilities.

4.7.1 Flexibilities as to method of implementing TRIPS obligations

These result from the wording of article 1.1 of the TRIPS Agreement. Under these flexibilities, WTO members can exploit creative solutions to transpose those concepts that the TRIPS Agreement simply enunciates but does not translate into national law and practice. Examples of

²⁹⁰Id para 7.82.

²⁹¹See P. Cullet *supra* at page 146.

these flexibilities include concepts such as novelty, inventiveness, or situations of extreme urgency for the purposes of compulsory licences.²⁹²

4.7.2 Flexibilities as to substantive standards of protection

These flexibilities can operate either downward or upward, ie they may permit measures that reduce or limit the rights conferred, or measures that raise the level of protection above minimum standards established by the TRIPS Agreement. The latter are referred to as 'TRIPS-plus'.

Examples of the former are the introduction of exceptions to rights conferred (such as experimental use and the 'Bolar exceptions'²⁹³ and the limitation of the use of trademarks in packaging and advertising products considered prejudicial to health, like alcohol and tobacco).

Examples where the level of protection has been raised are the introduction of temporary protection of industrial property rights before the grant of protection; the extension of the term of patents to compensate for delays in granting the marketing approval of?? products; or the extension of the scope of patentability beyond the minimums established by article 27.²⁹⁴

4.7.3 Flexibilities as to mechanisms of enforcement

In the field of enforcement, the TRIPS Agreement (Part III) identifies the mechanisms that members are obliged to adopt in order to make enforcement rights available to IP owners. It also prohibits members from adopting measures against defenders more stringent than those established under the Agreement. Nevertheless, members can turn to their own legal systems and

²⁹²See WIPO 'Advice on Flexibilities under the TRIPS Agreement' available at http://www.wipo.int/ip-developments/en/legislative_assistance/advice_trips.html. (Date used 17 April, 2013.)

²⁹³Many countries provide an exception relating to the use of patented products (particularly pharmaceutical products) to obtain regulatory approval to place the product on the market. Such exception is often termed the 'Bolar exception' on the basis of *Roche v Bolar Pharmaceuticals* 733 F 2d 858 (Fed Cir 1984). The CAFC ruled that the research exemption in the US did not cover Bolar's acts to carry out equivalent tests for the regulatory approval of the generic medicine before the expiration of the relevant patent owned by Roche. The US legislators considered that it was not appropriate to prevent generic manufacturers from starting to prepare and obtain regulatory approval for the generics, since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term. Consequently, an explicit exception was introduced in the patent law, stating that acts solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products, other than those products primarily manufactured using certain genetic manipulation techniques, were not infringing acts.

²⁹⁴See WIPO 'Advice on Flexibilities under the TRIPS Agreement' available at http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (Date used 17 April, 2013.)

practices to implement enforcement obligations.²⁹⁵ WTO members are, for example, free to maintain their own judicial systems. They can also use enforcement measures to implement flexibilities as to standards of protection.²⁹⁶

4.7.4. Flexibilities as to areas not covered by the TRIPS Agreement

The TRIPS Agreement does not cover a number of areas of IP subject matter, either because no consensus could be achieved during the negotiation of the agreement, or because the areas in question had not yet emerged, or simply because the negotiators of the TRIPS Agreement did not consider that there were barriers-to-trade issues in those areas. Some of those areas are of particular interest to DCs are, for example, utility models, traditional knowledge, and handicrafts.

Unlike the ‘upward’ standards of protection mentioned above, these flexibilities lie outside the scope of the TRIPS Agreement. Therefore countries’ legislation on those topics/areas need not conform to the principles and provisions of the agreement. For example, the protection of traditional knowledge can be extended to foreigners on the basis of reciprocity only.²⁹⁷

4.8. Policy options for the implementation of TRIPS flexibilities

A government may use the flexibilities in the TRIPS Agreement to shape the broad scope of exclusive rights to medical substances both before a patent has been issued (pre-grant) and after a patent has been issued (post-grant).

Pre-grant flexibilities constitute a proactive tool by which a government may design generally applicable IP laws, while post-grant flexibilities are generally limited to particular cases where the government considers an existing monopoly right to be too broad. Governments wishing to limit exclusive rights to medical substances would be well-advised to pay particular attention to the pre-grant flexibilities as these may reduce the need to use post-grant tools. This is particularly important in the light of the possible tensions surrounding post-grant tools such as compulsory

²⁹⁵See Reichman JH & Hasenzahl INITIALS ‘Non-voluntary Licensing of patented inventions: The Canadian Experience’ online publication UNCTAD-ICTSD Issue No (2003) 8.

²⁹⁶See WIPO ‘Advice on Flexibilities under the TRIPS Agreement’ above referenced.

²⁹⁷See http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (Date used 13 June, 2013.)

licensing and parallel importations. Overall, national policy makers should be aware and may wish to take full advantage of both pre- and post-grant flexibilities.

For the purposes of this thesis, I shall focus principally on compulsory patent licensing as a post-grant remedy aimed at curtailing existing monopoly rights in DCs and LDCs.

4.8.1 Compulsory licences

Compulsory licences are mechanisms used by public authorities to authorise the use of patent-protected inventions by the government or third parties without the consent of the patent holder. Patent holders receive adequate compensation, usually in the form of a royalty. As clarified by the Doha Declaration, WTO members are free to determine the grounds upon which compulsory licences may be granted.²⁹⁸ Practice shows that they may be issued on various grounds of general interest -- such as public health -- and this is a common feature of patent law in both developed and developing countries. A government-use order is a specific type of compulsory licence, usually issued in the form of an order by a competent administrative or judicial authority, authorising a government or a party acting on behalf of the government, to exploit a patent provided that the exploitation is in the interests of the country in question.²⁹⁹

4.8.2 Rights under a compulsory licence: Doha developments

The licensee is authorised by the government to use the patented invention without the permission of the patent holder. However, as the licence is non-exclusive, the compulsory licence may face competition in the market from the patent holder and other licensees. This limitation may dampen the generic suppliers' interest in the market, unless the economic prospects are otherwise favourable, for example where countries coordinate their procurement strategies and, where necessary, pool the relevant compulsory licences.

²⁹⁸According to the TRIPS Agreement as interpreted by para 4 of the Doha Declaration.

²⁹⁹In the US a third party who uses a patented invention in the performance of a government contract in effect obtains immunity from liability for patent infringement. This is based on 28 US Code s 1498(a) which states that: 'Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.'

Another important qualification involves the exportation of products manufactured under compulsory licences, while the patent holder remains free to export its entire production, the TRIPS Agreement requires the compulsory licensee to use its production predominantly for supply to/in the domestic market (art 31(f)).³⁰⁰

This requirement has, however, been waived for exports to countries with insufficient pharmaceutical manufacturing capacity, as these countries would otherwise be unable to make effective use of compulsory licensing.

‘The waiver, as included in the 2003 WTO Para 6 Decision and the 2005 TRIPS Amendment Decision (draft art 31bis), enables a compulsory licensee to export his/her entire production to country in need of certain drugs that it cannot itself produce. In order for this waiver to apply, a system has been set up, which establishes different requirements for importing and exporting members.’³⁰¹

Attached to both the 2003 Paragraph-6 Decision, and draft article 31bis of the TRIPS Agreement, is a note from the Chairman of the Council for TRIPS, which elaborates on certain of the issues contained in the waiver.³⁰² These and other important issues on compulsory patent licensing are considered in detail in Chapters 5 and 6 of this thesis.

4.8.3 Parallel imports (parallel trading)

Companies often charge lower prices for a medicine in one country than in another, taking into account a range of market forces. This means that a country with limited resources can sometimes save by purchasing a patented medicine abroad at a lower price and importing it, rather than the purchasing country buying it directly from its domestic market at a higher

³⁰⁰See Jerome H Reichman & Christp Spenneman *Using Intellectual Property Rights To Stimulate Pharmaceutical Production In Developing Countries-A Reference Guide* (2011) 131.

³⁰¹See P Roffe, C Spennemann & J Von Braun ‘From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health’ in *Negotiating Health: Intellectual Property and Access to Medicines* (2006) 9-26, 20-22. See also C Correa ‘Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’ WHO Health Economics and Drugs EDM Series No 16 (2004); P Vandoren & JC Van Eeckhoutte ‘The decision on paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health: Making it work’ (2003) 6/6 *Journal of World Intellectual Property* 779 ff.

³⁰²In particular, the statement provides for some best practices developed by companies to prevent the diversion of products to markets they were not destined for.

price.³⁰³ Many countries' patent laws determine that once a patent owner sells its goods in any country, it has no right to control the resale of those goods (the so-called 'regime of international exhaustion').³⁰⁴³⁰⁵ In legal terms, the patent owner has 'exhausted' its property rights in the product actually sold. It maintains the exclusive right to manufacture the product, but it cannot use its IP rights to prevent resale of those units.

An intermediary could, therefore, buy a patented medicine in one country at the lower price set by the company and then resell it in another country at a price that is higher but still undercuts what the manufacturer is charging for its patented medicine in that country. This is termed 'parallel importation'.

Parallel imports are, therefore, possible only if the patentee's use and sales are exhausted in the importation destination. In the pharmaceutical context, where price differences between countries may be considerable, parallel imports constitute an important means of providing DCs with access to low-priced medicines.

In addition, they may provide an important source of pharmaceutical substances needed by generic manufacturers for their own production. For example, the exhaustion of patent rights in active pharmaceutical ingredients ('APIs') will enable local manufacturers to use these APIs in the production of pharmaceutical end-products.³⁰⁶

Parallel imports or parallel trading, however, falls outside the scope of this thesis. I have referred to it briefly for the purposes of clarity and illustration of the basic flexibilities available under the TRIPS Agreement.

³⁰³See UNCTAD *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A reference guide* (2009) 113-114.

³⁰⁴Article 6 of the TRIPS Agreement states that, for the purposes of dispute settlement under that Agreement, subject to the provisions of articles 3 and 4, nothing in the TRIPS Agreement shall be used to address the issue of exhaustion of intellectual property rights. The Doha Declaration clarified that the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of IP rights was to leave each member free to establish its own regime for such exhaustion without challenge, subject to the most-favoured-nation treatment and national treatment provisions contained in articles 3 and 4.

³⁰⁵See Correa & Yusuf n 167 above 61 where they state: 'The lack of regulation of this issue clearly shows the imbalance that the TRIPS Agreement has created between the interests of developed countries and those of developing countries.'

³⁰⁶Note that patent exhaustion in this case would not enable the local production to start making its own APIs as a copy of the imported API, because the exclusive right of 'making' (art 28 (1) (a) TRIPS Agreement) is not affected by exhaustion. By contrast, the imported APIs as such may be in the pharmaceutical production process.

4.9 Special provisions in the TRIPS Agreement relating to medicines

Articles 8 and 27 address the relationship between TRIPS and Public Health and provide in relevant part:

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

This article allows members to adopt measures necessary to protect public health and nutrition through national legislation. The measures taken must be consistent with the provisions of the TRIPS Agreement, although it appears that the article stresses that no member can be prevented from taking its own public interests into account.

27.2 Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

27.3 Members may exclude from patentability;

a) diagnostics therapeutic and surgical methods for treatment of humans or animals; ...

The Doha Declaration is an interpretative statement on the TRIPS Agreement in relation to health issued at the Fourth Session of the WTO Ministerial Conference in Doha on 14 November 2001.³⁰⁷ The Declaration states in paragraph 4, that the members agree that the TRIPS Agreement does not and should not prevent members from taking steps to protect public health.

Accordingly, while reiterating their commitment to the TRIPS Agreement, the members affirmed 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 regard, the members reaffirmed the right of WTO members to use, to the full, the

³⁰⁷See WTO 'Declaration on the TRIPS Agreement and Public Health' Fourth Ministerial 14 Nov 2001 Doha, Qatar WT/MIN(01)/DEC/2 available at <http://www.wto.org/english/thewto-e/min01-e/mindecl-trips-e.htm> (Date of use 28 April 2013.)

provisions of the TRIPS Agreement which provide flexibilities for this purpose. Paragraph 5 of the Declaration states that in the light of paragraph 4 above, while maintaining the commitments under the TRIPS Agreement, members recognise that these flexibilities include:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles;
- (b) each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; and
- (c) each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Furthermore, in order to resolve the problem of members with insufficient or no manufacturing capacity in the pharmaceutical sector facing difficulties in making effective use of compulsory licensing, following up on paragraph 6 of the Declaration, WTO members decided, in 2003, on a 'waiver' that removed limitations on exports under compulsory licences to LDC members and other members that have insufficient or no manufacturing capacity in the pharmaceutical sector for the patented product in question.³⁰⁸

4.9.1 TRIPS standards in respect of pharmaceuticals that developing countries should include in their patent legislation

1. Availability of patents for both pharmaceutical products and processes, inventions that are new, involve an inventive step (ie are non-obvious) and are capable of industrial application (or are useful).
2. Protection of the product directly obtained using a patented process.

³⁰⁸Decision of the General Council 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health available at http://www.org/English/tratop_e/implem_para6_e.htm (Date used XXXX.)

3. Availability of procedures at national level to enable patent owners to protect their rights against infringement.

In addition, if exceptions to patents rights and compulsory licenses are incorporated into patent legislation, they should be, respectively, limited and conditional to conform with the TRIPS Agreement.³⁰⁹

4.10. Conclusion

The TRIPS Agreement introduced global minimum standards for protection and enforcement of most forms of IP right, including patents. The TRIPS Agreement compelled WTO members to provide protection for a pharmaceutical product or process for a minimum term of twenty years. International conventions predating the TRIPS Agreement did not specify minimum standards for patent protection. At the time of the negotiations for its introduction more than 40 countries granted no patent protection for pharmaceutical products. The TRIPS Agreement also introduced detailed obligations for the enforcement of IP rights.

The TRIPS Agreement provides for transition periods, permitting DCs additional time to bring national legislation and practices into conformity with its provisions. The transition periods have meant that that pharmaceuticals or medicines patented before DCs implemented their obligations under the TRIPS Agreement will not receive patent protection. This, in turn, means that generic competition remains possible.

However, the TRIPS Agreement also contains provisions that allow a degree of flexibility and room for countries to fashion their own patent and intellectual property systems in the light of their developmental needs. This derives, in some cases, from the wording of its provisions – for example articles 1, 7, 27, 28, 30 and 31 – and, in others, from the absence of any specific rule either in the Agreement itself or in the Paris Convention prohibiting member states to adopt necessary measures to protect public health and nutrition through national legislation. But none of these clauses takes away from the fact that the TRIPS Agreement obliges countries to give up much of the diversity and flexibility in IP law and practices that existed beforehand.

³⁰⁹ Available at globaljournal.com/wp-content/uploads/2011/02/Janodia-et-al-41.pdf

CHAPTER 5

COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS

5.1 Introduction

The most important flexibility available under the TRIPS Agreement and the Doha Declaration is compulsory licensing. Compulsory licences are not a new phenomenon in international law. Their first recognition in legal statutes can be traced back to the United Kingdom statute of Monopolies of 1623.³¹⁰

Compulsory licensing promotes competition by establishing domestic competitors, assures affordability of drugs by promoting a domestic industry while at the same time it enables a patent holder to be compensated for the use of its invention.³¹¹ Many countries in the developed and developing world have provisions on compulsory licensing on their statute books.³¹² These are generally defined as ‘authorisations permitting a third party to make, use, or sell a patented invention without the patent owner’s consent.’³¹³ Because they limit the power conferred by patents, compulsory licences have long been controversial.³¹⁴ However, it is in the context of the Paris Convention for the Protection of Industrial Property of 1883, that the notion acquired its contemporary meaning.

5.2 Compulsory Licensing under the TRIPS Agreement

³¹⁰ C Correa ‘Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries’, Working Papers No 5 Geneva South Centre 1999.

³¹¹ See Holger Hestermeyer *Human Rights and the WTO: The case of patents protection and access to medicines* (2007) 329.

See also WTO OMC ‘Fact Sheet: TRIPS and Pharmaceutical Patents’ Sept 2006 6 available at http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_epdf discussing import and export guidelines related to compulsory licenses under TRIPS (Date used 14 April, 2013.)

³¹² See Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000) 7.

³¹³ See FM Scherer & J Watal ‘Post-TRIPS Options for Access to Patented Medicines in Developing Countries’ Comm’n on Macroeconomics & Health, Working Paper No WG4:1 (2001) 12 available at http://www.cmhealth.org/docs/wg4_paper1.pdf. (Date used 14 April, 2013)

³¹⁴ Although this thesis focuses on compulsory licences in the patent context, these licences also arise in the context of other intellectual property, such as copyrights. See Robert A Gorman & Jane C Gingsburg *Copyright* 6 ed (2002) 498-505 where they describe the introduction of compulsory licensing into US copyright law in 1909 and discuss 17 US Code s 115 which permits the taking of licences to publicly distributed phonograph records without the permission of the copyright holder.

Article 31 of the TRIPS Agreement sets out a regulatory framework for compulsory licensing. It must be pointed out that article 31 is by no means exhaustive as members may rely on other grounds to invoke the use of compulsory licensing.³¹⁵ The TRIPS Agreement contains a more comprehensive framework for the compulsory licensing of patented inventions than that provided by the Paris Convention.³¹⁶ The Agreement also makes it clear that, for public health reasons, countries may suspend patent protection over drugs.³¹⁷

Article 31, which is entitled 'Other Use without Authorisation of Right Holder' permits WTO member countries to authorise compulsory licences for use by government³¹⁸ or third parties subject to certain restrictions. Under all circumstances, patentees are to receive 'adequate remuneration ... taking into account the economic value of the authorisation.'³¹⁹ Before licences are granted, the proposed user must have tried, unsuccessfully, for a reasonable period to secure a licence on reasonable terms.³²⁰

However, this requirement is waived if there is 'a national emergency' or 'a circumstance of extreme urgency', or if the patented invention is for 'public non-commercial use'.³²¹ Such use must be non-exclusive and non-assignable. Additionally,³²² unless the patentee has engaged in anti-competitive behaviour, the use must be predominantly for domestic market.³²³

³¹⁵ R Elliot *Trips and Rights: International Human Rights Law, Access to Medicines, and the interpretation of WTO Agreement on Trade Related Aspects of Intellectual Property Rights* (2001) 50.

³¹⁶ In the 1980s and early 1990s, a diplomatic conference attempted to revise the oldest international convention providing some protection for patented inventions outside of the domestic laws. See Jerome H Reichman 'Compulsory licensing of patented pharmaceutical inventions: Evaluating the options' 2009 *Journal of Law, Medicine and Ethics* 247.

³¹⁷ Where a DC finds that it is in the public interest to encourage domestic production of patented medicines for the purposes of controlling and preventing diseases, and in the interests of availability and affordability, compulsory licensing will be a vital tool. However, this may not be sufficient. At present, only around four DCs -- Argentina, Brazil, India and China -- have strong enough national pharmaceutical sectors to be able to develop and manufacture new medicines through the process of reverse engineering. Therefore, these are the DCs that are in a position to use compulsory licences to enable domestic firms to manufacture patented drugs. See Balasubramaniam K 'Access to Medicines: Patents, Prices and Public Policy - Consumer Perspectives' paper presented at Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement? Brussels 20 March 2001.

³¹⁸ Compulsory licenses for government use are often framed in broad terms and may be subject to less procedural requirements than are compulsory licenses. See 'Regional Issues Brief: Intellectual Property Rights and Access to Medicines' (2001) 4.

³¹⁹ TRIPS Agreement art 31(h).

³²⁰ Id art 31(b).

³²¹ Ibid.

³²² Id art 31(d)-(e).

³²³ Id art 31(f)-(k).

Finally, the scope and duration of use is limited to the purpose authorised within a licence and is subject to termination ‘if and when the circumstances which led to it cease to exist and are unlikely to recur’.³²⁴

Article 30 authorises general exceptions to patent protection, presumably including compulsory licensing, but states that these exceptions must neither ‘unreasonably conflict with a normal exploitation of the patent’, nor ‘unreasonably prejudice the legitimate interest of the patent owner.’³²⁵

While articles 30 and 31 apply to patents in all fields, articles 8 and 27, as well as the Doha Declaration, explicitly address the relationship between TRIPS and public health. Article 8 states that: ‘Members may ... adopt measures necessary to protect public health’, but adds the requirement that ‘such measures [must be] consistent with the provisions of this Agreement’.³²⁶

Article 27 allows member countries to exclude inventions needed to protect public health from patentability.³²⁷

5.3 Grounds for the grant of compulsory licences

The TRIPS Agreement does not set any explicit limitation on permissible grounds for the issuing of compulsory licences. From the wording of article 31 of the TRIPS Agreement, WTO members are free to determine several reasons specified in their national laws for the grant of compulsory licences for pharmaceutical patents.³²⁸

Nevertheless, the TRIPS Agreement refers to five specific grounds for the granting of compulsory licenses.

- Refusal to deal (article 31 (b))³²⁹

³²⁴ Id art 31(g).

³²⁵ Id art 30.

³²⁶ Id art 8(1).

³²⁷ Id art 27(2).

³²⁸ The TRIPS Agreement does not set any explicit limitation of the permissible grounds for the issuing of compulsory licences. From the wording of the TRIPS Agreement, WTO members are free to determine several other reasons as specified in their national laws. See Correa *Intellectual Property Rights, The WTO and Developing Countries. The TRIPS Agreement and Policy Options* (2000) at page 7

³²⁹ Chinese and Argentine patent laws have established the ‘refusal to deal’ by a patent-holder as a legal ground for a compulsory licence.

- Emergency and extreme urgency (article 31 (b))
- Anti-competitive practices (article 31(k))
- Non-commercial use (article 31(b))
- Dependent patents (article 31 (l)).

Article 31 of the TRIPS Agreement provides that a member may, without authorisation of the rights holder and under the stipulated conditions, allow use other than that permitted under article 30. Those other uses are typically compulsory licences and government use without the authorisation of the rights holder. The conditions laid down in article 31 are:

- “(a) Authorisation of such use shall be considered on its individual merits;
- “(b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.

In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.³³⁰ In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

- “(c) The scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.
- “(d) Such use shall be non-exclusive;
- “(e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

³³⁰ This was the case when Zambia granted a compulsory licence to Pharco Ltd (compulsory licence No CL 01/2004) on 21 September 2004. Immediately thereafter the Zambian government sent letters to the two right holders concerned, informing them of the compulsory licence.

- (f) Any such use shall be authorised predominantly for the supply of the domestic market of the member authorising such use;³³¹
- (g) Authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation;
- (i) The legal validity of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;
- (j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorisation if and when the conditions which led to such authorisation are likely to recur;³³²

³³¹ Abbott has pointed out that this provision constitutes an obstacle to realising access to medicines for poor populations as in Africa in two ways. 'Firstly, by limiting availability of export drugs made under compulsory licensing, it invariably restricts countries that are unable to support manufacturing under compulsory licensing (or where patent protection is not in force) in the availability of supply of generic drugs. Secondly, requiring compulsory licensees to restrict a predominant part of their production to domestic market, limits flexibility of countries to authorise the export of compulsory-licensed drugs and thus to exploit economy of scale.' See FM Abbott 'WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries' report prepared for Intellectual Property Rights Commission (2002) 17. However, if and when use is a remedy for anti-competitive practices, there is no limitation on exports.

³³² This provision is very important and may be used as an exception to the limitation under Article 31(f) and the paragraph 6 Decision of the Council for TRIPS. It also appears from this provision that a generic manufacturer operating under a compulsory licence could do so on a large scale for export purpose especially when a non-special and a non-para 6 compulsory licence have been granted in the importing country.

See B.K Baker, 'Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health', 14 Indiana International and Comparative Law Review (2004) p.613 at p.664.

Furthermore Article 31(k) is not subject to paragraph 6 of the Decision of the Council for TRIPS as paragraph 9 of the Decision itself provides thus:

'This Decision is without prejudice to the rights, obligations and flexibilities that members have under the provisions of the TRIPS Agreement other than paragraph (f) and (h) of Article 31, including those reaffirmed by the

- (1) Where such use is authorised to permit the exploitation of a patent ('the second patent') which cannot be exploited without infringing another patent ('the first patent'), the following additional conditions shall apply:
- (i) Inventions claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.
 - (ii) Owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
 - (iii) Use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.”

When granting a compulsory licence, several conditions must be met. First, there needs to be a case-by-case evaluation and decision, meaning that each case must be considered on its individual merits.³³³

Secondly, prior request to the patentee for a voluntary licence has to be made and a determination of the scope and duration of the licence must be completed.³³⁴

Thirdly, the licence must be non-exclusive and preferably for the domestic market, which means that a compulsory licence with the purpose of supplying a third market, is not permitted unless local supply is dominant or it involves anti-competitive issues.³³⁵

Fourthly, the patent holder must receive adequate remuneration³³⁶ and the possibility of requesting the revision of decisions and revocation of the licence must exist.³³⁷

Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement’.

Article 31(k) may be interpreted as allowing for reduced remuneration or even for a “royalty-free” licence. In the US, many compulsory licenses have been granted in order to remedy anti-competitive practices. In some cases, these licences have been granted “royalty-free”. See Fugate 1991.

³³³ TRIPS, Article 31(a)

³³⁴ Prior negotiation is not required under Article 31 (b) and (k) of the TRIPS Agreement where the license is being sought with respect to: (1) an emergency or other matter of extreme urgency (note: HIV/AIDS, TB, and malaria are presumptively such emergencies, Doha Declaration, Paragraph 5(c) ;

(2) governmental, non-commercial use; and

(3) remedies for anti-competitive practices.

³³⁵ TRIPS, Article 31(f)

³³⁶ TRIPS, Article 31(h)

The conditions that govern the granting of compulsory licences will determine the extent of the system's effectiveness in promoting local innovation and the transfer of technology. It should be noted that, as reported in the case of the United Kingdom,³³⁸ the fact that the number of applications for such licences may be low does not necessarily mean that the system is ineffective. The existence of a statutory provision itself may persuade right holders of the need to act reasonably in cases of requests for voluntary licences, while strengthening the bargaining position of potential licensees.

Such licences are a critical tool in promoting effective price negotiations with patent holders and for enabling local production, importation, and distribution of patented medicines at affordable prices.³³⁹

All in all, the granting of a compulsory licence is in compliance with the TRIPS Agreement if the provisions and qualifications imposed by article 31 are met, and the other provisions of the Agreement are taken into consideration.

5.4 Scope and duration

In terms of the TRIPS Agreement, the scope and duration of the authorisation 'shall be limited to the purpose for which it was authorised'.³⁴⁰

Among the options that DCs may consider, is whether to grant the compulsory licence for the manufacture and/or the importation of the protected products. In many cases (such as where large investments are required, where there are barriers to accessing operative technology, or where there is a need to remedy anti-competitive practices or to address emergency situations), the only effective way of using a compulsory licence would be through importation.

In addition, in order to be effective a compulsory licence should in most cases be granted for the life of the patent since a shorter period may not permit the amortisation of required investments.

³³⁷ TRIPS, Article 31(g)

³³⁸ See Cornish, W. (1989), Intellectual Property, Patents, Copyright, Sweet & Maxwell, London, p. 205

³³⁹ See, A comprehensive description of Thailand's public health approach to the provision of medicines, can be found at Ministry of Public Health and National Health Security Office, Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, February 2007, ISBN 978-974-94591-5-7.

³⁴⁰ TRIPS, Article 31(c)

5.5 Preconditions for exploiting compulsory licences

In order for a country to be able to invoke compulsory licensing as a public policy instrument to promote access to medications, the following must be established:

1. It must be shown that the party granting the license within the country has the capability to exploit it either through manufacturing subject invention or importing it. This obviously requires financial ability or technical capability.³⁴¹
2. If local manufacturing of the subject of invention is to be undertaken, there must be evidence of adequate purchasing power among the local population to justify investment by the party exploiting the license (or opportunities must be available). Where the population is small or poor, as in most African countries, there may not be a guarantee of returns for investment.³⁴²
3. Where the government is the party exploiting the compulsory licence that is for government – use- or as purchasing agent on behalf of the population acquiring the invented subject, there must be evidence of financial resources or technical capability.³⁴³
4. There must be evidence of an existing sound legal and political structure to permit the granting and monitoring of the license.³⁴⁴

It would appear that in the light of by these preconditions for exploiting compulsory licences only developed countries and few DCs would be able to make use of this mechanism successfully.

Many African countries, with the possible exception of South Africa and Egypt, lack the financial capacity and the technical expertise to meet these pre-conditions.

This notwithstanding, the issuing of compulsory licences, especially in case of export, remains a viable tool in advancing access to medicines and the right to health in Africa and many other DCs.

³⁴¹ F.M. Abbott, WTO TRIPs Agreement and its implication for Access to Medicines in Developing Countries, a report prepared for the Intellectual Property Rights Commission (Washington DC, Intellectual Property Rights Commission 2002) p. 13.

³⁴² F.M. Abbott supra at p.13.

³⁴³ F.M. Abbott supra, at p.13

³⁴⁴ F.M. Abbott supra at p. 14

5.6 Obstacles to the use of compulsory-licensing provisions under the TRIPS Agreement

It is important that the right of governments to use compulsory licences is upheld and respected.

The above provisions of the TRIPS Agreement are subject to numerous conditions, making them difficult to be used effectively and speedily. More significantly, although the TRIPS Agreement allows for these measures to be undertaken for the protection of public health, some developed countries have sought to give a narrow interpretation of the provisions relating to compulsory licences to restrict the scope of the measures. This situation led to the perception that there is a lack of legal clarity or common understanding of the provisions in the TRIPS Agreement.

In 2001, the Africa Group led by Zimbabwe, stated

... recent legal challenges by the pharmaceutical industry and some members in national law and the WTO/DSU have highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement.

This was a reference to the cases of Brazil and South Africa. In the WTO, Brazil was taken by the USA to the WTO dispute settlement system for enacting legislation (which was yet to be enforced) allowing for compulsory licensing in cases of non-local working, ie, where the patent is not exploited locally.³⁴⁵ In South Africa, the government was challenged in the court by 39 pharmaceutical companies³⁴⁶ which sought a court order that the South African legislation on compulsory licensing was illegal. The companies later abandoned the case.

These cases have made it extremely difficult for DCs to include such legislations into their national laws for fear of sanctions from developed countries like the United States.

³⁴⁵ “Brazil, a country that has provided comprehensive HIV care to all citizens in need since 1996, including highly active antiretroviral therapy received a direct challenge in 2001 from the U.S. after Brazil threatened to issue compulsory licenses for some ARVs. The U.S. filed a complaint in the WTO Dispute Settlement Body, charging that Article 68 in the Brazilian intellectual property law which permits compulsory licensing directly violates TRIPS. Brazil countered that Article 68, to the contrary, promoted the objectives established in TRIPS of ensuring the protection of public health in pharmaceutical matters. Under enormous international pressure, the U.S. withdrew its WTO complaint against Brazil, marking victory for activists”.

See t’Hoen EFM. TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha, and beyond. In Agence Nationale de Recherches sur le Sida, editors. Economics of AIDS care in developed countries: issues and challenges. Paris: Agence Nationale de Recherches sur le Sida; 2003.p. 39-67.

³⁴⁶ Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa. Case No. 4183/98 (Filed on 18th February, 1998)

Some developed countries in conjunction with their corporations and industry lobbies were also exerting political pressure on DCs to prevent them from exercising their rights under the TRIPS Agreement,³⁴⁷ and from enacting policies and laws on compulsory licencing for HIV/AIDS and other drugs.³⁴⁸ ³⁴⁹ Examples of this pressure include the bilateral pressure applied on the South African government by the US administration, which was subsequently eased when AIDS activists caused significant embarrassment and damage to Al Gore's presidential campaign. Thailand was the target of similar US pressures. In Thailand, US pressure was brought to bear on the Thai government to ban parallel imports, and to restrict the use of compulsory licences under threat of high tariffs on Thai exports.³⁵⁰

Non-compliance with the obligations stipulated by the TRIPS Agreement may only lead to action by other states and not by affected private parties. In a situation where a WTO member fails to adhere to certain minimum standards, no country can unilaterally apply trade sanctions against the erring WTO member. Such complaints are expected to be referred to the Dispute Settlement Understanding ('DSU') and dealt with under the multilateral procedure established by it.

This clearly outlaws unilateral retaliation as applied by the USA under section 301 of the US Trade Act.³⁵¹

³⁴⁷ Medecins Sans Frontieres (MSF) 2001: US Action at WTO Threatens Brazil's successful AIDS Programme.

³⁴⁸ Affordable, quality generic medicines are a critical component of treatment programs. About 80% of the HIV medicines that MSF uses are generics, and MSF routinely relies on generic drugs to treat TB, malaria, and a wide range of infectious diseases. Infact all the major donors and leading international treatment providers, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, The US President's Emergency Plan For AIDS Relief (PEPFAR), UNITAID and UNICEF, rely on quality affordable generic drugs for the programs they support. PEPFAR which purchases about 80 to 90% of its ARVs drugs from generic supplies has reported significant savings through the purchase of generic medicines. See <http://jama.ama-assn.org/content/304/3/313.short>

³⁴⁹ The first generation of HIV drugs have come down in price by 99% over the last 12 years, from US\$10,000 per person per year in 2000 to roughly US\$60 today, thanks to generic production in India, Brazil and Thailand, where these drugs were not patented. This dramatic price drop has been instrumental in helping scale up HIV/AIDS treatment for more than six million people in developing countries. About 80% of donor funded anti-AIDS drugs to treat children with AIDS across the developing world comes from generic manufacturers. See Doctors without borders/Medecins Sans Frontieres (MSF) Campaigns for Access to Essential Medicines TPP Brief-Sept 2011.

³⁵⁰ Barshefsky, C. 2000. Letter from USTR Charlene Barshefsky to Supachai Panitchpakdi, Thailand's Deputy Prime Minister and Minister of Commerce.

³⁵¹ See Carlos Correa 2000 supra at page 11.

Threats by the USA are completely illegitimate under the TRIPS Agreement. They disregard binding international rules, and deprive DCs of their right to take the necessary time to introduce legal reform and adopt measures that mitigate their eventual negative economic and social impact.³⁵²

Pressure from the USA is exerted principally with regard to pharmaceutical products under the direct influence of the powerful US pharmaceutical industry. The US government has shown no interest in accelerating conformity with the TRIPS Agreement in other areas, such as geographical indications, plant breeders' rights, or industrial designs.³⁵³

5.7 The use of compulsory licensing for medicines in selected developed countries

5.7.1 Introduction

A large number of DCs have provisions in their national legislation which allow the government and/or third parties to use a patented invention without the authorisation of the right holder, under certain circumstances and subject to certain conditions. These provisions differ from other exceptions, since, while the injunctive relief is significantly limited, the right to remuneration for the use is maintained. In general, these provisions are regarded as an instrument to prevent abuse of the exclusivity inherent in patent rights.

They are also seen as tools to ensure that the patent system contributes to the promotion of innovation in a competitive environment, and to the transfer and dissemination of technology, meeting the objectives of the system and responding to the public interest at large. They can also be used by governments as safeguards to ensure national security and to respond to national emergencies.

5.7.2 Compulsory licensing in Canada

³⁵² Illustrative of this situation is the case of Argentina, where the Parliament approved a new patent law in May 1995. During the legislative process, the US government repeatedly threatened Argentina with unilateral trade retaliations. Its main argument was lack of retroactive ("pipeline") protection for pharmaceutical patents, ignoring the transitional period that Argentina can apply in accordance with Article 65 of Agreement.

See Carlos Correa supra at p. 12

³⁵³ See Carlos Correa 2000 supra at p. 10

Canada has the most extensive experience in the use of compulsory licences for pharmaceutical drugs.³⁵⁴ Under pressure from the USA, and as a condition for joining the North American Free Trade Agreement (‘NAFTA’), Canada had to abandon its compulsory licensing regime which operated almost automatically. Canada routinely³⁵⁵ granted compulsory licenses on pharmaceuticals, with compensation based upon royalties, typically set at four per cent of the competitor’s sales price.³⁵⁶ Any would-be generic distributor could apply for a ‘license of right’, and if successful, could produce and market the patented medicine at competitive prices in return for this four per cent royalty. In Canada compulsory licensing was used to promote price competition for medicines for almost 70 years.³⁵⁷

Following an anthrax outbreak in the USA in 2001, the government of Canada announced that it had overridden Bayer’s patent on *ciprofloxacin*, the antibiotic thought to be most effective against anthrax, and granted a compulsory licence to a Canadian generics producer so that the government might secure low-cost and prompt access to supplies. *The New York Times* reported:

“These are extraordinary and unusual times”, said Paige Raymond Kovach, a spokeswoman for Health Canada. “Canadians expect and demand that their government will take all steps necessary to protect their health and safety”.³⁵⁸

³⁵⁴ See Jessica J. Fayerman, *The Spirit of TRIPS and the Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 *NW J. Int’l L. & Bus.* 257, 265 (2004).

³⁵⁵ See F. M. SCHERER, *The Economic Effect of Compulsory Patents Licensing* (1977) at p 83. The Canadian Parliament abolished the program in 1993 after intense lobbying by the U.S. government during NAFTA negotiations. Objecting vigorously to Canada’s broad embrace of compulsory licensing, the U.S. government feared that other countries might follow suit. See REICHMAN & HASENZAHN *Non-Voluntary Licensing of Patented Inventions Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, Issues paper number 5; Geneva: UNCTAD-ICTSD Project on IPRs and Sustainable Development. Note 7, at 21-22

³⁵⁶ S. Flynn, A. Holis, and M. Palmedo, in “An Economic Justification for Open Access to Essential Medicines Patents in Developing Countries,” *Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 184-209, cast a yearning glance back to the days before the 1992, when Canadian law imposed a “license of right” on all patented pharmaceutical products marketed in that country.

³⁵⁷ Beginning in the early 20th century Canada actively encouraged industrial development by stimulating local production through its patent law. It required patentees to work the patent locally, which meant that production within Canadian borders or licensing on reasonable grounds was a prerequisite to maintaining a patent. In 1935, compulsory license replaced revocation of the patent as a remedy for failure to work locally. Canada took these measures because it considered its level of development insufficient to merit more stringent patent policies.

³⁵⁸ Amy Harmon and Robert Pear, ‘Canada Overrides Patent for Cipro to Treat Anthrax’, *NY Times* (19 October 2001). The Canadian government later took the position that the actions of its Health Department had been a mistake, and entered into a settlement with Bayer and the local generics producer. The later actions by the Canadian government were publicly taken in such air of confusion that, in retrospect, Canadian officials would not be faulted

5.7.3 Compulsory licensing in the United Kingdom

The use of compulsory licensing in the UK dates back 1623 when the UK Statute of Monopolies permitted the taking of patents for lack of working.³⁵⁹ Section 23 of the UK Patent Act of 1883 allowed the use of compulsory licensing for cases in which the patent was not being worked in the UK, the reasonable requirements of the public were not being satisfied, or any person was prevented from working or using an invention.

The UK further has a history of Crown use in the provision of generic medicines to the National Health Service ('NHS'). In 1965 Pfizer challenged this practice arguing³⁶⁰ that the 'use drugs to treat hospital patients was not use "for" the Crown'. The case reached the House of Lords which ruled in favour of the Ministry of Health.

5.7.4 Compulsory licensing in the United States of America

During the 1990s several trends came together in the USA to focus greater attention on drug pricing. The most prominent of these was the 'relentless escalation' of health care costs.³⁶¹ By 1992, the USA devoted fourteen per cent of its gross national product to health costs, more than any other industrialised country.³⁶² There was an increase in the price of drugs than it was on other goods and pharmaceutical profitability was higher than those of other industries. The unsuccessful Hart Bill of 1993 and Affordable Prescription Drugs Act of 1999, made a proposal for compulsory licensing of health-related patents in different circumstances, such as unreasonable pricing..³⁶³

for wondering if they might have been better off playing out their opening hand. See Brian Laghi and Heather Scofield, 'Ottawa Pays Twice for Cipro', *Globe and Mail* (23 October 2001)

³⁵⁹ See C. Correa, 'Intellectual Property Rights and the Use of Compulsory License: Options for Developing Countries', Working Papers No.5 (Geneva, South Center 1999)

³⁶⁰ *Pfizer v Ministry of Health* RPC 261 (HL)

³⁶¹ Scherer, Pricing, supra note 50, at 97.

³⁶² Id.

³⁶³ See Joseph A. Yosick, Compulsory Patent Licensing for Efficient Use of Inventions, 2001 U. ILL.L. REV. 1275, 1278 (2001)

In 2000 and 2002, Presidents Clinton and Bush respectively blocked the implementation of bills that would have enabled prescription drug wholesalers to import drugs from countries where they were cheaper.³⁶⁴

In the 1960s and 1970s, the USA government produced and used *tetracycline*³⁶⁵ and *meprobamate*³⁶⁶ for the military without permission from the patent holders. Similarly, during the 2001 anthrax outbreak, the threat of compulsory licensing was used to drive down the price of the patented drug *Cipro* by almost 50 per cent.³⁶⁷ In the United States many compulsory licenses have been issued as a result of antitrust orders. These compulsory licenses were granted to remedy patent abuse. One of the important and significant early cases on patent abuse was in respect of an antibiotic price-fixing scheme, which involved the licensing of tetracycline, ampicillin, and similar products. This was part of court judgment against Pfizer, American Cyanamid and some other pharmaceutical companies.^{368 369 370}

³⁶⁴ See Mason Essif, Prescription Drugs are Crossing Borders to Buyers, CNN.com, Mar. 12, 2001, at <http://www.cnn.com/2001/HEALTH/03/12prescription.drugs>.

See also Robert Pear, Plan to Import Drugs from Canada Passes in Senate, but Bush Declines to Carry It Out, N.Y. Times, July 18, 2002, available at 2002 WL 24463223

³⁶⁵ See SCHERER & JAYASHREE WATAL,, POST-TRIPS OPTIONS FOR ACCESS TO PATENTED MEDICINES IN DEVELOPING COUNTRIES 13 (Comm'n on Macroeconomics & Health, Working Paper No. WG4:1, 2001), available at http://www.cmhealth.org.docs/wg4_paper1.pdf (last visited, August.12,2010) note 3 at 26

³⁶⁶ *Carter –Wallace, Inc. v. United States*, 496 F.2d 535 (CT. Cl. 1974).

³⁶⁷ In November, 2001, the consideration given by the US government to use compulsory licensing in order to obtain adequate supplies of anti-anthrax antibiotics 'brought the story of WTO patent rules into the living rooms of millions of people. See Ruth Mayne Global Campaign on Patents: Oxfam Perspectives, published in Global Intellectual Property Rights: Knowledge, Access and Development ed. by Peter Drahos and Ruth Mayne , at p.252

³⁶⁸ FM Scherer in Royalties on Compulsory Licenses,2003 in his remarks on the extensive use of compulsory licensing as a remedy to anticompetitive practices stated as follows:

“The United States has led the way in issuing compulsory licensing to restore competition when violators of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred.. By the end of the 1950s, compulsory licenses had been issued in roughly 100 antitrust cases covering an estimated 40 to 50 thousand patents, including AT & T 's basic transistor concept patents, IBM's Computer and tabulating card machine patents, General Electric Flourescent and incandescent lamp patents, Dupont's nylon patents, and Eastern Kodak's colour film processing patents. Additional cases since then have led to licensing of Xerox's plain paper copying machine patents, the tranquilizer metrobamate, synthetic steroids, the antibiotic Griseofuluin, Cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent patent rights assembled under pharma AB with Upjohn.....Some of the US anti- trust decrees, such as those covering General Electric's Incandescent Lamp patents and many of the patents in AT & T's portfolio, required licensing at Zero royalty rates. Most provided for “reasonable” royalties.....”

³⁶⁹ SCHERER & WATAL, supra note 3, at 17.

³⁷⁰ See In Am. Cyanamid Co., 63 F.T.C. 1747 (1963); Peter Temin, Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry, 10 BELL J. ECON. 429, 435-41(1979)

Most national patent laws have special provisions for use of inventions by the government or contractors providing goods or services to the government. In the USA such use is provided under 28 USC 1498.³⁷¹ Under this statute, the USA government does not have to negotiate for the use of a patent or copyright: any federal employee can use or authorise the use of any patent or copyright and cannot be sued for infringement.

According to Professor Reichman:³⁷²

‘When evaluating the workings of section 1498, one should understand that it does not empower the government to convert a patentees’ exclusive rights into the kind of non-exclusive use rights available to private parties under a typical compulsory licensing provision imposed for reasons of public interest.³⁷³ In this respect, government use of patents and other intellectual property rights (including copyrights, plant breeders’ rights, and semiconductor chip design rights). Hence courts and commentators often characterized section 1498 as ‘a compulsory licence in eminent domain’ and the government is not treated on the same footing as an ordinary infringer in cases arising under the statute.’³⁷⁴

5.8 The use of compulsory licensing for medicines in selected developing countries

5.8.1 Brazil

Brazil, a middle-income country, has led the way in ensuring that patents do not prevent appropriate care for the sick, by reforming its law to break patents monopoly in order to continue providing free ART for HIV-positive Brazilians. Brazil’s AIDS program has been the most

³⁷¹ 28 USC Section 1498 (a) states that:

“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without licence of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be an action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture”.

³⁷² See Reichman J.H, *Compulsory Licenses: History and Legal Principles*, 2003.

³⁷³ See J.H Reichman and Hasenzahl, *Non-voluntary Licensing of Patented Inventions Historical Perspectives, Legal Framework under TRIPs, and an overview of the practice in Canada and the USA*, Issues paper number 5, Geneva: UNCTAD Project on Intellectual Property Rights and sustainable development.

³⁷⁴ Brunswick, 36 Fed. CL at 2007 (adding that “this exercise of the government’s right is not a taking in violation of the fifth Amendment, for the government has statutory right to use a patented devise”.

successful in the world because it has the ability to produce these medicines locally.³⁷⁵ Eight ARVs are produced locally as generics in Brazil.³⁷⁶

In the past Brazil has actively used compulsory licensing as a threat to negotiate lower prices for AIDS drugs.³⁷⁷ In 2001 Brazil received a direct challenge from the USA after it threatened to issue compulsory licences for certain ARVs. International pharmaceutical companies threatened to withdraw investments from Brazil and persuaded the USA to request a WTO dispute settlement. The USA filed a complaint in the WTO dispute settlement body,³⁷⁸ charging that the new article 68³⁷⁹ in Brazilian IP law directly violates the TRIPS Agreement. The Brazilian government decided to stand up to the USA³⁸⁰ and because of the success of its AIDS program, gained strong support from AIDS activists and NGOs both in Brazil and globally.

Under great pressure the USA withdrew its WTO complaint against Brazil.³⁸¹ This marked a huge victory for health activists worldwide and encouraged the Brazilian government to threaten compulsory licensing. The threat of compulsory licensing has enabled the government to negotiate enormous price reductions for ARVs from major pharmaceutical companies.³⁸²

³⁷⁵ See Tina Rosenberg, 'Look at Brazil', Sunday Magazine (28 January, 2001)

³⁷⁶ These are: Zidovudine, Stavudine, Didanosine, Lamivudine, Nevirapine, Ritonavir, Saquinavir and Indinavir (Brazil Ministry of Health presentation at the International AIDS Society meeting (IAS) 2005)

³⁷⁷ The Brazilian government was the first to aggressively (and successfully) use compulsory licensing threats in their negotiations with several U.S Pharmaceutical companies for affordable AIDS drug imports. See Roger Bate, Threats to Patents, Treat to Health, TCS Daily (July 21, 2005) available at <http://www.techcentralstation.com/072105H.html>.

³⁷⁸ See Request for consultation by the United States, Brazil-measures affecting patent protection, WT/DSS199/1/G/L/385, IP/D23, 8 June 2000 and Request for the Establishment of a Panel by the United States, Brazil-measures affecting patent protection, WT/DS199/39, January 2001.

³⁷⁹ Article 68 permits compulsory licensing if the patent holder does not produce a product locally within three years of the granting of the patent.

Industrial Property Law Act No. 23 (1998), which provides: 'A patent owner shall be subject to the grant of compulsory license of his patent if the rights resulting therefrom are exercised in abusive manner or if the patent is used in abuse of economic power, as proven by an administrative or judicial decision pursuant to the provisions of the law.'

³⁸⁰ Brazil argued that its ART 68 was in line with the letter and spirit of the TRIPS Agreement, including Art 5.4 of the Paris Convention, which allows for compulsory licensing if there is failure to work a patent.

³⁸¹ See Joint Communication Brazil-United States, 25 June 2001. The US had by this time effectively been condemned by the UN Commission on Human Rights (Resolution 2001/33, Access to Medication in the Context of Pandemics such as HIV/AIDS, 57th Sess. April 2001)

³⁸² BBC News. New anti-HIV drug deal for Brazil. <http://news.bbc.co.uk/1/hi/world/americas/3281683.stm> (accesses 8/April/2014).

Brazil also enacted a decree on compulsory licensing which established rules for the granting of compulsory licences in instances of national emergency and public interest.³⁸³ In the post-Doha scenario, public health crisis is an accepted ground for compulsory licensing. However, the decree goes much further than that and provides that compulsory licences can be granted in cases where public interest is involved.

5.8.2 Thailand

Like Brazil and many other DCs, Thailand was also facing rising drug costs because of the need to access second-line ARVs that were patent protected in the country. As result of these high drug prices, the government of Thailand issued government-use ('GU') orders between 2006 and 2007 for three drugs on its national essential medicines list. The government measures were urgent as the drugs were simply not available.

Although the measures taken by the government were both compliant with and permitted under the TRIPS Agreement and the Doha Declaration, they nonetheless drew criticism from politicians, pharmaceutical companies, and the media. Abbott, the pharmaceutical company that held patents for the drugs, not only announced that it would no longer register new drugs into Thailand's market, but also launched a campaign to spread false information about Thailand's licensing process. It stated that Thailand 'has chosen to break patents on numerous medicines, ignoring the patent system.'³⁸⁴ Between 2005 and 2007 Thailand's foreign investment dropped by \$10 billion.³⁸⁵

In fact, to date Thailand is the only country to have issued a compulsory licence for an antiretroviral drug and explains why other countries have been reluctant to follow suit.

5.9 Compulsory licences issued by selected sub-Saharan African countries

³⁸³ Brazil: Presidential Decree on compulsory licensing, Decree No 3, 201 of 6 October, 1999.

³⁸⁴ Cawthorne et al. (2007 May) Access to drugs: the case of Abbott in Thailand. Retrieved from <http://www.science-direct.com/science/article/B6W8X-4NTFGJO-4/2/05f2eecb78d0b237f390986>

³⁸⁵ Bhaopichtr et al. (2007) Thailand Economic Monitor, page. World Bank Office Bangkok. Retrieved from http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2008april_tem.pdf

5.9.1 Ghana

The Ghanaian Minister of Health issued a GU order for the importation of generic versions of selected ARVs patented by Glaxo-SmithKline (GSK) in October 2005.³⁸⁶ The imported HIV/AIDS drugs were to be for government use in the treatment of infected people without commercial gain. The drugs were to be supplied by generic manufacturers based in India.

Prior to these developments, Ghana had entered into discussions with Canadian NGOs with a view to using the Canadian patent reform implementing the paragraph 6-mechanism -- the Jean Cretiens Pledge to Africa Act (formerly known as Bill C9) -- to import generic drugs. Ghana wished to secure a compulsory licence and to act as a regional hub through which to benefit other member countries of the Economic Community of Western African States ('ECOWAS').³⁸⁷ Bill C9 was intended to enable Canada's robust generic industry (robust due in part to past use of compulsory licence flexibilities by the Canadian government) to take advantage of the WTO decision for the benefit of DCs. Regrettably, these negotiations stalled.³⁸⁸ Apart from coordination difficulties in Ghana, features of Bill C9 itself created further impediments, including restrictions on eligible drugs (Schedule 1), eligible recipients (only listed countries can use the mechanism, and not NGOs or others), and a limited two-year duration for the compulsory licence which makes it difficult for the generic manufacturers to recoup their costs. The attempt stalled even before the WTO Council notification stage.³⁸⁹

5.9.2 Mozambique

On 5 April 2004, the Mozambican Deputy Minister of Industry and Commerce issued compulsory licence 1/MIC/04 to Pharco Mozambique Ltd for the manufacture of a fixed-dose combination ('FDC') of the main first-line antiretroviral drug regimen under patent rights in the

³⁸⁶ Ministry of Public Health of Republic of Ghana, Notification of Emergency and Issuance of Government Use Compulsory License, 26 October, 2005 available at <<http://www.cptech.org/ip/health/cl/Ghana.png>>

³⁸⁷ The AIDS in Africa Working Group and the Access to Drugs initiative 2007, p. 10.

³⁸⁸ See Ben Krohmal, Noah Novogrodsky on "Compulsory Licensing in Ghana – the Continuing Barriers to Affordable Medicines", Consumer Project on Technology (Nov 9, 2006), at <http://www.cptech.org/blogs/drugdevelopment/2006/11/noah-novogrodsky-on-compulsory.html>.

³⁸⁹ See Ben Krohmal, Noah Novogrodsky supra

country.³⁹⁰ This was in line with the provisions of article 70 no 1 point b of Decree 18/99. The fixed remuneration was two per cent of total sales.³⁹¹

5.9.3 Zambia

An application for a compulsory licence was also made by Pharco Ltd in September 2004 in Zambia, just as the company had done in Mozambique. Pharco's plan was to produce a generic version of the triple FDC³⁹² with a maximum royalty rate of 2,5 per cent of the total turnover of the product. On 21 September 2004 the Zambian government issued the compulsory licence.³⁹³

Under the terms of the compulsory licence manufacture of the generic combination is expected to expire as soon as the conditions of national emergency and extreme urgency come to an end, or upon the expiry of the six-month period of emergency, as declared in the statutory instrument known as Patents (Manufacture of Patented Anti-retroviral drugs) (Authorisation) Regulations of 2004. Furthermore, the licence also restricts the exportation of generics produced under the compulsory licence.³⁹⁴

5.9.4 Rwanda and the first notification of the use of the paragraph-6 system

In 2006, the Rwandan government enacted a law that made it possible for generic medicines to be imported for use in the country.³⁹⁵ Following this, on 19 July 2007, Rwanda informed the WTO Council for TRIPS that because of its public health needs it intended importing 260 000 packets of *TriAvir* over two years from the Canadian company Apotex Inc.³⁹⁶ In compliance with the requirements of the Canadian Patent Act, Apotex first sought for a voluntary licence from the patentees but the patent-holding companies declined to issue a licence.

³⁹⁰ Ministry of Industry and Commerce of the Republic of Mozambique, Decree no. 18/99, 5 April 2004.

³⁹¹ Khor 2009.

³⁹² The FDC in question was composed of stavudine +lamivudine+nevirapine.

³⁹³ Ministry of Commerce, Trade and Industry of the Republic of Zambia, Compulsory License No. CL 01/2004, 21 September 2004, available at <<http://www.cptech.org/ip/health/c/Zambia/zcl.html>>.

³⁹⁴ See Avafia T 2009: The Impact of WTO 30 August Decision and ARIPO on SADC Countries. Workshop on Intellectual Property, Trade and Access to Medicines, Pretoria, South Africa, 13 May 2009. Available at <http://www.docin.com/p-67186557.html>

³⁹⁵ Kerry and Lee 2007

³⁹⁶ Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health-Rwanda, July 19, 2007 (IP/N/RWA/1)

Following this development, Apotex applied for an export licence under the Canadian Access to Medicines Regime ('CAMR') in order to supply Rwanda. Fortunately, the application was accepted and a notification was sent to the TRIPS Council.³⁹⁷ There was a significant delay in granting the compulsory licences.³⁹⁸

The idea of compulsory licensing is to serve populations who are in urgent need of medical aid, but Rwanda did not receive the Apo *TriAvir* shipment until four years after Apotex first started working on the drugs. The delay in providing the medicine resulted from the WTO provisions and Canada's legislation which set strict outlines relating to eligible drugs that can be exported, as well as consent from the patent holder. Because Apo *TriAvir* is a combination drug and was not on the list of eligible drugs for export, Apotex had to submit further applications to have Apo *TriAvir* approved. Moreover, the case resulted in huge economic losses for Apotex due to production costs, transaction costs, legislative costs, as well as royalties to the patent holder³⁹⁹

5.10. Compensation for the patent owner under article 31 of TRIPS Agreement

The rule under article 31 requires that the patent owner be compensated. The relevant provisions relating to remuneration in article 31 are:

1. Authorization of such use shall be considered on its individual merits. Thus, some decisions must be based upon the facts relevant to the patented invention.⁴⁰⁰
2. Efforts must first be made to 'to obtain authorization from the right holder on reasonable commercial terms and conditions.'⁴⁰¹

³⁹⁷ Gsk, Shire and BI.

³⁹⁸ Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health- Canada, Oct. 5, 2007 (IP/N/10/CAN/1) See also FDA News (2007 October 8) Canada Notifies WTO about compulsory licenses to Export Generic Drugs. Retrieved from <http://www.fdanews.com//newsletter/article?article=99471> & issued-10827

³⁹⁹ Tsai, G (2007) Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration. Retrieved from [http://heinonline.org/Hol/page?Handle=hein.journal/vajint49&div=28&g_sent=1\\$collection=Journals#1073](http://heinonline.org/Hol/page?Handle=hein.journal/vajint49&div=28&g_sent=1$collection=Journals#1073)

⁴⁰⁰ Article 31 (a)

⁴⁰¹ Article 31(b)

3. Prior negotiation on “reasonable commercial terms and conditions” is waived in three special cases.

a. Public non-commercial use.⁴⁰²

b. National emergency or other circumstances of extreme urgency.⁴⁰³ or

c. Where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.⁴⁰⁴

4. When governments authorize non-voluntary use of a patent, they must provide patent owners ‘adequate remuneration’, for the ‘circumstances of each case, taking into account the economic value of the authorization.’⁴⁰⁵

5. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration.⁴⁰⁶

6. When a non-voluntary license is issued to allow the exploitation of a patent (the second patent) that cannot be exploited without use of another patent (the first patent), the owner of the first patent is entitled to a cross-license to the second patent on ‘reasonable terms...’⁴⁰⁷

7. Any decision relating to remuneration must be subject to judicial or other independent review by a distinct higher authority.⁴⁰⁸

5.10.1 Article 31(h) of the TRIPS Agreement

The general rule is in article 31(h) which states that

⁴⁰² Article 31 (b)

⁴⁰³ Article 31 (b)

⁴⁰⁴ Article 31 (k)

⁴⁰⁵ Article 31 (h)

⁴⁰⁶ Article 31 (k)

⁴⁰⁷ Article 31 (1) (ii)

⁴⁰⁸ Article 31 (J)

the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

In many respects, this is the most fundamental obligation in article 31. It is clear that countries have a considerable discretion in setting compensation. Article 1 of the TRIPS Agreement states that:

Countries shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.⁴⁰⁹

There are, of course, limits to what would satisfy this requirement, but there is already a rich diversity of national approaches in terms of compensation in compulsory licensing and government use, and the WTO would be hard-pressed to justify intrusive reviews of this.⁴¹⁰

5.10.2 The effect of the Doha Declaration on the remuneration of the patent owner

The interpretation of the Doha Declaration is that the TRIPS Agreements requirements in article 31(b) for prior negotiation with patent owners on reasonable commercial terms is waived if there is a public health crisis.⁴¹¹

Paragraph six of the Declaration required the WTO to find a solution to the limitations on exports of medicines manufactured under a compulsory licence. The problem raised in negotiations over the implementation of paragraph 6 was the provision in article 31(f) that normally limits exports to less than half of production when goods are produced under a compulsory licence. This restriction is waived when licences are issued as a remedy to anti-

⁴⁰⁹ See James Love (2001), Access to Medicines and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries. Published by Third World Network at pages 16 -19.

⁴¹⁰ Article 31 (I) and (J) also provide that grants of licenses and decisions determining the rate of compensation shall be subject to review by national courts or "other independent review by a distinct higher authority". The standards set out in TRIPS allow members significant discretion in their implementation of this review provision. See UNCTAD-ICTSD, Resource Book on TRIPS and Development (New York: Cambridge University Press, 2005) at 477-79

⁴¹¹ See WHO Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies.(WHO Remuneration Guidelines) WHO/TCM/2005 James Love Consumer Projects on Technology Washington D.C, at page 13.

competitive practices. Additional flexibility for exports under a limited waiver of article 31(f) was finally agreed upon by the WTO in 2003.⁴¹²

The 2003 Paragraph-6 Decision requires the exporting country to provide ‘adequate’ remuneration to right owners, consistent with article 31(h) of the TRIPS Agreement, ‘taking into account the economic value to the importing Member.’⁴¹³ In these cases, the importing country’s obligation to remunerate right owners is waived. In short, the right owner must receive remuneration, but the amount is set in the exporting country which must consider the ‘economic value’ of the product in the importing country.⁴¹⁴

The rules under the TRIPS Agreement, when taken together, require ‘adequate remuneration’ for right owners, taking into account the ‘economic value of the authorization’ and in some cases⁴¹⁵ require prior negotiation on ‘reasonable commercial terms and conditions’. On the other hand, the Doha Declaration calls upon members to implement their domestic laws in a manner that promotes ‘access to medicine for all’.⁴¹⁶

5.10.3 Examples of royalty setting

Establishing the criteria for remuneration of the patent owner does not need to be a complicated issue. Countries may choose from a wide range of factors in coming to a conclusion on the

⁴¹² WT/L/540, 1 September 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. Decision of the General Council of 30 August 2003.

⁴¹³ The effect of Article 31 (h) was clarified, under para 3 it requires that, upon the grant of a compulsory licence, the patent owner shall be given “adequate remuneration.....taking into account the economic value of the authorization”. If this remuneration is paid in the exporting country, then article 31(h) is waived. It is however misleading to describe para 3 as a “waiver” of article 31 (h). The effect of 31 (h) is merely procedural and clarifies that remuneration should not be paid twice. Patent owners are still entitled to remuneration as before.

⁴¹⁴ See James Love. ‘Consumer Projects on Technology Washington D.C: Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies WHO/TCM/2005.1 at pages 10-12

Under Article 31(h) of the TRIPS Agreement, the obligation to pay a remuneration is waived in the case of a compulsory licence granted under the system established by the WTO Decision of 30 August, 2003(incorporated as Art. 31bis of the TRIPS Agreement, but still subject to ratification) to import pharmaceutical products in cases where the country has established that it lacks sufficient manufacturing capacity in pharmaceuticals. Payment in these cases will only take place under the compulsory licence granted in the exporting country.

⁴¹⁵ When the authorization is not for public non-commercial use, emergencies or cases of, urgency, or a remedy to anticompetitive practices.

⁴¹⁶ See Paragraph 4 of the Doha declaration.

remuneration that is to be paid. The wide range of options available to DCs are discussed below.⁴¹⁷

In a compulsory licensing case concerning patents for an ulcer drug, the UK awarded a 45 per cent royalty for a compulsory licence for the drug, while the Philippines chose to issue a 2,5 per cent royalty. Japan, in a related case, issued a 3,5 per cent royalty on the same patents.⁴¹⁸

In the 1970s and 1980s, Canada maintained the world's most active programme for the compulsory licensing of medicines. It generally set royalties at four percent.⁴¹⁹

The USA issues compulsory licences through a number of programmes and under a number of laws, including for government use of patents and to remedy anti-competitive practices. Historically, USA royalties for government use have ranged around six per cent (but much lower in some important cases), though they have moved higher in recent years. Royalties for licences issued to remedy anti-competitive practices are typically low, and frequently zero.⁴²⁰

In recent years, a number of countries have issued compulsory licenses for HIV/AIDS drugs. Malaysia set a royalty rate of four per cent for these licences; Mozambique established a two per cent royalty; Zambia set a 2,5 per cent royalty; and Indonesia arrived at a 0,5 per cent royalty.⁴²¹

Many governments in practice usually select very different outcomes, each of which may be suitable, under their own legal tradition. For example, Smith Kline French ('SKF') held the patents on Cimetidine, the active ingredient for an Ulcer drug marketed by SKF as Tagemet. Generic competitors initiated compulsory licensing proceedings against Cimetidine in the Phillipines, the Netherlands, and in the United Kingdom. There was also similar infringement proceedings in Japan.. In the United Kingdom SKF was awarded an extremely high royalty of 45

⁴¹⁷ See WHO Remuneration Guidelines at page 15.

⁴¹⁸⁴¹⁸ See F.M Scherer, The Economics of compulsory drug patent licensing. Paper presented at the World Bank, June 2003.

⁴¹⁹ See J.H Reichman and C. Hasenzahl Non-Voluntary Licenses supra at p.65

⁴²⁰ See FM Scherer, The Economics of compulsory drug patent licensing. Paper presented at the World Bank, June 2003.

⁴²¹ See WHO Remuneration Guidelines at p. 32

percent of the sale price of the patent owner.⁴²² In the Philippines a lower royalty rate of 2.5 percent of the sale price of the generic competitor was granted,⁴²³ while the Japanese court awarded 3.5 percent royalty.

As noted earlier, the WTO TRIPS accord provides that '[WTO] Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.'⁴²⁴

5.10.4 Methods available for calculating royalties

There are variety methods that can be used to determine what constitutes reasonable or adequate remuneration for the use of a patent, and each method shows a particular set of policy objectives.⁴²⁵

1. The 1998 Japan Patent Office (JPO) Guidelines (for government-owned drug patents) specify royalties that amount to 2 – 4 per cent of the generic product price; this amount can be increased or decreased by as much as 2 per cent for a range of 0 - 6 per cent.⁴²⁶

2. The 2001 United Nations Development Program ('UNDP') Human Development Report proposed a base royalty rate of 4 per cent of the generic drug price. This can be increased or decreased by 2 per cent, for a range of 2 - 6 per cent, depending on various factors (how innovative the medicine is, or the role of governments in paying for research and development).⁴²⁷

3. In accordance with the WTO Paragraph-6? Decision, the 2005 Canadian government established royalty guidelines for compulsory licensing of patents to countries that lack the

⁴²² First Division (G.R. No. 121267. October 23, 2001), *Smith Kline & French Laboratories, Ltd. Plaintiff-appellant, vs. Court Of Appeals And Danlex Research Laboratories, INC., defendant – appellant.*

⁴²³ See WHO Remuneration Guidelines at pp 29-33.

⁴²⁴ TRIPS, Article 1.1

⁴²⁵ See Love J. Remuneration Guidelines for Non-voluntary use of a patent on Medical Technologies. WHO: Geneva (WHO/TCM/2005.1)p. 83-85

⁴²⁶ See Love. J (n. 449 above)

⁴²⁷ See Love J. (n. 449 above)

capacity to manufacture medicines. The royalty rate (between 0,02 and 4 per cent of the price of the generic drug) is determined by a country's ranking in the UN Human Development Index. For most DCs, the royalty rate is less than 3 per cent For most countries in Africa, the rate is less than 1 per cent.⁴²⁸

4. There is something peculiar and unusual with the tiered-royalty method in that the royalty rate is based upon the brand –name drug, and not the generic equivalent, in the high income country in which the patent is owned. The base royalty of 4 percent is usually played around to account for income per capital, or for countries with a particular high burden of disease, relative income per diseased person.⁴²⁹

Just as it is the case with most Article 31 of the TRIPs agreement, the most important obligation is to find a fair and equitable means of getting a reasonable result. In reality, the target royalty payment could be an approximation of the average or median royalty paid on a pharmaceutical product, for which there exists reasonable competition. In the recent Indian case of *Natco v Bayer*,⁴³⁰ the patent office granted Natco a non- exclusive licence, and awarded Bayer a royalty of six per cent of the net sales. However, on appeal, the Chennai based Intellectual Property Appellate Board ('IPAB') hiked the royalty which Natco would have to pay from six to seven per cent.

The royalty practices/guidelines adopted globally are those of the UNDP which specifically recommended that rates normally to be set at four per cent and adjusted upwards by as much as two per cent when the development of the product has been partly supported with public funds, ie a range of 2 - 6 per cent.

It will be interesting to see the outcome of Natco's appeal against the seven per cent royalty, which is higher than the 2005 (Canada), 2001 (UNDP), and 1998 (Japan) royalty guidelines, and about two points higher than the median royalties in the parr study.

5.10.5 What is a reasonable royalty?

⁴²⁸ See Love J. (n. 449 above)

⁴²⁹ See Love J. (n. 449 above)

⁴³⁰ Bayer v Natco decision of the Indian High Court in March, 2012 in suit no. (CS/OS) 1090/2011.

On 2 June 2003, at a World Bank seminar, Scherer reviewed the historical experience with compulsory licensing of pharmaceutical patents in the United States, Canada, the UK and other countries.⁴³¹ . In summary, there is a wide range of flexibility in the system that responsible government agencies and the courts have used in arriving on the amount of remuneration to be awarded to patent holders when compulsory licenses have been issued against patents. The United States has provided the minimum generous remuneration in key antitrust case orders whilst the United Kingdom has provided the maximum generous remuneration in its drug licensing decisions. It is worthy to note that, none of the royalty determinations discussed above has established rates approaching those that would emerge under a 'lost profits' criterion.⁴³²

There are important lessons here for nations that seek to apply the compulsory licensing provisions available under the TRIPS Agreement. High royalty rates, as in the British drug licensing experience, could undermine the objective of making drugs widely available to low-income consumers on competitive terms; low royalty rates, as in the Canadian experience, could provide the basis, assuming that other conditions are satisfied, for competitive drug supplies while compensating patent holders to at least some extent for their research and development contributions. . Most industrialised nations have made choices which provide enough precedent for royalty-setting on the modest side of the range of possibilities.⁴³³

5.10.6 The royalty obligation should not undermine access

As discussed above, for DCs in general, and in particular for those countries that have the fewest resources or which face public health crisis, royalties should be relatively low. The primary reasons for this are as follows:

1. Royalties must be affordable to promote access to medicine.
2. When the market for medicines in developing countries is but a small fraction of the global Market, remuneration will not have a first order impact on global R&D decisions.

⁴³¹See F.M. Scherer, The Economics of Compulsory Drug Patent Licensing. Paper Presented at the World Bank, June 2, 2003.

⁴³² See F.M. Scherer, *supra* (n 455 above)

⁴³³ See F.M. Scherer, *supra* (n. 455 above)

3. The benefits of increased access to medicine in the poorest countries are greater than the benefits of higher contributions to global R&D that would obtain from high royalty payments.

4. Governments can support R&D through a variety of mechanisms, including some that are less restrictive in terms of access to medicine, or more efficient in terms of health care priorities. Simply put, as royalties increase, prices rise (with the VAT and retail mark-ups, more than the royalty itself).⁴³⁴

If the overriding policy objective is to increase access to the medicine, when access is constrained by the price the royalties have to be modest or the policy objective will be undermined.⁴³⁵

It is also important to note that when prices are so high that the poor go without access to a lifesaving medicine, the social cost is unconscionably high.⁴³⁶ This view is at the core of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which declared:

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. 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.⁴³⁷

The policy objective of promoting access to medicine is central to the decision regarding the general level of remuneration, and proposals for royalties that undermine access goals should be rejected.

5.11 Conclusion

In this chapter, I have shown how compulsory licensing has become a feature of the patent law system. Developed countries like Canada, the USA, and the UK have in the past relied on these

⁴³⁴ See WHO Remuneration Guidelines at P.51

⁴³⁵ See WHO Remuneration Guidelines at p.51

⁴³⁶ See WHO Remuneration Guidelines WHO/TCM/2005.1

⁴³⁷ See Paragraph 4 of the Doha declaration.

licences in order to limit the exclusive rights, and prevent the abusive and anti-competitive practices in the patent system. The grounds and conditions on which compulsory licences can be granted, as illustrated above, show its flexibility and potential to address a multiplicity of public interests and concerns.

However, for the DCs and LDCs, compulsory licences should not only be regarded as an essential element in patent law, the grounds and conditions for their grant should also be carefully determined before the system is introduced into national law. These countries should also strive to design and develop their compulsory licences in accordance with their national interests and prioritise the protection of health and the transfer of much needed technology.

This chapter has shown how in many instances, the inclusion of compulsory licensing flexibility in national patent laws has facilitated negotiations for voluntary licences at reasonable prices.

The appropriate options for the 'adequate remuneration' of the patent owner as provide for in article 31(h) of the TRIPS Agreement, was also considered in detail. The general rule is that remuneration must be adequate, taking into account both the particular circumstances of each case and the economic value of the compulsory licence. Some methods that have been used to calculate remuneration in some countries were also briefly discussed.

CHAPTER 6

THE DOHA DECLARATION

6.1 Introduction

The increase in the standards of patent protection brought about by the introduction of TRIPS Agreement led to higher prices of the patented medicines in DCs. The inability of the poor people living in these DCs to afford the price of these medicines led to disruption of future supplies.⁴³⁸

In principle, DC governments needing drugs at prices lower than those charged by the patentees, could issue compulsory licenses under article 31 of the TRIPS Agreement. In reality, most of these countries lacked the capacity to manufacture the drugs in question, or otherwise to obtain the key active ingredients, in which case the granting of a compulsory licence could amount to an empty gesture for lack of access to non-infringing generic substitutes.

Although some countries with manufacturing capacity might be willing to assist a needy country by issuing compulsory licences of their own with a view to exporting supplies of the drug in question. But that type of altruism was limited by article 31(f) of the TRIPS Agreement which expressly required products manufactured under a compulsory licence to be 'predominantly for the supply of the domestic market' which in effect limits these exports to 49,9 per cent of the total output. Moreover, even middle-income countries with growing manufacturing capacity, such as India and Brazil, might themselves need a drug that they are unable to manufacture locally, in order to temper a patentee's prices. In such case, any willing supplier – if one could be found in a developed country – would similarly be subject to the limitation on exports under article 31(f).⁴³⁹

⁴³⁸ For the reasons, see S Flynn, A Hollis & M.Palmedo 'An economic justification for open access to essential medicine patents in developing countries' (2009) 37/2 *Journal of Law, Medicine & Ethics* 184-209. See also [scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2747 & context...by JH Reichman---2009](http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2747&context...by JH Reichman---2009)

⁴³⁹ Jerome H. Reichman 'Compulsory licensing of patented pharmaceutical inventions: Evaluating the options' (2009) 37 *Journal of Law Medicine & Ethics* 247-263. Available at http://scholarship.law.duke.edu/faculty_scholarship/2126. Reprinted in Carlos Correa (ed) *Research Handbook On the Protection Of Intellectual Property Under WTO Rules* vol 2 (2010) Chap 17.

The tensions generated by these prospects of rising price of essential medicines came to a head in the late 1990s, at the very time when the developed countries wanted the DCs to agree to yet another round of multilateral trade negotiations, to be known as the Doha Round. This unsatisfactory state of affairs was, as shown above, strongly criticised by civil society groups. Most notably, the NGOs *Medicines Sans Frontiers* ('MSF') and Oxfam clamoured for the supremacy of the human right of access to essential medicines over IPRs.

The DCs made removal of constraints on their public health authorities under the TRIPS Agreement a *sine qua non* for their participation in the Doha Round. The outcome was a momentous Ministerial Declaration on the TRIPS Agreement and Public Health in 2001, which, affirmed in paragraph 4 that this Agreement 'can and should be interpreted in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all.'⁴⁴⁰

6.2 The WTO Doha Declaration on Access to Medicines

The WTO has two principal bodies: The Ministerial Conference, and the General Council of which the Ministerial Conference is the higher. The Ministerial Conference consists of representatives from all WTO member states and meets at least once every second year. It performs the functions of the WTO and is authorised to take appropriate action necessary to carry out this task. Furthermore, the Ministerial Conference has the authority to: take decisions on all matters under any of the multilateral trade agreements;⁴⁴¹ adopt interpretations of the provisions of the WTO agreement and the multilateral trade agreements;⁴⁴² and, in special circumstances, waive an obligation imposed on a member by the WTO Agreement or any of the multilateral trade agreements.⁴⁴³ After each Ministerial Conference a declaration which provides the authorisation for negotiations on different subjects, is issued and later adopted by the WTO.

⁴⁴⁰ See Declaration on TRIPS n 5 above para 4 (emphasis added).

⁴⁴¹ Agreement Establishing the WTO art IV, 1.

⁴⁴² Id art IX, 2.

⁴⁴³ Id art IX, 3.

The Declaration from the fourth Ministerial Conference in Doha held between 9 and 14 November 2001 ('the Doha Declaration') was adopted on 14 November 2001.⁴⁴⁴ The Declaration consists of 52 paragraphs divided into three sections.

Throughout the Declaration it is clear that the issue of DCs/LDCs and their participation in the multilateral trading system is very important as it constitutes a major part of the Declaration and the issues of special and differential treatment are discussed under almost every topic in the work of the programme. Furthermore, the issue of pharmaceutical patents was on the agenda once again, as past developments had proven that DCs/LDCs had not reached consensus on this point.

The Ministerial Conference adopted a declaration on the question of access to medicines in the context of the TRIPS Agreement. However, this constitutes only a partial answer to the question of access to drugs since it does not address the relevance and impact of the introduction of product patents in the health sector.⁴⁴⁵

Paragraph 5(b) of the Declaration reiterates members' right to grant compulsory licences, as well as the right to determine the grounds for doing so. Paragraph 5(c) emphasises a member's right to determine what constitutes a national emergency or other circumstances of extreme urgency, such as, but not limited to, HIV/AIDS, malaria, and tuberculosis.⁴⁴⁶ In a nutshell, the Doha Declaration sought to assure that the TRIPS Agreement was responsive to the healthcare needs of DCs and to highlight how DCs could use its flexibilities to that end. Despite that Declaration, uncertainties remained, especially with regard to DCs which lack the manufacturing capacity to exploit the right to grant compulsory licences.⁴⁴⁷

⁴⁴⁴ The Doha Declaration on TRIPS, adopted in October 2001 by the WTO Ministerial Conference, affirms that countries may undertake compulsory licensing for public health reasons. This has been heralded as a major step forward in paving the way for cheap drugs for the poor.

⁴⁴⁵ See, eg, Ellen 't Hoen 'TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha' (2002) 33 *Chicago J Int'l L* 27, 28.

⁴⁴⁶ While DCs have pressed for a broad interpretation of the Doha Declaration, and thus a large list of diseases for which patent rules will be relaxed, drug companies and their respective governments have advocated for a narrow interpretation of the Declaration. See Sarah Bosely & Charlotte Denny 'Prescription for World's Poorest Stays Unwritten: WTO Conference Deadlock as US Shows no Sign of Loosening Veto on Pharmaceutical Patent Rights' *The Guardian* 20 Feb 2003 available at http://www.economist.com/agenda/displayStory.cfm?story_id=1589657. (Date used 13 March, 2014.)

⁴⁴⁷ See Ellen 't Hoen 'TRIPS, pharmaceutical patents, and Access to Essential Medicines: A Long Way From Seattle to Doha, *Chicagos Journal of International Law*: Vol 3: No1, Art 6 Who describes the Declaration as an 'important achievement' that 'broke new ground in guaranteeing Members' access to medical products'. At page 28. Also available at <http://chicagounbound.uchicago.edu/cjii/vol3/iss1/6>

Even if a DC in this position were to grant such a licence there would be no domestic manufacturing capacity to use it. Article 31(f) of TRIPS limits the supply of medicines produced under a compulsory licence predominantly to the domestic market of the WTO member granting the licence. In other words, the medicines must be used within the territory of the member granting the compulsory licence. This qualification poses further practical difficulties for most governments in sub-Saharan Africa and other similarly placed DCs, where the infrastructure needed to support the manufacturing process simply does not exist.⁴⁴⁸

6.3 The negotiating history of the Doha Declaration

International NGOs and African states played no significant role in the negotiations leading up to the conclusion of the TRIPS Agreement. The two most striking features in terms of actors involved in the post-TRIPS scene, have been the engagement of international NGOs in TRIPS Agreement issues, and the leadership role assumed by the Africa Group on health and biodiversity issues. The Organisation of African Unity ('OAU – now the African Union ('AU')), Ethiopia, Kenya, the Third World Network, and the Institute for Sustainable Development have been prime movers in developing model legislation for African states which sets out regulatory principles for the ownership and use of biological resources and related local community knowledge.⁴⁴⁹ The special sessions of the TRIPS Council on the issue of IP rights and access to medicines, the first of which was held in June 2001, were inspired by a proposal from the Africa Group that was discussed and agreed to at a TRIPS Council meeting in April 2001. This initiative ultimately culminated in the Doha Declaration.⁴⁵⁰

There is little doubt that the rise in influence of the Africa Group has been enabled by a partnership with NGOs. In a study conducted for the UK Commission on Intellectual Property Rights, every DC negotiator interviewed commented on the positive role that NGOs have played

⁴⁴⁸ Among sub-Saharan countries, only South Africa has a limited primary manufacturing capacity (ie is capable of producing active pharmaceutical ingredients). See Berger M, Murugi I, Buch F, Ijsselmuiden C, Moran M & Guzman J *Strengthening pharmaceutical innovation: Choices for decision makers and countries* (2010).

⁴⁴⁹ See P Drahos 'Commission on Intellectual Property Rights Study Paper 8: Developing Countries and International Property Standard Setting' 26. See also Larry Crump, S.Javed Maswood (eds) *Developing Countries and Global Trade Negotiations* (2007) available at Books.google.co.za/books?isbn=0203962834 (Date used 26 May, 2013.)

⁴⁵⁰ See Drahos n 280 above.

in the debate over the TRIPS Agreement and access to medicines.⁴⁵¹ (The role of the Quaker Geneva Secretariat came in for express mention. Another interviewee said ‘what negotiators like me failed to accomplish Oxfam and MSF have accomplished’.)

Northern NGOs have broadly followed the reactive sequence of regulatory change which Braithwaite and Drahos identify empirically as one of the sequences that results in global regulatory change.⁴⁵² This sequence begins with a crisis that sees a regulatory entrepreneur seize the initiative by putting a regulatory model on the table -- a model that eventually extends globally.

The death toll in Africa from AIDS has created one of the greatest international public health crises in history. Using this crisis, NGOs have reframed the contest of principles surrounding IP rights.⁴⁵³

During the TRIPS Agreement negotiations, US multinationals framed the contest as one of the protection of private property rights versus piracy by DCs. During the late 1990s NGOs presented the contest as one of the right of states to protect public health versus the extension of patent monopoly power. The Doha Declaration, the outcome of this contest, elevates the former principle over the latter. The Doha Declaration represents a weak coalition making a gain that an observer would not have predicted given the power and resources of the USA-led coalition.⁴⁵⁴

The explanation for this success lies in the fact that we live in a networked world. And in such a world, as John Braithwaite has observed, ‘the prescription for potency is not to sit around waiting for your own power to grow ... rather the prescription is to actively network with those with power that you do not yourself control.’⁴⁵⁵ Through networking the weak actor becomes

⁴⁵¹ See P Drahos ‘Intellectual Property Standard Setting and Developing Countries’ Paper for the UK Commission on Intellectual Property Rights available as Study Paper 8 available at <http://www.iprcommission.org>. The role of the Quaker Geneva Secretariat came in for express mention. One interviewee stated ‘what negotiators like me failed to accomplish Oxfam and MSF have accomplished’.

⁴⁵² J Braithwaite & P Drahos *Global Business Regulations* (2000) 33.

⁴⁵³ Id 575-576.

⁴⁵⁴ See Drahos n 162 above 18-19.

⁴⁵⁵ John Braithwaite ‘Responsive regulation and developing economics’ (2006) 34 *World Development* 884, 892.

connected to other pools of capacity/power, pools that can then flow through the network to achieve the goals of members of the network.

The Africa Group could never have achieved the Doha Declaration because they were, and remain, a weak group. But an Africa Group that joined with a large coalition of DCs -- which included Brazil and India -- that drew on the power of Northern NGOs to work the Northern mass media, that gained the quiet support of some European states, that drew on independent technical expertise to evaluate the draft text, that gained resources from Geneva-based NGOs, was a group strengthened by many ties.⁴⁵⁶ If the TRIPS Agreement was about a form of networked governance in which the powerful built ever larger circles of consensus in the shadow of credible threats of trade coercion, the Doha Declaration was about the weak networking networks that surrounded and eventually isolated the USA, and in the final instance its pharmaceutical industry. At Doha the then USTR, Robert Zoellick, faced a choice between appearing to be against access to medicines or abandoning the USA pharmaceutical industry. Neither was an especially palatable alternative – Zoellick chose the latter.⁴⁵⁷

There was, however, a further factor at play. The networking of networks by the weak had created a form of sanction that cast its shadow over Doha: that of the court of global public opinion. Northern NGOs had succeeded in reducing the complexities of patent law and HIV/AIDS to a simple choice readily understood by the ‘masses’.

Moreover, WTO negotiations were globally visible and transparent in ways that FTA negotiations had simply not been. With the world press watching, the USA-led coalition was faced with coming out in support of a declaration that unambiguously helped to prevent millions of needless deaths, or declaring itself in favour of putting patents and profit first. The former was a basic moral canon understood by all. No individual, country or organisation could be seen to be opting for the latter.⁴⁵⁸

⁴⁵⁶ For a detailed account of how these factors played out in the negotiation see John Odell & Susan Sell ‘Refraining the issue: The WTO Coalition on Intellectual Property and Public Health 2001’ in John S Odell (ed) *Negotiating Trade: Developing Countries in the WTO and NAFTA* (2006) 85.

⁴⁵⁷ See Drahos n 285 above 19.

⁴⁵⁸ Id 11-39.

The Doha Declaration is an example of a rare negotiation success for DCs in the context of IPRs. However, DCs had no common or even individual strategy for exploiting its potential. The negotiations over the Doha Declaration were not about trade gains in any conventional sense. Instead, as the opening paragraph makes clear, the negotiation was about recognising that DCs were facing severe public health problems and the TRIPS Agreement (and consequently the WTO) had to be part of the solution rather than part of the problem. The Declaration does not create new rights that override the TRIPS Agreement. Rather it provides a constitution-like ordering of principle in which the principle of intellectual property protection is expressly subordinated to the right of states to protect public health.⁴⁵⁹

Following on from this constitutional ordering in paragraph 4 of the Doha Declaration, paragraph 5 lists some of the flexibilities that the TRIPS Agreement contains and that can be used to serve the principle of protecting public health. Winning a contest of principles, however, is only the beginning in securing a desired regulatory outcome. Principles are by their nature open ended and so have to be secured through practices and rules that institutionalise them. Victory in a contest of principle that is not secured through institutionalisation can be lost, if the losing party shifts the contest to another forum, or counters by generating a rule complexity that does not support the spirit of the principle.

The actors that secured the Doha Declaration were more a network than a coalition, and the like-minded group of countries that achieved little at the WTO Ministerial Conference in Doha in 2001 (and probably could be said to have failed) was a coalition and not a network.⁴⁶⁰

6.4 Analysis of the Doha Declaration

As outlined above, the international framework on IPR seems to be in place. However, the parties on the international scene do not agree on what direction the future development of IP

⁴⁵⁹ Id 23.

⁴⁶⁰ For an excellent case study of the Like Minded Group see Narlikar Amrita & John S Odell 'The strict distributive strategy for a bargaining coalition: the Like Minded Group in the World Trade Organisation' in John S Odell (ed) *Negotiating trade: Developing Countries in the WTO and NAFTA* (2006) 115.

protection should take. Eric Alsegard in ‘Global pharmaceutical patents after the Doha Declaration’ states as follows:

‘Not only are there issues of future changes to the legislation, but there is also a debate on the legitimacy and interpretation of the existing wording of the Doha Declaration on TRIPS and Public Health.’⁴⁶¹

The analysis below will present the general problems and solutions provided by the Doha Declaration to issues surrounding the TRIPS Agreement and public health.

The Doha Declaration contains seven paragraphs (see Annex 1 for full text). The first four paragraphs set out the scope, background, and basic principles of the Declaration.

6.4.1 Paragraph one

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

6.4.1.1 Comments

This paragraph has no major importance when it comes to patent rights and compulsory licensing. In draft of 21 October,⁴⁶² (the first draft), only HIV/AIDS was mentioned. Tuberculosis and malaria were however added in the draft of 13 November 2001.

6.4.1.2 Problems

Post Doha, certain countries⁴⁶³ have claimed that this paragraph should be interpreted as limiting the scope of the subsequent paragraph 6 to epidemics and pandemics concerning HIV/AIDS,

⁴⁶¹See Erik Alsegard ‘Global Pharmaceutical Patents after the Doha Declaration: What lies in the future’ (2004) 1:1 SCRIPTed 12, <<http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp>> At page 18.

⁴⁶² In this connection see the ‘Harbinson Text on TRIPS from 21 October, 2001’. Although the text only highlights the example of ‘HIV/AIDS the intention is not to limit the use of Doha Declaration to only the epidemy of HIV/AIDS, but to illustrate some of the problems facing DCs.

⁴⁶³ Eg The US in IP/C/W/358 and Japan (Fatoumata Jawara)???

tuberculosis and malaria. This would limit the possibilities of protecting public health for the DCs/LDCs. However, in my view such an interpretation is incorrect as a broad notion of public health is adopted in the subsequent paragraphs, and ‘other epidemics’ are mentioned. Against this background the paragraph should not be limited to specific diseases.⁴⁶⁴

6.4.1.3 Solutions

This paragraph seems to serve as no more than an acknowledgement of the public health problems faced by several DCs/LDCs. The paragraph cannot be said to provide any solutions in the conflict between patent holders and the incentive to produce new medicines and access to medicine for all.

6.4.2 Paragraph Two

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

6.4.2.1 Comments

It appears that this paragraph was included to show that WTO members recognised that IP was not the only factor affecting access to medicines. In the initial draft the wording was slightly different in that not only the TRIPS Agreement, but also the interpretation and implementation of the Agreement should lead in the action to address the problems.

6.4.2.2 Problems

It seems to be a victory for the DCs/LDCs that the TRIPS Agreement should form part of the action to address the problems mentioned in paragraph 1, but there is no clear statement on

⁴⁶⁴ This approach is supported by Ruth Mayne (Homi Katrak, 2004) who says that a limited approach to which diseases should be included would restrict DC and LDC access to generic versions of new drugs for major killer diseases such as pneumonia, gonorrhoea, heart disease and cancer.

exactly *how* this is to happen. This leaves the DCs/LDCs vulnerable to counter-interpretations by the developed countries as no change has been made to the text of the TRIPS Agreement.⁴⁶⁵

6.4.2.3 Solutions

Paragraph 2 must be seen as a victory for the DCs/LDCs.⁴⁶⁶ Although the paragraph offers no legal or practical solution, it does acknowledge that a solution should be found, and the TRIPS Agreement should be part of the solution.

6.4.3 Paragraph Three

Paragraph Three reads: ‘We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.’

6.4.3.1 Comments

This paragraph recognises the connection between patents and high medicines prices and the difficulties this creates for DCs.⁴⁶⁷

The ministers acknowledge the conflict that exists between DCs/LDCs and developed countries, as they recognise both that IP protection serves as an incentive to foster R&D of new medicines, and the concern about the effect of IP protection on prices. Compared to the first draft, the wording has changed considerably. In the first draft the ministers not only recognised the concerns surrounding the possible effects of IP protection on prices, they stated categorically that it ‘can affect the prices of medicines’.

⁴⁶⁵ This belief is also recognised by Erik Alsegard who believes that the definitions of what constitutes a national emergency or situation of other extreme urgency, will still lead to conflicts and different interpretations. See Erik Alsegard, ‘Global pharmaceutical patents after the Doha Declaration’ available at <http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp> at pages 15-16

⁴⁶⁶ The NGOs and the Africa Group have welcomed this development, however they do not recognise it as a landmark agreement. . See Erik Alsegard, ‘Global pharmaceutical patents after the Doha Declaration’ (2004) at page 4. Available at <http://www.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp>

⁴⁶⁷ See Carlos Correa Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Health Economics and Drugs EDM Series, Nr 12. Geneva: World Health Organisation 7.

The Declaration is the first acknowledgment by the WTO that medicine prices can prevent access to medicine in DCs and LDC⁴⁶⁸. This acknowledgement was, however, stronger in the first draft.

6.4.3.2 Problems

The major problem with this paragraph is the acknowledgement of the concerns about the effect of patent rights on prices. At first glance it appears to reflect a victory for the DCs and LDCs in that their concern has been recognised. However, there is no acknowledgment of the accuracy of the concern which once again opens to the door to divergent interpretations. Had the wording of the first draft remained, it would have led to greater certainty as regards interpretation.

6.4.3.3 Solutions

Generally, this paragraph provides no solutions: it merely acknowledges an existing problem.

6.4.4 Paragraph Four

Paragraph Four provides:

‘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.’⁴⁶⁹

6.4.4.1 Comments

⁴⁶⁸See Carlos M. Correa , Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Health Economics and Drugs EDM Series, Nr 12. Geneva : World Health Organisation. (2002) at page 7.

⁴⁶⁹ WT/MIN(01)DEC/2 para 4.

The phrase ‘measures to protect public health’ is not limited to medicines but includes vaccines, diagnostics, and other health tools needed to facilitate the use of these products.

This is a summary of paragraphs 6 and 17 of the Doha Ministerial Declaration. However, the wording used differs slightly. In paragraph 6 of the Ministerial Declaration it is said that ‘... no country should be prevented ...’, whereas paragraph 4 adds that the TRIPS Agreement ‘does not and should not’ prevent members from protecting public health.

This difference in wording could lead to further conflict rather than provide solutions. In the past members have interpreted the TRIPS Agreement in different ways. This is particularly true of article 31 which addresses compulsory licensing. Therefore it is clear that the statement that the TRIPS Agreement ‘does not prevent members from taking the necessary measures’, depends on the issues involved. Furthermore, the word ‘should’ does not bear the same legal meaning as the word ‘shall’. It would have provided a better guideline in the process of ensuring medicines for all, had the wording been: ‘We agree that the TRIPS Agreement must not and shall not prevent members from...’.

The use of the words ‘can’ and ‘should’ in the second sentence of the paragraph may result in further conflict. Stating that the agreement ‘can’ be interpreted in a way which supports public health clarifies nothing, it merely states that this specific interpretation could be accepted. Moreover, it appears that in order to interpret the TRIPS Agreement in a way supportive of public health, certain provisions or limitations must be met. Referring to the above section of the first sentence of the Declaration, the word ‘should’ also seems inadequate.

On the other hand, the present wording can be interpreted to contain both a promise and an obligation to interpret and implement the TRIPS Agreement in a manner supportive of public health and the promotion of access to medicines for all.

6.4.4.2 Problems

This paragraph provides no clear-cut answers as the wording is open to different interpretations of the Declaration, which must be seen as a major problem. It seems that this paragraph aims at creating a solution to the conflict, but does not succeed in doing so as it merely states that the TRIPS Agreement should be interpreted so as to be supportive of access to medicines.

Although at first glance the impression is created that patients' rights prevail over patent rights, no clear-cut solution is offered.

6.4.4.3 Solutions

This paragraph affirms that public health should take precedence over patent rights, and thereby confirms that the TRIPS Agreement allows flexibility in support of members' rights to protect public health and access to medicines. Moreover it states that the TRIPS Agreement should be interpreted in a manner supportive of promoting access to medicines for all which, if interpreted similarly by members, would seem to provide a solution to the conflict.⁴⁷⁰

6.4.5 Paragraphs Five, Six and Seven

Paragraphs Five, Six and Seven are the substantive sections of the Declaration.

Paragraph Five lays out the key measures and flexibilities within the TRIPS Agreement, such as compulsory licensing, that can be used to overcome intellectual property barriers to access to medicines. It reads:

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

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

⁴⁷⁰ This opinion is shared by the TRIPS Council on their webpage (www.wto.org).

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

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

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

6.4.5.1 Comments

The use of the term 'include' in the first sentence of this paragraph makes it clear that the flexibilities in implementing the TRIPS Agreement are not limited to those listed in the Doha Declaration.⁴⁷¹ It is clear from the provisions that a country can grant compulsory licences to deal with national emergencies and other situations of extreme emergency.

6.4.5.2 Problems

On the whole this paragraph offers solutions. However, there are several problems attached to it.

First of all, patent laws are territorial, the right to import does not amount to the right to export unless the law in the country where production for export takes place authorises such use. In other words, a country may declare a state of national emergency and alone decide what constitutes one, but if the country lacks domestic production capacity, this independence does

⁴⁷¹ See Correa n 2 above 90 where he states that: 'TRIPS Agreement does not limit the members' right to establish compulsory licenses on other grounds not explicitly mentioned therein, for instance, to protect the environment or for reasons of "public health".'

not lead to results.⁴⁷² Moreover, when read with the other paragraphs of the Declaration, I find it; questionable whether DCs and LDCs will be able to make use of their right to grant compulsory licences.

6.4.5.3 Solutions

The biggest victory for the DCs and LDCs appears to be the right to decide independently and without approval what constitutes a national emergency and the grounds upon which a compulsory licence may be issued. This was the weakness in the TRIPS Agreement as regards access to medicines⁴⁷³ as the existing paragraphs 30 and 31 of the TRIPS Agreement require members to obtain authorisation from the right-holder before granting a compulsory licence.

Read independently this paragraph can be seen as a solution to the ongoing conflict surrounding patent rights, as it should prevent retaliation and trade sanctions from other countries. The practical effects, however, remain to be seen.

Paragraph 6, which deals with production for export under a compulsory licence is discussed separately in paragraph 5.5 below.

Paragraph 7 reads:

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

⁴⁷² Which is of course recognised by the Ministerial Declaration on TRIPS and Public Health para 6.

⁴⁷³ Arvind Panagariya, Developing Countries at Doha: A Political Economic Analysis (September, 2002). Published in the World Economy Volume 25, Issue 9 pages 1205-1233 at p. 1206.

for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.’

6.4.5.4 First Comment

The first part of paragraph 7 reaffirms ‘the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2 of the TRIPS Agreement.’

LDCs have repeatedly raised concerns at the Council for TRIPS about the lack of effective action by developed countries to comply with article 66.2 of the TRIPS Agreement.⁴⁷⁴ Though some developed countries provide different forms of technical assistance on IP rights-related issues, LDCs have repeatedly noted that no or little action has been taken by developed countries specifically to implement their obligations under article 66. 2

6.4.5.5 Problems

The problem is that this re-affirmation by the Doha Declaration of such obligations has had no positive practical impact on developed countries’ actions in this area.

6.4.5.6 Solution

Only an improved production capacity in certain LDCs in Africa and elsewhere will constitute positive implementation. The USA has provided funding for the study of transfer of technology options for the pharmaceutical sector in Latin America.⁴⁷⁵

⁴⁷⁴ Paragraph 11.2 of the Implementation Decision adopted on 14 November 2001 states the following: ‘Reaffirming that provisions of Article 66.2 of the TRIPS Agreement are mandatory, it is agreed that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed-country members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and information shall be updated by Members annually’. For information on home country measures encouraging transfer of technology, see IP/C/W/132, ADD. 1-7.

⁴⁷⁵ Frederick Abbott has served as technical expert for a project funded by USAID regarding transfer of technology in the pharmaceutical sector with respect to Colombia, which project has also involved extensive consultations in Brazil. Such projects are over and above the requirements of Art 66.2, which addresses LDCs.

These initiatives suggest that there are concrete mechanisms by which technologically advanced countries might support the improvement of pharmaceutical research, development, and production capacity in DCs.⁴⁷⁶

6.4.5.7 Second Comment

For LDC members the second part of Paragraph Seven extends the transition period for the implementation of pharmaceutical product patents and the protection of undisclosed test data from 2006 to at least 2016. As many LDCs had already granted those rights, it also allows them not to enforce such rights until at least 2016.

While Paragraph Five provides an interpretation of existing rights under TRIPS, paragraph Seven creates new rights for LDCs. This was incorporated in the WTO rules by a decision of 8 July 2002.⁴⁷⁷

6.4.5.8 Problems

The major problem with the extension of the transitional period of patent protection with regard to pharmaceutical products is that the Doha Declaration provides the greatest benefits to countries already providing patent protection. Extending the transition period to 2016 does not appear to be linked with meaningful benefits for public health. Rather it appears that the benefits implied by the Declaration may only be realised after patent protection has been provided.

The problem is that countries which do not provide patent protection have no basis on which to issue a compulsory licence. In other words, the extended transition period can turn out to be a burden to the LDCs, as they would need to forego the benefits associated with the extended period in order to access the benefits from the Declaration and the solution of the paragraph 6 problem.

⁴⁷⁶ See Frederick M Abbott and Jerome H Reichman ‘The Doha Round’s public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions’ (2007) 10/4 *Journal of Int’l Economic Law* 946.

⁴⁷⁷ WT/L/478.

6.4.5.9 Solutions

The extension given in paragraph 7 must be seen as an opportunity for DCs and LDCs to take advantage of the Declaration and implement new national legislation for pharmaceuticals and patents.

6.5 Paragraph 6 of the Doha Declaration: Production for export under a compulsory licence

Article 31(f) of the TRIPS Agreement stipulates that production under a compulsory licence must be ‘predominantly for the supply of the domestic market’ except when the compulsory licence is granted to remedy an anti-competitive practice (article 31k).⁴⁷⁸

This restriction limits the quantity of products that can be produced for export. This limitation was a key issue that led to the Doha Declaration because it could render local production of a drug uneconomical for a WTO member, even if – in principle – production was legally permissible under the compulsory licence.

Paragraph 6 of the Doha Declaration reads:

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

Ellen F.M. ‘t Hoen⁴⁷⁹ states:

⁴⁷⁸ Paragraph 6 refers to compulsory licence, but art 31 of the TRIPS Agreement refers to the broader concept of ‘unauthorized use’ which as a practical matter covers both compulsory licences and non-commercial, government use, or ‘crown use’ as it is called in the United Kingdom.

⁴⁷⁹ See Ellen F.M. ‘t Hoen *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (2009) 36.

‘However, the cooperative spirit of Doha quickly evaporated once negotiators were back in Geneva. It took the TRIPS Council nearly two years to reach an agreement to allow the export of medicines produced under a compulsory licence.’

6.5.1 Comments

This paragraph is of major importance in the process of finding a solution to the conflict between patent rights and the right to access to medicines for all, as it addresses a fundamental problem arising from the TRIPS Agreement, ie where a member that has a patent on a medicine cannot find an efficient, affordable, and dependable source of medicines because of restrictions on the manufacture and export of medicines under the Agreement.

If a country does not have the necessary manufacturing capacity to handle a national emergency, the ability to grant a compulsory license does not present an effective solution.

This is of vital importance in the public health arena as countries facing epidemics require access to essential medicine. It is further emphasised by statistics which show that approximately 78 per cent of the countries have either reproductive capabilities only, or no pharmaceutical industry at all.⁴⁸⁰ Generally this exposes an inadequacy in the TRIPS Agreement as these countries will not be able to exercise the right to grant compulsory licences in light of 31(f) of the Agreement which provides that production under a compulsory licence should predominantly be for the domestic market. The rationale behind this provision is, of course, the territorial nature of patent rights and the injunction on member states to outlaw the circumvention of patent rules. In this vein it would not be in compliance with article 31(f) of the TRIPS Agreement to grant a compulsory licence with the aim of supplying a foreign country. This is also known as the ‘Paragraph-6 problem’⁴⁸¹.

Moreover the wording of the paragraph is questionable in that there can be little doubt that countries with no manufacturing capacity, *do* face difficulties in making effective use of

⁴⁸⁰ Philip McCalman ‘The Doha Agenda and Intellectual Property Rights, ‘A Study On Regional Integration and Trade: Emerging Policy Issues For Selected Developing Member Countries. (October, 2002 pages 6-9. .Available at <http://www.international-food-safety.com/pdf/The%20Doha%20Agenda%20Intellectual%20property%20Rights.pdf>

⁴⁸¹ Oxfam , TRIPS and Public Health, The Next Battle, London, Oxfam, 2002. .

compulsory licences. The text, however, only acknowledges that these countries *could* face difficulties.

The first draft stated:

‘We welcome steps to make available medicines at discounted prices or under aid schemes to developing and least-developed countries to encourage Members to take measures to prevent the diversion of such medicines from those for whom they are intended into other markets’.⁴⁸²

This paragraph was removed in its entirety during the revision of 13 November 2001 and replaced by the final paragraph 6, which must be said to benefit the industrialised world and disadvantage DCs and LDCs facing epidemics of all kinds. The ‘Harbinson Draft on TRIPS and Health’ of 11 October 2001 took things a step further by stating that it would be appropriate for a member to afford every assistance, including supplying a patented product, to another member which declares a state of national emergency. This would have been an adequate solution to the Paragraph-6 problem.⁴⁸³

However, the wording was again changed, and again tipped the balance in favour of the industrialised countries, by providing that rather than affording a solution, an appropriate solution to the problem should be sought by the end of 2002.

6.5.2 Problems

The major problem with paragraph 6 is that countries with no manufacturing capacity cannot use the Doha Declaration because of article 31(f) of the TRIPS Agreement.⁴⁸⁴ However, there are several other problems arising from this paragraph.

First, the definition of how to determine whether a country lacks domestic capacity to produce pharmaceuticals may be problematic. If this provision is to provide the best possible result, clear criteria should be established. This would exclude the possibility of countries claiming that

⁴⁸² Harbinson Text of October 2001, para 6.

⁴⁸³ See pure.au.dk/portal/files/2036/000136959-136959.pdf

⁴⁸⁴ Which was, however, also recognised by the Ministerial Conference in Doha.

another member has sufficient manufacturing capacity, judged solely on, for example, its technical ability. It should be left to the country in question to determine whether it has sufficient production capacity.

Secondly, it appears that even if the problem of domestic capacity could be overcome, finding a suitable source of supply presents problems of its own. This may be attributed to the fact that, as indicated above, approximately 78 per cent of countries have capacity to reproduce only, or have no pharmaceutical industry at all. Until recently it was possible to import generic drugs from DCs which did not offer patent protection, which would in certain instances reduce costs by up to 70 per cent.⁴⁸⁵ India, formerly the biggest exporter of generic drugs, is now TRIPS-compliant and no longer able to produce and export cheap drugs.⁴⁸⁶

Thirdly, while paragraph 6 states that compulsory licensing is an effective way of securing access to medicines, this is not always the case. Most DCs and LDCs have no or only limited experience in the use of compulsory licences to address national emergencies, which translates into a lack of the know-how necessary to benefit from the process. This means that issuing compulsory licences may not be as effective a solution as paragraph 6 would appear to imply.

In the fourth place, note should be taken of the incentive structure implied in the paragraph. Given that any solution will assist in establishing a moderately inexpensive source of supply, the incentive for a domestic industry could most probably be diluted.⁴⁸⁷

Fifthly, there appears to be a problem when a country has no patent protection for pharmaceuticals, as compulsory licences can only be granted once a patent exists. The wording

⁴⁸⁵ Oxfam, TRIPS and Public Health, The Next Battle. London, Oxfam, 2002.

⁴⁸⁶ This opinion is supported by Fatoumata Jawara & Aileen Kwa who agree that the process will be too costly and time consuming for developed countries pursue.

⁴⁸⁷ This is also suggested by Carlos Correa See 'Implications of Doha Declaration on the TRIPS Agreement and Public Health (June 2002) Health and Economics and Drugs EDM Series No 12. Available at <http://apps.who.int/medicinedocs/pdf/523ole/523ole.pdf> Where he stated that there will be no rise in R&D in pharmaceuticals due to recognition of product patents, because development of new chemical entities is outside the reach of local companies in DCs/LDCs, since there are no firms big enough to finance the high costs of pharmaceutical R & D.

of paragraph 6 is limited to cases where patent protection of pharmaceutical products is in force in the country of import.⁴⁸⁸

Lastly, the major problem with paragraph 6 is that it does not succeed in bringing any concrete development or solution; it merely makes it clear that the issue of compulsory licensing and patent rights needs to be prioritised in the TRIPS Council's future negotiations.⁴⁸⁹

6.5.3 Solutions

Even though several issues surrounding paragraph 6 have been identified above, the most pressing problem must be said to be the injunction to find an expeditious solution which will make the use of compulsory licensing effective. However, the Paragraph-6 problem appears to be purely technical and this implies that a solution should not be inconceivable.⁴⁹⁰ Prospects for a solution are further enhanced by the fact that the Declaration acknowledges the needs and problems faced by certain DCs and LDCs.

6.6 The Decision of 30 August 2003: The Paragraph-6 Decision

At the meeting of the TRIPS Council in March 2002, four possible solutions advanced.

- * an authoritative interpretation of article 30 of TRIPS;
- * an amendment to article 31 of TRIPS in order to overcome the restrictions in article 31(f);
- * a dispute settlement moratorium with regard to non-compliance with the restrictions in article 31(f) of TRIPS;
- * a waiver with regard to article 31(f).

⁴⁸⁸ This view is supported by Philip McCalman in, 'The Doha Agenda and intellectual Property Rights, 'A Study On Regional Integration and Trade: Emerging Policy Issues For Selected Developing Member Countries. Available at <http://www.international-food-safety.com/pdf/The%20Doha%20Agenda%20Intellectual%20property%20Rights.pdf> Who fears that a solution may be found to the problem which would not be available to the LDCs not complying with TRIPS.

⁴⁸⁹ This has also been criticised by several NGOs who believe that a solution should be found to the problem immediately. See Erik Elssegard, "Global pharmaceutical patents after the Doha Declaration – What lies in the future?", (2004) 1:1 SCRIPTed 12, <http://www.law.ed.ac.uk/ahrc/scripted/docs/doha.asp>. See also Ellen F.M 't Hoen "The Global Politics of Pharmaceutical Monopoly Power" (2009) at pages 37-38. Available at http://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS-book-Globalpolitics.pdf

⁴⁹⁰ This has also been stated by the members of WTO (eg the EC, the Africa Group and the Pacific Group of States)

As mandated by the Doha Declaration, a solution to the Paragraph-6 problem was expected by the end of 2002. This, however, proved impracticable as consensus could not be reached. One of the main points of conflict was the scope of diseases to be included in the decision. The Chairman's proposal of 16 December 2002 was consequently blocked by the USA delegation which was unwilling to accept the scope of diseases proposed.⁴⁹¹

Abbott and Reichman⁴⁹² wrote:

'The waiver decision was a result of long and complex negotiation among a substantial number of interested stakeholders, many of whom had widely different perspectives regarding the optimal outcome. Both the waiver and the Amendment nonetheless represent a formal lowering of intellectual property (IP) protection standards imposed by the TRIPS Agreement. The traditional demanders of high standards of IP protection lose something they gained in the GATT Uruguay Round negotiations.'

Finally, on 30 August 2003, a decision was adopted which later became an amendment to article 31 of the TRIPS Agreement.⁴⁹³

6.7 Analysis of the Paragraph-6 problem: Does the Paragraph-6 Decision provide answers to the problems identified during the Doha Declaration on the TRIPS Agreement and public health?

The implementation decision outlines the conditions under which countries with no or insufficient manufacturing capacity can use compulsory licences to import generic medicines,

⁴⁹¹ After initially agreeing to do so in the Doha Declaration, the United States, for nearly two years, blocked meaningful efforts to liberalise access to generics and in particular blocked an expeditious and efficient solution to the production-for-export dilemma. These measures include parallel importation, relaxation of the predominantly for domestic use rule in art 31 (f) of the TRIPS Agreement.

⁴⁹² Note 307 above 932.

⁴⁹³ An Annex to the Decision, provides that LDCs are automatically deemed to have no or insufficient manufacturing capacity in the pharmaceutical sector and provides guidelines to be used by other DCs in establishing that they have no or insufficient manufacturing capacity.

and makes it possible for countries to waive the provision in article 31(f) of the TRIPS Agreement.⁴⁹⁴

This waiver can, however, only be used if the purpose of production and exportation is to supply an eligible importing member.⁴⁹⁵ It therefore appears that the problem has been resolved in that the implementation decision provides a legal framework to ensure that DCs and LDCs can purchase, for example, antiretroviral medicines at affordable prices.⁴⁹⁶ Generally, even though a legal framework has been created, the practical effect remains illusionary.

6.7.1. Scope of diseases covered

As already indicated, DCs demanded that the solution be applied broadly to diseases and treatments.⁴⁹⁷ The USA attempted to restrict the scope of the solution to HIV-AIDS, malaria, tuberculosis, and a potentially small group of other infectious diseases, while also seeking to limit the countries that would benefit from the solution.⁴⁹⁸ At a critical juncture in the negotiations, the EC proposed that the solution be confined to ‘grave’ public health problems, which raised the specter of WTO intervention to determine when a public health problem was serious enough to warrant attention.⁴⁹⁹

⁴⁹⁴ As described in WT/L/540 para 1(c).

⁴⁹⁵ Id para 1(b).

⁴⁹⁶ This appears to be at least a solution to the para 6 mandate as it would enable any country that has not waived the privilege to issue a compulsory licence for a medicine it could not produce and then seek help from any other country having that capacity that was willing to assist it.

⁴⁹⁷ ‘Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health’ “The South African Nonpaper” .Submitted to the TRIPS Council by South Africa 4 November 2002, WTO Ref Job (02)/156. For a list of supporting countries, see Abbott ‘WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, American Journal of International Law, Volume, 99, 317-358 , at pages 328-329.

⁴⁹⁸ It is worth noting that the US initially proposed limiting permissible exporting countries, but this was not strongly pursued. Moreover, the US, like the EU, was opposed to allowing use of the presumptively more liberal art 30 approach, as distinct from the presumptively more restrictive art 31 approach.

⁴⁹⁹ ‘Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health: Elements for a compromise solution’ reprinted in *Inside US Trade* as ‘Text :EU TRIPS Paper, 1 November 2002’. The same EC proposal sought to require that formulation of active ingredients into final products was to take place in the importing member if it maintained the capacity for formulation. This would in some cases require territorial division of the manufacturing process in a way that would make little sense from a cost-efficiency standpoint. The EC further sought to require that the patent holder should always have the right to make an offer of products at ‘strongly reduced prices’, which could be rejected on ‘reasonable grounds’. [www.europarl.europa.eu/.../EXPO-INTA_ET\(2007\)381392_EN.pdf](http://www.europarl.europa.eu/.../EXPO-INTA_ET(2007)381392_EN.pdf).

Both the Paragraph-6 Decision and the pending 2005 Amendment, establish a broad spectrum of medicines and related supplies that may be supplied under the system.⁵⁰⁰ Their definition of ‘pharmaceutical products’ refers to products ‘of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health’.

Paragraph 1 of the Doha Declaration is clear and contains no limitation on the application of the Declaration to specific diseases or medicines. Moreover, ‘pharmaceutical product’ as defined in the Paragraph-6 Decision and 2005 Amendment, expressly covers active ingredients and diagnostic kits used to establish whether pharmaceutical treatments are required. The definition is also broad enough to include vaccines in that vaccines qualify as ‘products of the pharmaceutical sector’.⁵⁰¹

6.7.2 Lack of domestic capacity

As we have seen, paragraph 6 failed to define when a country will be regarded as ‘lacking domestic manufacturing capacity’.⁵⁰² I am of the view that clear criteria are required to guide countries in making this determination.

⁵⁰⁰ Paragraph 1(a), implementing paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health (30 August, 2003), Doc. WT/L/540 (1 September, 2003) [The implementation Decision] ; para 2 article 31*bis*, WTO General Council Decision of 6 December 2005, Amendment of TRIPS Agreement, WT/L/641, 8 December, 2005, with attachment ‘protocol Ammending the TRIPS Agreement’ (with Annex setting out Article 31 *bis*) [hereinafter ‘Protocol of Amendment’ or ‘Amendment’]. Article 31 *bis* incorporates an “Annex to the TRIPS Agreement”. Further references to “Annex” herein are to this “Annex to the TRIPS Agreement” incorporated by Article 31 *bis*.

⁵⁰¹ *The Financial Times* and *The Wall Street Journal* opined, in response to the grant of a compulsory license on Plavix (*clopidogrel*) by Thailand, that the WTO compulsory licensing rules were never intended to cover conditions such as heart diseases. As noted above, members of the European Commission have expressed similar views. Although these opinions were offered in the context of Thailand’s use of Article 31 of the TRIPS Agreement, and not the August 30 Decision, they provide continuing evidence that Pharma’s advertising and lobbying influence will seek to distort the plain language of the TRIPS Agreement and Doha Declaration when it suits their purpose. scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2490&context...

Declaration, the Waiver *Decision* of 30 August 2003 and the Article 31*bis* ... A. Adverse Impact of the *TRIPS Agreement* on the Provision of the *European Commission* have expressed similar views. Although these opinions were offered in the context of Thailand’s use of Article 31 of the TRIPS Agreement, and not

⁵⁰² Under art 31*bis*, a country must either (1) be an LDC, or (2) make a determination that it has insufficient or no manufacturing capacity for the product in question. Paragraph 2(a)(ii) art 3*bis* Annex and Appendix to Annex.

Under paragraph 2(a)(ii) of the implementation decision, it is up to the importing member to establish whether or not it has adequate manufacturing capacity. However, this assessment must be conducted in a way that either establishes that the country has no pharmaceutical capacity, or that the existing capacity is insufficient to meet its needs.⁵⁰³

This requirement imposes no significant burden on a prospective importing member. When there is adequate domestic capacity to produce the product in a way that would reasonably satisfy the country's needs, there is no reason to obtain supplies elsewhere. Developing WTO members succeeded on this issue, despite a proposal to divide the API and formulation markets (which might have created significant inefficiencies).⁵⁰⁴

In conclusion, it appears that the problem regarding the definition of when a country lacks the necessary domestic capacity to produce pharmaceutical products has been resolved in that such a judgment by a member cannot be questioned by another member.⁵⁰⁵

6.7.3 Finding a suitable source of supply

Another important issue is how the DCs and LDCs with no manufacturing capacity can find an appropriate source of supply, which at first glance seems to have been resolved by the implementation decision. However, in my view this predicament persists, even after the entry into force of the implementation decision. Paragraph-5 Decision indicated above, very few countries will be willing to grant compulsory licences in the face of threats from the USA and the pharmaceutical industry. This means that the countries with insufficient manufacturing capacity will, once again, be forced to attempt to import the product from a country which does not

⁵⁰³ Annex to WT/L/540.

⁵⁰⁴ The 'Chairperson's statement', indicates that: 'To promote transparency and avoid controversy, notifications under paragraph 2(a) (ii) of the Decision would include information on how the member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.' Irrespective of the legal status of the Chairperson's Statement, this adds nothing material to the Amendment. A statement that the importing country had examined relevant available data would suffice.
www.law.fsu.edu/faculty/profiles/abbott/study_TRIPS.pdf

⁵⁰⁵ However, several NGOs fear that the developed countries will try to create a system where the DCs/LDCs will be divided into a system of categories, preventing small DCs/LDCs with manufacturing capacity, but a market too small for manufacturing, from making use of the system.

provide patent protection, which since the 2005 Amendment entered into force has only been LDCs.

In other words, the problem of finding a suitable source of supply has not been overcome even though the legal framework for doing so is in place.⁵⁰⁶

6.7.4 Lack of know-how and access to trade secrets

The 2005 Amendment recognises the need to improve pharmaceutical capacity in countries with insufficient or no capacity, and encourages members to ‘use the system in the way which would promote this objective’.⁵⁰⁷ It also includes an ‘undertaking’ by members to address this problem within the framework of article 66.2 of the TRIPS Agreement and related commitments to LDCs.⁵⁰⁸

Most DCs and LDCs have no or very little experience in the use of compulsory licensing to deal with national emergencies. Consequently they lack the technical know-how and access to the trade secrets necessary to make effective use of the licence.

As the system set out in the implementation decision opens up the possibility of importing generic drugs, it appears that the importing countries in question, will not gain technical know-how or access to valuable trade secrets. In other words, the system would not appear to promote transfer of technology and capacity building⁵⁰⁹ as countries without the necessary manufacturing

⁵⁰⁶ This opinion is shared by Erik Alsegard who states that the decision does not solve problems which may still hamper the use of the new rights under the decision. Among other things he states that the developed countries may very well fear threats from the US and therefore decide not to participate in the system. See Erik Alsegard, Global pharmaceutical patents after the Doha Declaration –What lies in the future?, (2004) 1:1 SCRIPTed 12, <http://www.law.ed.ac.uk/ahrac/script-ed/docs/doha.asp> at page 17.

⁵⁰⁷ WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641 8 Dec 2005, with attachment ‘Protocol Amending the TRIPS Agreement’ which includes an Annex setting out art 31*bis*.

⁵⁰⁸ The TRIPS Agreement Article 61.2, requires developed country members to ‘provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer’ to LDCs, so that the latter ‘may create a sound and viable technological base’. See Agreement on Trade Related Aspects of Intellectual Property Rights, Marrakesh, 15 April, 1994, repr. In International Legal Materials 33: 1197. The TRIPS Agreement already discussed in chapter 4 of the thesis.

⁵⁰⁹ As desired in terms of para 7.

capacity will simply import the product instead of developing a domestic industry.⁵¹⁰ At the end of the day the DCs and LDCs will still lack the know-how and access to trade secrets. This will provide little opportunity for the development of their local industries.

6.7.5 The incentive structure

The implementation decision Paragraph-6 Decision has failed to create a source of cheap medicines; it has merely opened the door to medicines cheaper than patented drugs. The fact is that only countries with sufficient manufacturing capacity are in a position to export drugs to members with insufficient manufacturing capacity -- in most cases DCs. This will, of course, for some time create access to medicines at lower prices than under the TRIPS regime, but once Brazil, China and India comply with the TRIPS Agreement, the possibility of importing generic drugs at significantly low prices will no longer exist.

6.7.6 Countries with no patent protection

Compulsory licences can only be issued when a patent exists, and in terms of paragraph 1(a) of the Paragraph-6 Decision implementation decision, a pharmaceutical product is defined as a 'patented product, or product manufactured through a patented process'. In other words, the system only applies when patent protection is granted, which is not the case in most LDCs. Consequently, LDCs are unable to make effective use of the system until they have introduced patent protection – in effect in 2021.

6.7.7 No real solution

As discussed above in analysing the Paragraph-6 problem, the Doha Declaration has not succeeded in providing an actual solution. The implementation decision is a response to the instruction to find a solution and as such the mandate has been met. However, considering the issues highlighted so far, the implementation decision has not, in my view, provided the desired

⁵¹⁰ Which in the author's view, seems unrealistic taking the economic situation and the existing manufacturing facilities in DCs/LDCs into consideration.

result in that it does not appear to provide access to medicines for all. The system established still prevents members from taking the measures necessary to protect public health.⁵¹¹

6.8 The Chairman's Statement

First, the statement recognises that the system as set out in the implementation decision should be used in good faith to protect public health and,⁵¹² without prejudice to paragraph 3 of article 31*bis* of the amendment [paragraph 6 of the Waiver Decision and -- except in regard to the RTA provision -- that it will not be an instrument through which to pursue industrial or commercial policy objectives.⁵¹³

Secondly, it addresses the concerns expressed relating to the risk of diversion by establishing that all reasonable measures should be taken to avoid diversion of medicines from the market for which they were produced. Finally, it sets out ways in which any differences arising from the implementation of the system can be settled expeditiously and adequately.⁵¹⁴

6.9 Conditions of use

With respect to the implementation decision, an 'eligible importing member' is one of the LDCs and any other member which notifies the TRIPS Council of its intention to use the system as an importer.⁵¹⁵ Notification from an importing member must therefore:

- specify the names and expected quantities;

⁵¹¹ See Chakravathi Raghavan, NGOs Demand 'Pro-Public Health', interpretation of TRIPS, TWN, 19 June 2001. Available at <http://twinside.org.sg/title/pro.htm>

⁵¹² This requirement is of crucial importance since non-violation complaints can prejudice the overall applicability of the system. See the General Council Decision WT/L/641 6 December 2005.

⁵¹³ The text of the Chairman's Statement is available at <http://www.wto.org>.

⁵¹⁴ The aim of the system is to support public health needs, and not primarily to advance industrial policy objectives. See Frederick M Abbott 'The Doha Round's public health legacy: Strategies for the production and diffusion of patented medicines under the Amended TRIPS provisions' (2007) 10/4 *J Intl Economic Law* 945.

⁵¹⁵ TRIPS: Council for TRIPS Decision of 30 August 2003 IP/C/W/405 available at <http://www.chr.up.ac.za/undp/global/docs/wto3.pdf>

- confirm, with the exception of LDCs, that the importing member has insufficient or no manufacturing capacity for the product in question;
- confirm, that if the product is patented in the importing country, a compulsory licence is or will be granted.⁵¹⁶

Paragraph four requires an importing member to use reasonable measures, proportionate to its administrative capacity and the risk of trade diversion, to restrict the re-exportation of products imported into its territory under the system.

The exporting/manufacturing members would have to issue a compulsory licence in order to export a generic version of a patented medicine. The exporting members must also notify the TRIPS Council of the grant of a compulsory licence and the conditions attached to it.

In addition, the following conditions must be met:

- Only the amount necessary to meet the needs of the eligible importing member(s) may be manufactured under the licence and the entire production must be exported to the member(s) that has(have) notified its (their) needs to the TRIPS Council.
- Products produced under the licence must be clearly identified as being produced under the system set out in the Council's Decision through specific labeling or marking.⁵¹⁷ The licensee is required to post the quantities being supplied and the distinguishing features of the product(s) on a website.⁵¹⁸

6.10 Procedural requirements

⁵¹⁶ WTO, Implementation of paragraph 6 of the Declaration on the TRIPS Agreement and public health, WTO Doc. WT/L/540 (2003), online: WTO http://www.wto.org/English/tratop_e/implem_para6_e.htm [Council's decision] at para. 2(a)

⁵¹⁷ Id para 2(b)(i)-(ii).

⁵¹⁸ Id para 2(b)(iii).

Carlos Correa has outlined the procedures that are required when using the system.⁵¹⁹

- Unless the prior request for a voluntary licence does not apply, an entity in the importing country must seek a voluntary licence from the patent owner.⁵²⁰
- Failing this, an application for a compulsory licence must be submitted and the licence be obtained in the importing country (pursuant to procedures satisfying article 31 of the TRIPS Agreement including individual determinations, article 31(a) limited scope and duration, article 31(c) and (g) ⁵²¹non-exclusivity and non-assignability, articles 31(d) and (e) and rights of review articles 31(i) and (j)).
- The importing country must assess its generic industry's capacity to produce the required medicine locally.
- If capacity is inadequate, it must notify the WTO of its decision to use the paragraph 6 system.
- The interested importing party must identify a potential exporter.
- That exporter must in turn seek a voluntary licence from the patent owner on commercially reasonable terms for a commercially reasonable period.⁵²²

⁵¹⁹ See Carlos, "TRIPS and Access to Drugs: Towards a Solution for Developing Countries without Manufacturing Capacity?" (2003) 17 Emory International Law Review 389 at 399-402.

⁵²⁰ Non-exclusive voluntary licences with relaxed geographical limitations could have some advantages. In the best-case scenario, the patent holder could transfer technology and manufacturing know-how to the voluntary licensee, which might produce greater efficiencies and ensure quality. In addition, the patent holder would ordinarily allow its licensee to obtain registration by comparing bio-availability and bio-equivalence of the generic product to confidential data previously filed with the drug registration authority.

⁵²¹ Article 31(c) limits a licence to the purpose for which it was authorised; Article 31(g) mandates termination when the circumstances which led to it cease to exist and are unlikely to reoccur; and the Annex to the Implementation Agreement limits it to the period that local capacity is insufficient. In the event of ordinary public health licenses, the duration would at least be as long as the public health problem prevails. However, the duration can be shortened further because of increased capacity in the domestic pharmaceutical sector. Paragraph 6 Implementation agreement, supra note 16, Annex, Option ii. infojustice.org/download/.../access.../baker%20article%204.pdf.

⁵²² This requirement is needlessly repetitious and irrational, especially since the company involved probably first sought a voluntary licence in the importing country, the current text of art 31(b) and the failure of the Paragraph 6 Implementation Agreement to address this second negotiation would seem to require such a ridiculous result. See Brook K Baker, "Arthritic Flexibilities For Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6

- If the voluntary licence is refused, the potential exporter must seek a compulsory licence (to be granted on a single-supply basis) from its own government.
- Compensation by royalty must be individually determined based on economic value in the importing country.
- The exporter will need to seek product registration and prove bio-equivalence and bioavailability, as required by national law in the importing country (despite the patent holder's effort to prevent 'unfair commercial use of its confidential registration data').⁵²³
- If exclusive rights (as promoted by the USA) are granted in the importing country with regard to data submitted for the registration of a medicine, the supplier will have to obtain authorisation from the possessor of the data to use them, or to develop its own studies on toxicity and efficacy.
- Before shipment begins, the licensee shall post information about the quantities being supplied and the distinguishing features of the product on a website.⁵²⁴
- The exporting member must notify the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁵²⁵

One potential consequence of the issuing of double compulsory licences in the importing and exporting members was that the remuneration provided for under article 31(h) of the TRIPS Agreement might have to be paid twice. The 2005 Amendment avoids this outcome by providing that remuneration be paid in the country of export, taking into account the economic

Of The Doha Declaration On TRIPS Agreement and Public Health. Published in 14 *Indiana International and Comparative Law Review*, 613, 92004) at page 653

⁵²³ See the TRIPS Agreement art 39.3.

⁵²⁴ See para 62 (b)(iii) of the Implementation Decision.

⁵²⁵ See C Correa 'TRIPS Agreement and access to drugs' (2003) 17/2 *Emory International Law Review* 401-402.

circumstances of the importing country. This reasonable solution to the remuneration issue should not lead to difficulties.⁵²⁶

While the Amendment does strive to resolve the Paragraph-6 problem, the procedure introduced is very cumbersome. There are several hurdles that need to be overcome before a LDC or any other member can invoke the use of a compulsory licence. It further does not serve the interest of the marginalised and vulnerable people worst affected by life-threatening diseases. This is not in the spirit of the Doha Declaration: it is akin to giving with the right hand and taking with the left. No other country wishes to have the type of experience that Rwanda had.

The remuneration requirement that a royalty is payable even if the medicine is being produced for a country where it is not patented, is highly regrettable. In this regard an importing poor country is worse off under the Implementation decision than it would have been had it had local capacity to produce medicines. As the ultimate consumer, the importing, non-patent member will be required to pay the added cost of a licence royalty even though there would have been no royalty on locally produced medicines. This is yet another example of how the Implementation decision is unfairly biased against generic imports.⁵²⁷

6.11 Proposals for the amendment of the TRIPS Agreement

The Council for TRIPS in paragraph 11 of its 2003 Implementation Decision, mandated members to work towards a permanent solution to the problem which will involve the amendment of article 31(f).⁵²⁸ Unfortunately, it took a while before this solution could be found. Several meetings by the Council to find a solution to the problem ended in deadlock. Developed countries, led by the USA and members of the EC, stood in the way of a permanent solution to the problem claiming that it would render patent rights meaningless. Developing countries on the other hand, and particularly the Africa Group, insisted on a permanent solution to the Paragraph-

⁵²⁶ See para 2 art 31*bis*.

⁵²⁷ See Brook K Baker 'Arthritic flexibilities for accessing medicines' (2004) *supra* at p. 648.

⁵²⁸ The Implementation Decision para 11 states that the decision is only temporary and will lapse when an amendment to the TRIPS Agreement is adopted.

6 problem of the Doha Declaration as the only way out to save the lives of millions of people dying of various diseases in Africa.⁵²⁹

In the following paragraphs, I briefly describe and analyse the proposals made by the USA, the Africa Group, and the EC.

6.11.1 The United States of America

The USA has been the most vocal⁵³⁰ active when it comes to putting across its views on how to implement paragraph 6 of the Doha Declaration,⁵³⁰ and also on how to amend the TRIPS Agreement in accordance with the implementation decision. This became very clear when the USA blocked the proposal from the Chairman on how to adopt paragraph 6.⁵³¹

One of the major issues for the USA when it comes to the amendment of the TRIPS Agreement is that the principles of good faith and prevention of re-exportation must be part of the text of the amendment.⁵³² In other words, the USA will not accept an amendment that does not include these issues. Generally, the USA affirms that the amendment of the TRIPS Agreement must be seen as a purely technical matter, and that no substantive issues should be revisited in the process⁵³³. The proposal for amendment made by the USA is that the implementation decision and the Chairman's statement are incorporated into the TRIPS Agreement by means of footnote – a quick, easy and straightforward solution.⁵³⁴

6.11.2. The Africa Group

⁵²⁹ See, Ebenezer Durojaiye 'Compulsory licensing and access to medicines in post-Doha era: What hope for Africa' 2008 *Netherlands International Law Review* LV:33-71, 54.

⁵³⁰ Eg in IP/C/W/358.

⁵³¹ As previously mentioned, all members had agreed on the text, however the US blocked it because the scope of diseases was not defined.

⁵³² IP/C/W/444 para 12.

⁵³³ IP/C/W/444 para 7.

⁵³⁴ Id para 9.

Although the Africa Group was not entirely satisfied with the Paragraph-6 Decision, they accepted it on the understanding that the system set up in the Decision would be temporary.⁵³⁵ The Africa Group was, therefore, battling to reach a solution to the amendment problem. As one can well imagine, the solution proposed by the Africa Group⁵³⁶ differs from that of the USA and shows the difficulty the two parties were experiencing in reaching a mutually acceptable solution.⁵³⁷

The proposal from the Africa Group on how to amend the TRIPS Agreement involved the amendment of article 31. More specifically, the Africa Group proposed that the existing text of article 31 become article 31.1 and the amendment become article 31.2. Generally, the provisions of the implementation decision are included in the proposed amendment. However, the Africa Group elected to omit a number of provisions which it considered to be unnecessary.⁵³⁸

Some of the provisions in paragraph 2 of the implementation decision were omitted, especially those providing for notification. The proposal simply stated that an eligible importing member is one who has notified the Council of TRIPS of its intention to use the system. Moreover, the provisions in paragraph 2(b)(i) of the implementation decision are omitted. This includes the requirement that the exporting country produce only the amount of medicine necessary to meet the needs of the importing country under the compulsory licence.⁵³⁹

Additionally, the provisions in paragraph 4 concerning diversion were omitted, as were the provisions in paragraph 8. The rationale for omitting these is, according to the Africa Group, that their purpose is already served by the TRIPS Agreement, or that they are simply superfluous.⁵⁴⁰

Furthermore, the Africa Group stated that they ‘... cannot and will not accept an interpretation of paragraph 11 that says that the August Decision and the Chairman’s statement in its entirety should form the amendment’.⁵⁴¹

⁵³⁵ IP/C/W/445 para 8.

⁵³⁶ IP/C/W/437.

⁵³⁷ This can be seen in IP/C/W/444 para 8 where the US criticises the proposal of the Africa Group.

⁵³⁸ IP/C/W/437 para 3.

⁵³⁹ See Sarah Hedelund ‘The new regime of compulsorylicensing’ at page 49.

⁵⁴⁰ IP/C/W/437 para 3.

Judging from this sequence of events, it is reasonable to conclude that the amendment to the TRIPS Agreement dragged on for so long a time because the parties did not share common views.

6.11.3 EC implementation⁵⁴²

Although the WTO decision on the amendment to the TRIPS Agreement is yet to be made, many EC member countries have already implemented the implementation decision in their national legislation.⁵⁴³

Although the EC identified two possible solutions to the implementation of paragraph 6 in its communication of 4 March 2002,⁵⁴⁴ its June communication of the same year identifies only a single solution.⁵⁴⁵

Before the implementation decision was adopted, the EC found that the appropriate way of implementing paragraph 6 was to add an extra paragraph to article 31 of the TRIPS Agreement which would allow for an exception to article 31(f). According the EC this offered the best guarantees for a ‘sustainable, balanced and workable solution to the problem raised under paragraph 6...’.⁵⁴⁶

The EC realised that a temporary waiver could fall short of providing the type of sustainable and legally secure solution it was aiming for.⁵⁴⁷ Like the USA, the EC wanted the amendment of the

⁵⁴¹ Id para 13.

⁵⁴² COM (2004) 737 ‘Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems’.

⁵⁴³ Among others, Canada (‘Bill C-9: An Act to amend the Patent Act and the Food and Drugs Act 14 May 2004) and The Netherlands (Policy Rules on issuing compulsory licences pursuant to WTO decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995, 21 December 2004).

⁵⁴⁴ IP/C/W/339.

⁵⁴⁵ IP/C/W/352.

⁵⁴⁶ Id para 5.

⁵⁴⁷ Id para 6.

TRIPS Agreement to remain essentially technical, and faithfully reflect what was agreed to in the Decision.⁵⁴⁸ In other words, the amendment process should not reopen issues for further discussion. For this reason the EC proposal appears to support its American counterpart as regards the content of the amendment, and the EC was accordingly unable to support the proposals from the Africa Group.⁵⁴⁹

The EC was, however, consistent in requiring that the process should be rapid and comply with the timeframe set out in paragraph 11 of WT/L/540.

6.12 The Protocol Amending the TRIPS Agreement

Paragraph 11 of the implementation decision provides that the Paragraph-6 Decision is only temporary and will terminate when an amendment to the TRIPS Agreement is agreed upon.⁵⁵⁰ Moreover, it states that the work on such an amendment shall be initiated by the end of 2003 with a view to adopting an amendment within six months.

Amending a WTO Agreement is very difficult. It involves two aspects: the legal process; and achieving consensus on how to amend the agreement. After the Ministerial Conference has received a proposal from either a member or one of the councils, it has 90 days⁵⁵¹ to decide to submit the proposed amendments to the members. This decision must be taken by consensus^{552 553} and serves as a guard against surprise proposals. If consensus is not reached within the period determined,⁵⁵⁴ the Ministerial Conference must decide by two-thirds majority, whether or not to submit the proposed amendment. Taking past negotiations into consideration and the highly divergent views of the members of the WTO, it came as no surprise that the process of amending the TRIPS Agreement took as long as it did.

⁵⁴⁸ IP/C/W/416 para 15

⁵⁴⁹ See Sarah Hedelund Skove 'The new regime of compulsory patents licensing' n XX above 52.

⁵⁵⁰ Waivers are subject to annual review, after which they may be extended, modified or terminated, Agreement Establishing the WTO art IX 4.

⁵⁵¹ Unless a longer period is agreed upon.

⁵⁵² Agreement Establishing the World Trade Organisation art X 1.

⁵⁵³ Consensus differs from unanimity- id art IX 1.

⁵⁵⁴ Which in the case of amending the TRIPS Agreement regarding the granting of compulsory licences will most probably be the case.

In fact, the Protocol amending the TRIPS Agreement adopted by the General Council in 2005 ('the Protocol'), is the first amendment of the WTO agreed to by WTO members since the WTO Agreement came into force in 1995. The General Council adopted the Protocol and submitted it to WTO members for acceptance. In substance, the Protocol closely tracks the Paragraph-6 Decision's August 2003 text. The decision on the amendment was also taken in the light of a re-reading by the General Council Chairman of his August 2003 statement.

The amendment was to take effect in accordance with article X(3) of the WTO Agreement.⁵⁵⁵ Under article X(3), two-thirds of WTO members must accept the amendment in order for the it to take effect.

The Protocol will be formally built into the TRIPS Agreement once two-thirds of WTO members have accepted the change. The original deadline for this was 1 December 2007.

The Protocol has not yet been approved by the required two-thirds of member states and the deadline for ratification has been extended on three occasions, most recently expiring at the end of 2011. The General Council extended the deadline to 31 December 2009; 31 December 2011; and 31 December 2013 by decisions on December 2007; 17 December 2009; and 30 November 2011.

Once two-thirds of members have formally accepted it, the Protocol will take effect in those members and will replace the 2003 waiver for them. For each of the remaining members, the waiver will continue to apply until that member accepts the Protocol and it takes effect. As at 5 November 2012, only 45 countries had ratified the Protocol.

6.12.1 Contents of the Protocol

No significant changes were made to the original paragraph 6 system implemented by the Paragraph-6 Decision 2003 Waiver Decision. The Protocol introduces three new elements to the

⁵⁵⁵ Id para 3.

TRIPS Agreement: a new article 31*bis*; an annex setting out the terms and conditions for the use of additional flexibilities; and an appendix to the annex dealing with the assessment of manufacturing capacities.

The new article 31*bis* (following on article 31 of the TRIPS Agreement), reiterates the non-application of non-violation complaints against any measures taken in conformity with the system and the need for existing flexibilities under the TRIPS Agreement to be preserved. It introduces two additional flexibilities in subsections 1 and 2.

Article 31*bis*.1 exempts exporting members from complying with article 31(f) of the TRIPS Agreement when granting compulsory licences to the extent necessary for the production of a pharmaceutical product(s) and their export to an eligible importing member. These undertakings must be in accordance with the conditions set out in paragraph 2 of the Annex to the TRIPS Agreement.

Article 31*bis*.2 restates the article 31(h) waiver rule contained in the Paragraph-6?? 2003 Decision under which the patent holder only receives compensation from the exporting member where both exporters and importers have to grant compulsory licences for the export of a product. Article 31*bis*.3 transposes the waiver of article 31(f) within the RTA.

6.12.2 Shortcomings in the Protocol to the TRIPS Agreement

Since the Protocol is based on the TRIPS Council Decision of 2003 the same criticisms levelled at the Decision identified above, apply to the Protocol. In fact, MSF has noted that it is disappointing, and almost unbelievable, that the Council adopted an amendment based on the unworkable and cumbersome Paragraph-6 Decision.⁵⁵⁶

⁵⁵⁶ MSF 'Neither Expeditious, Nor a Solution: The WTO August 2003 Decision is Unworkable' (2006) 6. Available at www.msfacecess.org/sites/default/files/msf_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf

Gathi adds that ‘in reality the practicability of the so-called amendment may prove illusory for poor countries due to the implausibility of the several conditions attached to it.’⁵⁵⁷ Since the 2003 Paragraph-6 Decision which has now given birth to the Protocol was adopted, only one country has been able to use it successfully.⁵⁵⁸

While it is conceded that this amendment to the TRIPS Agreement strives to resolve the Paragraph-6 problem of the Doha Declaration, it is doubtful whether it will achieve this aim. This is because the several hurdles to be overcome before a DC can invoke the use of compulsory licences under it, are a betrayal of the spirit of Doha Declaration. The Protocol does not serve the interest of DCs and is also not consistent with realising the right to health for the vulnerable and marginalised people most affected by life-threatening diseases.

6.13 Conclusion

The Doha Declaration has attempted to address real and urgent problems facing many DCs and LDCs in the area of public health. The Declaration did not intend to amend the TRIPS Agreement to any substantial extent, but rather sought to clarify the relationship between the TRIPS Agreement and the public health policies of member countries, and to confirm the rights that members have retained under the Agreement, particularly by defining the flexibilities allowed in certain important areas.

The Declaration addressed the concerns of DCs on the issue of public health. The Declaration makes it clear that in the event of a conflict between the TRIPS Agreement-standard and public health, the members – DCs and LDCs in particular – can take measures to protect public health. The Declaration sets the standard for a differentiation of IP policies when necessary to protect public health.

⁵⁵⁷ See J Gathi ‘How necessity may preclude state responsibility for the compulsory licensing under the TRIPS Agreement’ (2006) 31 *North Carolina Journal of International Law and Commercial Regulation* 956.

⁵⁵⁸ Rwanda being an LDC notified the Council for TRIPS in accordance with para 2(a) of the 30 August 2003 Decision to import triple combination *Triavir* from Canada. In the same way Canada also notified the Council in October 2007 to export the same drugs to Rwanda in line with para 2(c) of the 2003 Decision. The whole exercise took too long and was a bitter lesson for the two parties involved in the transaction.

As the mandate given in paragraphs 6 and 7 illustrates, the Declaration represents an initial step for rethinking the TRIPS Agreement in the light of public interest rather than the end of a process. The aim of paragraph 6 was to solve the problem created by the TRIPS Agreements' extension of patent protection for pharmaceutical products to all WTO members, irrespective of their level of development or their pharmaceutical manufacturing capacity. Furthermore, article 31(f) the TRIPS Agreement stipulates that production under a compulsory licence must be 'predominantly for the supply of the domestic market'. This restriction limits the quantity that can be produced for export. The Declaration elected to postpone a resolution of this problem to a later date, but called for an expeditious solution.

After more than two years of protracted and difficult negotiation, this solution was finally approved and initially embodied in a waiver, known as the Paragraph-6 Decision. This waiver is expected to be rendered permanent by virtue of a pending amendment to the TRIPS Agreement, known as article 31*bis*. The waiver remains in effect while governments take steps to ratify the Protocol. The Paragraph-6 Decision appears to provide solutions to most of the problems identified under paragraph 6. It is up to the country facing the national emergency not only to determine what constitutes a national emergency or other extreme urgencies, but whether the country lacks manufacturing capacity in the pharmaceutical sector.

However, even though there is now legal framework in place, and a mechanism to allow DCs and LDCs with insufficient manufacturing capacity to make effective use of compulsory licensing, the practical effect remains uncertain. As of 2009, the waiver had only been used once due, in part, to the cumbersome nature of the process. To date only one country has successful made use of the process.

CHAPTER 7

INDIA: THE PHARMACY OF THE DEVELOPING WORLD

7.1 Introduction

Before joining the WTO in 1995, India only allowed pharmaceutical patents for manufacturing processes used to produce drugs and did not permit patents for products.⁵⁵⁹ This system was designed ‘to encourage companies to compete in low-cost manufacturing, developing the nation’s industry and making medicines widely available at low prices.’⁵⁶⁰ By joining the WTO, India had to adapt its patent laws in order to comply with the WTO’s TRIPS Agreement.⁵⁶¹ Since the WTO classified India as a DC, the TRIPS Agreement allowed the country ten years in which to update its patent laws to conform fully to WTO standards.

The new Indian Patents (Amendment) Act of 2005 (‘Patents Act’) provides for patents on a much larger and more specific scale, including patents on pharmaceuticals, in order to comply with the WTO’s minimum protection for IP.⁵⁶²

These stricter standards present a challenge for India’s pharmaceutical industry since it largely depends on its ability to produce generic drugs at far lower prices than their patented counterparts.⁵⁶³ Although, the Indian Patents Act complies with the TRIPS Agreement, its section 3(d) rejects the widespread industry practice of extending a drug’s period of patentability by making minor, insignificant alterations to medications – a practice commonly known as ‘evergreening’.⁵⁶⁴ Through its careful construction, the section also reconciled the TRIPS Agreement and the Doha Declaration. The parameters of the Indian Patents Act were put to the

⁵⁵⁹ John S. James, India changes Patent Law to meet WTO Treaty, Making New Medicines less Available to most citizens, other countries, AIDS NEWS, Dec 31 2004, <http://www.aidsnews.org/2004/12/india-patent.html>

⁵⁶⁰ Id. at page 1

⁵⁶¹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex....., Legal instruments- Results of the Uruguay Round, 108 Stat. 4809,33 I.L.M.81, available at http://www.wto.org/English/docs_e/Legal_e.html#TRIPS

⁵⁶² The Patents (Amendment) Act, 2005, No 15, Acts of Parliament, 2005, sec 3(d), available at http://www.patentoffice.inc.in/ipr/patent/patent_2005.pdf

⁵⁶³ See Meredith Dearborn, India Restricts Generic Drugs, YES; mag., Summer 2005, <http://www.yesmagazine.org/article.asp?ID=1295>.

⁵⁶⁴ See Novartis Patent Challenge Dismissed in India, 11 Bridges: Wkly Trade News Dig., Sept. 5 2007, <http://www.ictsd.org/weekly/07-09-05/story3.htm> (quoting Tido von Schon-Angerer, Director of the Medicins Sans Frontieres campaign for access to essential medicines).

test when Novartis filed suit against the Indian government challenging the Controller General's refusal to grant its patent application for *Glivec*.

7.2 The Indian Patents Acts of 1970 and Amendment Act of 2005

Passed in 1970, India's Patent Act allowed the patenting of methods or processes that led to the production of drugs but did not allow the patenting of the drugs themselves. This system was designed 'to encourage companies to compete in low-cost manufacturing, developing the nation's industry and making medicines widely available at low prices.'⁵⁶⁵

Patent protection for pharmaceuticals was only granted for seven years as opposed to 14 years for other inventions. This Act became the cornerstone for a highly successful Indian generic industry. The salient provisions of the Act, and selected court decisions interpreting these provisions will be discussed in this chapter.

7.2.1. Exclusions from patent protection

Section 3 of the Indian Patents (Amendment) Act of 2005 is the key section on 'patent eligibility' and provides a list of subject matter which will not be considered to be an invention for the purposes of the Act. The implication, therefore, is that such subject matter cannot be patented in India. The most important provision is section 3(d). This section reads:

'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

[Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.]'

⁵⁶⁵ John S. James, India Changes Patent Law To Meet WTO Treaty, Making New Medicines Less Available to Most Citizens, Other Countries, AIDS Treatment News, Dec. 31, 2004. Available at <http://www.aidsnews.org/2004/12/india-patent.html>.

7.2.2 Novartis's challenge to section 3(d) of India's Patent Act

Section 3(d), and its explanation (as amended with effect from 1 January 2005), prescribes a class of invention which cannot form the subject matter of a patent. This section has severely restricted the number of patents that can be granted in India.

Novartis entered the Indian market during the period when the country began the process of updating its patent laws to comply with the requirements of the WTO's TRIPS Agreement. The company formally entered India in 1998, before the government amended its 1970 Patents Act. Although Novartis obtained the patents for *Glivec* in the United States and other countries in 1993, it did not attempt to secure a patent for *Glivec* in India until 1998.⁵⁶⁶ Since *Glivec* was not patented in India, generic forms of the imatinib-free base drug could be made available to cancer patients in the country.

When Novartis finally presented its application for an updated form of *Glivec* to the Indian Patent Office in 1998, the patent was placed in a 'mailbox'⁵⁶⁷ until India's Patents Act had been updated and no longer provided patents for 'a new form of a known substance'. The Patent Office evaluated Novartis's application for an enhanced form of *Glivec* pursuant to amended section 3(d) of India's 2005 Patents Amendment Act, which provides instructions regarding the granting of patents for

'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process,

⁵⁶⁶ In January 2003, India granted Novartis Exclusive Marketing Rights (EMR) to *Glivec*. Cancer Patients Association, The *Glivec* Story, <http://www.cpaaindia.org/aboutus/theglivecstory.htm>. Thereafter, "Indian courts forbade 6 out of 9 generic producers to market Imatinib Mesylate." Although this benefited Novartis, there were negative consequences for the Indian people as *Glivec* was not affordable to many.

⁵⁶⁷ Press Release, Health Global Access Project, Fact Sheet: Changes to India's Patents Act and Access to Affordable Generic Medicines After January 1, 2005, (Dec.14, 2004), http://www.healthgap.org/press_releases/04/121404_HGAP_FS_INDIA_patent.pdf (citing rule 70.8 of TRIPS that required India to establish a "mailbox" where patent applications could be filed between 1995 and 2005. After January 1, 2005, the mailbox (was) opened, and requests for patents considered by the Indian Patent Office".).

machine or apparatus unless such known process results in a new product or employs at least one new reactant'.⁵⁶⁸

Although Novartis attempted to demonstrate an enhancement of the drug's efficacy before the Patent Controller, the Patent Office determined that Novartis's data did not present convincing evidence that the drug's efficacy had been sufficiently enhanced as required by India's Patents Act.⁵⁶⁹ Novartis responded to the Controller's decision not to grant the patent by initiating two separate proceedings. First, it appealed to the Intellectual Property Appellate Board ('IPAB'), hoping that it would overturn the decision of the Patent Office.

Secondly, Novartis directly challenged section 3(d) of India's Patents Act in the High Court, claiming that the Act was 'arbitrary, illogical, vague', and unconstitutional, and that it violated India's compliance with the TRIPS Agreement. The two suits are summarised below.

7.2.2.1 *Novartis AG v Union of India & others* MP Nos 1-5/2007 and TA/1-5/2007/PT/CH (IPAB-2009)

This was an appeal to the IPAB against the Patent Office's decision to reject Novartis's patent application for its drug *Glivec*. The Patent Office had rejected the patent application on the basis that it failed to meet the requirements of section 3(d). Novartis's appeal was rejected by the IPAB, which agreed with the Patent Office's assessment that Novartis had failed to satisfy the criteria set by section 3(d) of the Patents Act. Novartis clearly recognised the negative impact which this decision would have on its potential profits for a patented version of *Glivec* and appealed to the Supreme Court of India.

7.2.2.2 *Novartis AG v India & others* (2007) 4 MLJ 1153

In this landmark case Novartis challenged the constitutionality of section 3(d) of the Patents Act on the ground that it was arbitrary as it vested unfettered discretion in the Patent Office. Section 3(d) barred the patenting of new forms of known substances unless the new form could

⁵⁶⁸ The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, section 3(d) available at http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.

⁵⁶⁹ See *Novartis Loses Patent Claim on Cancer Drug*, SIFY, Jan. 26, 2006, <http://sify.com/finance/fullstory.php?id=14127695>; see also Ali K, *supra* note 31 (noting that Novartis offered evidence showing that the drug had "an enhanced bioavailability of 30 percent in studies conducted on rats")

demonstrate an increase in properties related to efficacy. Novartis also sought a declaration that section 3(d) was not compatible with the TRIPS Agreement. In its judgment the Madras High Court ruled that section 3(d) of the Act was constitutional and that the section was also compatible with the TRIPs Agreement. The court went on to hold that 'efficacy' as understood in section 3(d) could be defined as 'therapeutic efficacy'. This meant that the Indian pharmaceutical industry could continue producing the generic form of the drug at a much lower price than if the drug were patented.⁵⁷⁰

Novartis was particularly frustrated with the Patent Office's decision because patents for the beta crystal form of *Glivec*⁵⁷¹ had been granted in nearly 40 other countries, including Russia, Taiwan and China.⁵⁷² However, despite Novartis's detailed and specific objections to India's new patent laws, the Indian High Court dismissed the suit.⁵⁷³

The Indian High Court's decision to deny Novartis's challenge to India's Patents Act has far-reaching implications for the global community. The decision to uphold the Act protects India's hugely successful generic pharmaceutical industry because the stringent standards of patentability upheld by the court mean that fewer medicines will be eligible for patents. However, the Indian High Court declined to address Novartis's claim that India's Patents Act violated the requirements of the TRIPS Agreement, asserting that it lacked jurisdiction to rule on international treaties.⁵⁷⁴ The court suggested that the WTO was the proper forum in which Novartis could challenge India's compliance with the TRIPS Agreement.⁵⁷⁵

Not surprisingly, NGOs and aid organisations such as *Médicins Sans Frontières* (Doctors Without Borders), which had sponsored a petition signed by almost half a million people urging Novartis to drop the case, praised the Indian High Court's ruling as a victory for the 'rights of

⁵⁷⁰ Press Release, Oxfam International, Novartis Lawsuit Threatens Access to Medicines for Millions (Jan. 29 2007) http://www.org/en/news/2007/pr070219/_novartis ("Glivec sells for \$27000 per patient per year in India, but the generic version sells for \$2,000 per patient per year.")

⁵⁷¹ See infra notes 72-73 and accompanying text.

⁵⁷² Press Release, Novartis, Novartis Concerned Indian Court Ruling will Discourage Investments in Innovation Needed to Bring Better Medicines to Patients (June 8, 2007) <http://cws.huginonline.Com/N/134323/dr/200708/1144199-5-2.html>.

⁵⁷³ See Novartis Patent Challenge Dismissed in India, supra note 1

⁵⁷⁴ Novartis, W.P. Nos 24759 & 24760, at para. 4

⁵⁷⁵ Novartis Patent Challenge Dismissed in India, supra n.1

patients over patents.’⁵⁷⁶ By contrast, Novartis argued that the decision ‘will have long-term negative consequences for research and development into better medicines.’⁵⁷⁷ While the decision made international headlines, the news generated equal attention in India.⁵⁷⁸ Supporters of India’s pharmaceutical industry clearly viewed the decision as a victory for both India’s pharmaceutical industry and the developing world.

I support the court’s judgment in this matter, India must not succumb to pressure from developed countries within the WTO to amend the controversial wording of its section 3(d) because the language of the Act satisfies the requirements set by the TRIPS Agreement. Additionally, the language of India’s victory against Novartis should encourage WTO members to reassess their own patent law regimes in light of both the TRIPS Agreement and the Doha Declaration.

Mr TC James, a patent law expert and Director of the National Intellectual Property Organisation (‘NIPO’) in his paper entitled ‘Patent Protection and Innovation’⁵⁷⁹ states that:

‘Section 3(d) only sets a standard for inventiveness and does not debar incremental innovations which meet the criteria for patentability. The removal of section 3(d) would result in ‘ever-greening’ and delay in the entry of generics and thereby adversely affecting public health.’

Commenting on the ruling of the Madras High Court, Shamnad Basheer and T Prashant Reddy in an article titled ‘Ducking’ TRIPS in India’,⁵⁸⁰ a saga involving Novartis and the legality of section 3(d), state as follows:

‘In India, the only statute implementing India’s TRIPS obligation is the Patent (Amendment) Act, 2005. Neither this Act nor any other statute expressly or impliedly bars the High Court from hearing a TRIPS challenge. Therefore, while the court could not have struck down Section 3(d) as being violative of TRIPS, It possessed inherent jurisdiction to entertain the matter. The court was

⁵⁷⁶ Gentleman, supra n. 5

⁵⁷⁷ Press Release, Novartis, supra note 24

⁵⁷⁸ See Praful Bidwadi, Health –India: Novartis Patents Case Far from Death, INTER PRESS SERVICE, Aug. 9, 2007, <http://ipsnews.net/news.asp?idnews=38840>; Rajesh Chaddramouli, Novartis Loses Fight for Cancer Drug Patent, TIMES OF INDIA, August 7, 2007, http://timesofindia.indiatimes.com/india/Novartis_loses_fight_for_cancer_drug_patent/articleshow/2260719.cms; Feroz Ali K, Novartis: Do Indian Patent Laws Stifle Research?, HINDU, August. 9, 2007, <http://www.hindu.com/seta/2007/08/09/stories/20070809501500.htm>.

⁵⁷⁹ National Intellectual Property Organisation (NIPO) (2010)

⁵⁸⁰ *Novartis AG v Union of India*, (2007) at 28. (Madras High Court)

therefore wrong in holding that it had ‘no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of TRIPS.’⁵⁸¹

The authors further state:

‘Since patentability criteria has not been defined under TRIPS, a deeming provision such as section 3(d) which caters to a specific technology sector is perfectly compatible with TRIPS. However, care must be taken to ensure that this provision is not interpreted in a manner that no pharmaceutical derivative or incremental innovation is ever patentable; else the provision runs the risk of falling foul of TRIPS.’⁵⁸²

They⁵⁸³ conclude that the Madras High Court was correct to defend the constitutionality of section 3(d). On the issue of compatibility with the TRIPS Agreement, they observe that the court was incorrect to have relied on a ‘contractual’ framework to ‘duck’ the issue. In their view the High Court ruling does not settle the TRIPS issue but only shifts the jurisdictional venue, and that if the matter were to come before the WTO, it is very unlikely that the panel would rule against India.

Basheer and Reddy, in their article titled ‘The ‘efficacy’ of Indian patent law: Ironing out the creases in section 3(d)’,⁵⁸⁴ further state:

‘Notwithstanding the constitutionality of section 3(d) and its laudable intent of preventing “evergreening”, it is a crudely worded provision. Illustratively, the main section and the explanation are inconsistent, particularly when it comes to the patentability of a “new form” that has a “new use”.’

The creases in section 3(d) need to be ironed out to make it work more effectively and to lend more certainty to the law. This becomes even more pertinent, given that there are more cases at

⁵⁸¹ *Novartis AG v Union of India*, (2007) at 28. (Madras High Court)

⁵⁸² See National Law School of India Review, Vol. 20 No. 2, pp. 131-15. (2008)

⁵⁸³ See Basheer, Shamnad and Reddy, Prashant, ‘Ducking’ TRIPS in india: A Saga Involving Novartis and the Legality of section 3(d) supra

⁵⁸⁴ See The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d) SCRIPTED, a Journal of Law, Technology & Society, Vol 5, Issue 2, 2008.

the Indian Patent Office that hinge on section 3(d)⁵⁸⁵ and several countries that are seeking to emulate this unique statutory provision.⁵⁸⁶

The article not only offers suggestions on how these creases could be ironed out, but goes on to build on these suggestions and propose an amendment to section 3(d).⁵⁸⁷

According to the authors, ‘though noble in intent, the drafting of section 3(d) leaves much to be desired. Riddled with uncertainty, the current version of section 3(d) is a litigators’ El Dorado. Based on our discussion above, this is the amendment that we propose to section 3(d).’⁵⁸⁸

Whilst Novartis lost its case against India, its drug *Glivec* is also currently facing problems in the US. One month’s dosage of the drug costs approximately \$7 000 in the US. Several health activists and cancer patients have filed a petition to the Obama government calling for a reduction in the cost of *Glivec*. The protest in the US against *Glivec*’s high pricing, ties in with the utility of section 3(d) in the Indian Patents Act 1970. Such provisions curtail the monopoly established by the multinational pharmaceutical companies thereby facilitating the provision of medicines to the public at lower prices.

Recently, in April 2013, the Supreme Court of India refused Novartis’s appeal to patent *Glivec*.⁵⁸⁹ Novartis, has therefore lost its six-year legal battle as the court ruled that ‘small changes and improvements to the drug *Glivec* did not amount to innovation deserving a patent’.⁵⁹⁰ Novartis argued that better physicochemical qualities, such as shape of the molecule,

⁵⁸⁵ To date, there have been very few cases where section 3(d) of the Patent Act has been used as the basis for the rejection of a patent application. The first was the patent application for *Glivec*, filed by Novartis and which was rejected for reasons already discussed in this thesis. More recently, the patent office rejected the claim for an anti-HIV Nevirapine composition, as falling short of satisfying the increased efficacy hurdle under section 3(d). It is also pertinent to note a recent court case, where the Delhi High Court declined to grant a temporary injunction to Roche, who sued CIPLA for infringement of its patent covering its anticancer drug, Tarceva. Cipla counter claimed invalidity, citing section 3(d) as one of the grounds. See *F.Hoffman-La Roche Ltd. & Another. V Cipla Ltd*, CS (OS) 89/2008, Delhi High Court.

⁵⁸⁶ GC Prasad, Copy Cats Popping Patent Law Pill, *Economic Times*, August 13, 2007 http://economic.indiatimes.com/News_By_Industry/Healthcare_Biotech/pharmaceuticals/Copcats_Poping_Patent_Law_Pill/articleshow/2276358.cms (last visited 15 May, 2013)

A recent law passed by Philippines bears strong resemblance to Section 3(d). See P Ollier, Philippines plans to follow India in limiting patentability, May 6 2008: <http://philippines-plans-to-follow-india-in-limiting-patentability.html> (last visited 15 May, 2013)

⁵⁸⁷ See *The Efficacy of Indian Patent Law: Ironing Out the Creases in Section 3(d)* supra (above referenced)

⁵⁸⁸ See *The Efficacy of Indian Patent Law: Ironing Out the Creases in Section 3(d)* supra (above referenced)

⁵⁸⁹ *Novartis Ag v Union of India and Others Civil Appeal NO. 278 OF 2013* (Arising out of SLP No. 32706 of 2009) (The judgment of the Supreme Court of India)

⁵⁹⁰ Para157 at pages 81-82 and see also para 195 at page 96

stability, hygroscopicity, and solubility, would satisfy the test of enhanced efficacy. But the Supreme Court held that the changes were simply an attempt at ‘evergreening’ – the practice, common in Europe and the US, of refreshing the drug so that a new patent will be granted.⁵⁹¹ The judgment opens the way for generic companies in India to manufacture and sell cheap copies of the drug in the developing world and has implications for anti-HIV and other modern drugs.

7.2.3 Other suits filed against section 3(d) of the Indian Patents Act

7.2.3.1 *F Hoffmann la Roche Ltd & another v Cipla Limited* 2008 (37) P TC 71 (Del), CS (OS) No 89/2008

This was the first case in which a pharmaceutical patentee, Roche, sought an interim injunction against a generic manufacturer which had manufactured a generic version of its ‘*erlotinib hydrochloride*’, a drug which Roche alleged was covered by its patents in India. The generic manufacturer, Cipla, challenged Roche's patent on the ground that it was barred by section 3(d). The Delhi High Court denied Roche ‘an interim injunction, in the terms sought’. The defendant was, however, ordered to furnish an undertaking to the court. The interim injunction was dismissed on the ground that it would be against ‘public interest’.⁵⁹²

The plaintiff filed an appeal against the dismissal of the interim application - FAO (OS) No 188/2008 – but this was dismissed on 24 April 2009.⁵⁹³ The court held that ‘since wherein there is no case made out for infringement, the question of grant of permanent injunction, damages or costs does not arise.’⁵⁹⁴

7.2.3.2 *Glochem v Cadila Healthcare Ltd & others* Writ Petition No 1605 of 2009 High Court of Bombay

⁵⁹¹ See paragraphs, 189, 190 and 191 of the judgment of the Supreme Court of India.

⁵⁹² See para 87 of the court’s judgment.

⁵⁹³ Id para 299.

⁵⁹⁴ Id para 301.

This is probably the first case where two Indian companies clashed over the section 3(d) issue. Glochem petitioned the court after its pre-grant opposition to Cadilla's drug patent application (No 413/Mum/2003A) was dismissed by the Assistant Controller of Patents.

In allowing the writ petition the Bombay High Court chose to interpret section 3(d) in a manner similar to the Madras High Court. The Bombay High Court then remanded the matter to the Patent Office, which is yet to decide on the matter.⁵⁹⁵

Glochem's chief objections were that the patent claims were neither novel nor capable of producing an enhanced therapeutic effect as required under section 25(1) and section 3(d) of the Indian Patents Act, a view upheld by the court. In its petition before the Bombay High Court, Glochem submitted that Cadilla had failed to provide admissible evidence before the authorities to support its claim; that Cadilla had failed to show that the new form of known substances on which the application was based, actually enhance existing therapeutic efficacy; and that the Assistant Controller of Patents dismissed its objections on an incorrect construction and wrong application of the provisions of section 3(d) of the Act.

7.2.4 Section 3(e): A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance

In *Hindusthan Lever Limited v Godrej Soaps Limited & another* AIR 1996 Cal 367 (1997) 1 CALLT 123 HC, 100 CWN 562, the plaintiff filed suit for a permanent injunction restraining the defendants from manufacturing, selling or offering for sale, or advertising any toilet soap bearing the trademark VIGIL or any other trademark having the composition covered by the plaintiff's patent no 17071. In granting an interim injunction in favour of the plaintiff, the Calcutta High Court held that 'a mere arrangement or rearrangement of known components functioning independently of each other in a known way was not prima facie, an invention under Section 3(e) of the Patent Act'.⁵⁹⁶

7.2.5 Section 3(f): The mere arrangement or re-arrangement or duplication of

⁵⁹⁵ See para 19 of the decision of the High Court of Bombay.

⁵⁹⁶ See paras 71 and 72 of the decision of the high court of Calcutta.

known devices each functioning independently of one another in a known way

In *Hind Mosaic & another v Shree Sahjanand Trading Corporation & another*,⁵⁹⁷ the plaintiff's claim was that its patent for a PVC threaded pipe joint system with certain accompanying unique features was being infringed by the defendants. During the hearing of the interim injunction the trial court, in dismissing the interim application for injunction, held that the patent was a non-patentable subject matter since the patent essentially 'covered a mere combination and/or arrangement or re-arrangement or duplication of known-device/integers without there being any synergy amongst different integers and combination of known devices functioning in a known way'.⁵⁹⁸

The High Court of Gujarat held that it is important that in order to be patentable, an improvement on something known before, or a combination of different matters already known, should be something more than a mere workshop improvement and must satisfy the test of invention or embody an inventive step independently.⁵⁹⁹ To be patentable the improvement or the combination must produce a new result, or a new article, or a better or cheaper article than before. The combination of old known integers may be so combined that by their working interrelation they produce a new process or improved result. Mere collection of more than one integers or things not involving the exercise of any inventive faculty, does not qualify for the grant of a patent.⁶⁰⁰

The court stated that the general principle deduced from the several judgments of both the English and the Indian courts is that it is settled law that in an action for infringement of the patent, an injunction will not be granted where serious controversy exists with regard to the validity of the patent itself. It is a rule of practice that if a patent is a new one, a mere challenge at the bar would be quite sufficient for a refusal of a temporary injunction. But if a patent is sufficiently old and has been worked, the court will, for the purpose of temporary injunction, presume the patent to be valid one. If a patent is more than six years old and there is/has been

⁵⁹⁷ See *Hind Mosaic and another v. Shee Sahjanand Trading Corporation & another*, MIPR 2008 (1) 402, (Gujarat High Court) (Judgment of the court).

⁵⁹⁸ See para 10 of the judgment of the Gujarat high court.

⁵⁹⁹ See para 18 of the judgment of Gujarat high court.

⁶⁰⁰ See para 18 of the judgment of Gujarat high court.

actual use, it would be safe for the court to proceed upon this presumption. The fundamental principle of patent law is that patent is granted only for an invention which is new and useful.⁶⁰¹

7.2.6 Section 3(j): Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals

The amended Indian Patents Act excludes from patentability 'plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species, and essentially biological processes for production or propagation of plants and animals.'⁶⁰² This provision was added to the Act by the 2002 amendments.⁶⁰³ This step was taken in order to codify the exclusion from patentability in the TRIPS Agreement of 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'⁶⁰⁴ in India's domestic law.

Given India's cultural traditions of great respect for animals, however, the potential patentability of any life form is a difficult concept for many.⁶⁰⁵ The position of the Indian Patent Office is that any 'living entity of natural origin' is not patentable, nor is any 'living entity of artificial origin such as transgenic animals and plants [or] any part thereof.' However, a 'living entity of artificial origin such as [a] microorganism [or] vaccines are considered patentable'.

In *Speaking Roses International Inc v Controller-General of Patents & another* 2007 (109) Bombay LR 630, the Patent Office rejected the patentee's application for an invention which puts an image on an organic product. The Patent Office attempted to reject the application on the ground of section 3(j) as the invention involved a live plant. The appellate court, however,

⁶⁰¹ See para 18 of the judgment of the Gujarat high court.

⁶⁰² The Patents Act, No.39 of 1970, section 3(j) (2005 Amendment).

⁶⁰³ See The Patents (Amendment) Act, No.38 of 2002, section 4, available at <http://indiacode.nic.in>.

⁶⁰⁴ TRIPS, supra note 3, Art.27. 3(b).The provision also mandates that "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." Id.

⁶⁰⁵ See WOLPERT, supra note 136, at 73 (observing as part of discussion of Hinduism that: Most Indians are gentle, nonviolent people, in part because they view life as interrelated, and believe in the potential cosmic significance of individual deeds or actions and their implications, extending over a hundred or more lifetimes. One must be careful where one reads, for the very earthworm beneath one's foot shares cosmic connections. We never know where the ripple current we set in motion could lead. Hindus have reported nightmares after eating beef, hearing a dead grandmother's voice crying out in agony at the pain caused by so violent a fall from vegetarian grace.).

rejected this contention on the ground that: ‘There is no bar to the grant of patent for making an image of an organic product by a non-biological process.’⁶⁰⁶

7.2.7 Section 3(p): An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components

The amended Patents Act also excludes from patentability ‘an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.’⁶⁰⁷ This exclusion is but one of several provisions inserted into the Amendment Act in an effort to prevent the exercise of proprietary rights over India’s genetic resources and indigenous knowledge.⁶⁰⁸ For example, the Act’s disclosure requirements mandate inclusion of the source and geographical origin of biological material used in the invention claimed,⁶⁰⁹ and interested parties may oppose or petition to revoke an Indian patent on the ground that the invention claimed therein is anticipated ‘having regard to the knowledge, oral or otherwise, available within any local or indigenous community or elsewhere.’⁶¹⁰

In Dhanpat Seth & others v Nil Kamal Plastic Crates Ltd AIR 2008 HP 23, the patent owner filed a case for infringement of his patent in which he claimed a device to haul agricultural produce as an invention. The court, however, refused to grant an interim injunction on the ground that the device was a part of traditional knowledge and as such barred from patenting under section 3(p).⁶¹¹

7.3 Limitations imposed by the Indian Patents Act on the exercise of patent rights

⁶⁰⁶ See para 13 of the judgment of the court.

⁶⁰⁷ The Patents Act, No. 39 of 1970, s 3(p) (universal 2005) (amended 2005).

⁶⁰⁸ . See N.S Gopalakrishnan, TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patents System, 27 EUR, INTELL. PROP. REV. 11, 17 (2005).

⁶⁰⁹ See The Patents Act, No. 39 of 1970, s 10(4) (ii) (D) (Universal 2005) (amended 2005).

⁶¹⁰ . Id sections 25(2) (k), 64(1) (q) (specifying grounds for post-grant opposition and revocation, respectively).

⁶¹¹ See para 8 and 9 of the judgment of the court

7.3.1 Government use of patented inventions

The Indian Patents Act provides the government with the necessary powers to curtail the exercise of patent rights. These limitations are usually referred to as government use ('GU') and entitle the government, or a third party who is authorised by the government, to use the patented invention without the authorisation of the patent owner. Under the Indian Patents Act the use can broadly be divided into two principal categories:

- Government use with the payment of reasonable royalties (section 47); and
- Government use or acquisition with the payment of reasonable royalties as may be determined by the High Court (Chapter XVII).

There have been conflicts in past cases that have come before the High Courts of Bombay and Delhi on the scope of sections 47 and 100 of the Indian Patents Act. The issue has been whether or not these sections should cover only those cases where the use of the limitation falls within the government's sovereign functions, or whether it should extend to non-government commercial activities carried out by government corporations and undertakings.

Section 47 of the Act states as follows:

- (a) The grant of a patent under this Act shall be subject to the condition that:-
- (1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;
 - (2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;
 - (3)
 - (4) in the case of patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other

dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette.'

Section 100(1) addresses the power of central government to use inventions for the purposes of government, and reads:

'Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorized in writing by it, may use this invention for the purposes of Government in accordance with the provisions of this Chapter.'

7.3.1.1 *Analysis of sections 47 and 100*

Section 47 provides that the grant of a patent is subject certain conditions. This section states that the government may import, or make or have made on its behalf, any patented product or product made by a patented process for purposes 'merely of its own use'. Section 100, on the other hand, provides that the government, or any person authorised by it, is empowered to use the patented invention 'for purposes of government'. The scope of section 47, therefore, is narrower than government use under section 100 where it is explicitly stated that 'the government, or any person authorised by it, is empowered to use the patented invention for purposes of government'.

In the landmark case Garware Wall Rope Ltd v AI Chopra and Konkan Railway Corporation Ltd,⁶¹² Garware Wall Ropes (plaintiff/applicant) filed an application for an injunction against the defendants/respondents to stop them from manufacturing, selling, and using their patented products. The patented products were being made and sold by the defendant, AI Chopra, to Konkan Railways under a contract. The defendants argued that any such making and use of the patented product was carried out for the work of railways, which is a department of central

⁶¹² Garware Wall Ropes Ltd v A.I. Chopra and another 2009 (111) Bom LR 479 (the judgment of the court)

government, and that the contract had been signed on behalf of the President of India.

The Bombay High Court, however, issued a temporary injunction restraining the alleged infringer by distinguishing between sovereign and non-sovereign government functions. It ruled that only sovereign functions fell within the purview of section 47. Any use for non-sovereign functions would require the payment of royalties to the patentee.

In delivering its judgment, the court held that even third party agencies can use a patented invention on behalf of the government, but only on the express authorisation obtained under section 100(1) by the third agency from the government, and on payment of an agreed remuneration to the patent owner under section 100 (3), based on a contract between the two parties. The court held that section 47 differs from section 100 in that section 47 restricts the use of the patented invention by the government to 'merely for its own use'.⁶¹³ However, if the government, or any other person authorised by the government, wishes to use the invention under section 100, this must be done on the basis of a contract, or by licence between the patentee and the government agency.

Furthermore, in this case it was specifically pointed out that a contract between a third party agency and the central government does not effectively serve as express authorisation to use the patented invention as required by section 100 (1).⁶¹⁴

It can therefore be inferred from the above that under section 47 there is no requirement for royalties to be paid to the patentee if the patented invention is being used by the government in the exercise of its sovereign functions, whereas under section 100 royalties must be paid to the patentee based on agreed terms between the stipulated parties.⁶¹⁵

On a different note, in the case of *Chemtura Corporation v Union of India & others*⁶¹⁶ the Delhi High Court did not draw the above distinction and instead allowed the alleged infringer to use section 47 as a legitimate defence in a hearing for an interim injunction. There were other contributing factors that led to the refusal of the injunction.

⁶¹³ See paragraph 21 of the judgment of the court.

⁶¹⁴ See paragraph 24 of the judgment of the court

⁶¹⁵ See paragraph 22 of the judgment of the court

⁶¹⁶ CS (OS) No. 930 of 2009, 2009 (41) PTC 260 (Del) (the judgment of the court)

One of the primary arguments raised by the defendants was that the second, third, and fourth defendants were manufacturing the infringing product on behalf of the first defendant (the Ministry of Railways) who had supplied the drawings of the product.

The defendants further argued that section 47(1), which states that the grant of a patent under the Patent Act shall be subject to the condition that any machine, apparatus, etcetera may be imported or made by or on behalf of the government for solely for own use, exempts the Railways and its agents – as a government agency – from being held liable for infringement under section 48 of the Patent Act.

The plaintiffs decided to counter this argument by repeatedly stating the contents of section 156 of the Patent Act – the patent shall bind the government. They also seemed to have put up a feeble defence on the basis of the Bombay High Court decision in *Garware Wall Ropes Ltd* discussed above.

The Delhi High Court ruled for the defendants holding that section 47(1) would bar the plaintiff from ‘seeking to prevent the second, third and fourth defendants from making the subject device since it is going to be manufactured and supplied only to the Railways for its own use.’⁶¹⁷ The court therefore concluded that the Ministry of Railways was the ‘government’ as understood by section 47 of the Act, and that the infringing products in question were being manufactured on behalf of the government and for the use of the government.

7.3.2 Limitations with respect to experimental use

Section 47(3) provides:

‘any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils’.

⁶¹⁷ See para 53 of the judgment of the court.

India's patent statute, like those of most countries other than the USA,⁶¹⁸ provides an explicit experimental use exemption from patent infringement liability. Section 47(3) of the Patents Act specifies that uses of patented inventions 'for the purpose merely of experiment or research including the imparting of instructions to pupils' are not actionable as patent infringement.⁶¹⁹

7.3.3 The 'Bolar exemption'

This exemption is known as the 'Bolar exception' on the basis of the case *Roche Products Inc v Bolar Pharm Co*,⁶²⁰ decided by the USA Court of Appeals for the Federal Circuit ('CAFC') in 1984. This case legitimised clinical trials and other tests conducted on patented drugs with a view to establishing the bio-equivalency of the generic drug in question, and the consequent submission of information in this regard to the drug regulator to secure approval. The Indian version is found in section 107A(a) which states that:

'For the purpose of this Act, (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; shall not be considered an infringement of patent rights.'

Thus, submission of information as part of regulatory review is a limitation to the rights enjoyed by the patentee. Section 107A(a) was inserted as a result of a recommendation made by a parliamentary committee.⁶²¹

The Indian provision in section 107A is broader in scope than its US counterpart. This Indian version of the 'Bolar provision' broadly exempts unlicensed data gathering uses of patented

⁶¹⁸ See generally Janice M. Mueller, The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University/Non Profit Research and Development, 56 BAYLOR L. REV. 917 (2004)

⁶¹⁹ The Patents Act, No. 39 of 1970, Section 47(3) (amended 2005)

⁶²⁰ *Roche Products v. Bolar Pharmaceuticals*, 733F 2D 858 (Fed Cir. 1984)

⁶²¹ See Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation', 68 U. Pitt. Law Rev. 491

inventions for purposes of seeking regulatory approval to market *any* product (not just drugs) in *any* country.

7.4 Compulsory Licensing provisions under the Indian Patents Act 1970, and the 2005 Amendment

The compulsory licensing provisions in India's Patents Act 1970 and the 2005 Amendment, are potentially applicable to all patents. India's compulsory licensing provisions are undoubtedly the broadest and most comprehensive of all the world's patent systems. The grounds upon which compulsory licenses may be granted go far beyond national emergency and situations of extreme urgency, public health crises, and anti-trust situations. They include:

'If the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by:

- (i) the patentee or person claiming under him;
- (ii) persons directly or indirectly purchasing from him; or
- (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement⁶²² and, even the non-availability of the patented invention at a 'reasonably affordable price'.⁶²³

These same grounds can even form the basis for the ultimate sanction against a patent holder, in the form of government revocation of its patent.⁶²⁴

⁶²² The Patents Act, No. 39 of 1970 Section 84(1)(c) (amended 2005)

⁶²³ Id. Section 84(1)(b)

⁶²⁴ The Patents Act, No. 39 of 1970, Section 85 (amended 2005) (titled "Revocation of patents by the Controller for non-working"). Section 85 provides that, two years after a compulsory license has been granted under a patent, the Central Government or any "person interested" may apply to the controller for an order revoking the patent. The grounds on which revocation may be granted under Section 85 are the same as those on which a compulsory license under Section 84 may be granted: i.e. "the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price." The Patents Act No. 39 of 1970, Section 85(1) (amended 2005). An application for revocation "shall ordinarily be decided within one year of its being presented to the Controller." Id. Section 85(4).

In sum, India's Amended patent law provides four avenues for seeking compulsory patents licensing. These four avenues are discussed in the following paragraphs.

7.4.1 Compulsory licensing under section 84 of India's Patent Act 1970 and 2005 Amendment

An application for a compulsory licence under section 84 may be based on any of the following three grounds: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; (b) that the patented invention is not available to the public at a reasonably affordable price; or (c) that the patented invention is not worked in the territory of India.

With regard to the above provisions of section 84(1)(a), (b), and (c), an India court recently (March 2012) issued a compulsory licence against Bayer, a German pharmaceutical company.

In the case of *Natco v Bayer*,⁶²⁵ the patentee, Bayer, held the rights to a patent for a cancer drug, *sorafenib tosylate*, otherwise marketed as *Nexavar*. Before bringing an application before the Court of the Controller of Patents for a compulsory licence, Natco, a generic drug manufacturer, approached Bayer for a voluntary licence. This was denied. The Controller had three substantive issues to consider.

a) Reasonable requirements of the public

Section 84(1)(a) of the Indian Patents Act requires that before a compulsory licence will be granted, the 'reasonable requirements of the public with respect to the patented invention' must not have been satisfied. Natco supplied statistical data showing that Bayer had not made the drug readily available to the public, and that excessive pricing of the drug partially contributed to lack of demand by the public. Bayer denied this and, interestingly, used sales figures of an alleged infringer in its argument. Bayer had, prior to this case, brought infringement proceedings against Cipla, another generic manufacturer, for infringement of the same patent. These proceedings were still pending. However, Bayer argued that sales by Cipla contributed to the reasonable requirements of the public being met.⁶²⁶

⁶²⁵ *Natco vs. Bayer*, AO/35/2012/PT/MUM Judgment delivered on the 4th March, 2013 (the court's judgment)

⁶²⁶ See paragraphs 36 and 37 of the court's judgment

The Controller, however, did not accept this argument, and stated that Bayer's conduct and that of any licensee was of importance. He found the basis for this reasoning in section 86(6) (i) of the Act which states that the measures taken by the patentee and licensee must be taken into account. On the facts, the Controller found that Bayer had not discharged its obligation to satisfy the reasonable requirements of the public as an insignificant amount of the drug had been made available to the public in the three years since the grant of the patent.⁶²⁷

b) Reasonably affordable price

Section 84(1)(b) of the Indian Patents Act requires that in order for a compulsory licence to be granted, the patented invention must not have been made available to the public at a 'reasonably affordable price'. Natco contended that the drug was excessively priced and unaffordable to the ordinary public. It also contended that Bayer was eligible for a drug tax credit which would have lowered the net cost of investment on research to Bayer. However, Bayer had not taken this opportunity to lower the price of the drug, and this proved abuse of its monopolistic rights.⁶²⁸

Bayer argued that innovation-based products cost more, and that the Controller had to take into account the total cost of R&D and the sustainability of future research. Bayer argued that a 'reasonably affordable price' should be reasonable to both the public and the patentee. The Controller did not agree and stated, without explaining his reasoning, that the reasonable price had to be construed with reference to the public. On the facts of the case, the Controller again found in favour of Natco.⁶²⁹

c) Patented invention not worked in India

Section 84(1)(c) of the Indian Patents Act allows for a compulsory licence if the patented invention is not worked in the territory of India. Natco argued that 'worked in the territory' meant 'manufactured in India'. They argued that since Bayer already had manufacturing facilities in India, there was no hurdle preventing them from manufacturing in the country, and as it did not manufacture the drug in India, it had not discharged its obligation.

⁶²⁷ See paragraph 38 of the court's judgment

⁶²⁸ See paragraph 39 of the court's judgment.

⁶²⁹ See paragraph 40 of the court's judgment.

Bayer stated that it did not manufacture the drugs in India for economic reasons, and argued, on the interpretation of other sections of the Indian Act, that ‘worked in the territory’ could not mean ‘manufactured in India’. However, after analysis and interpretation of the Act, the Controller held that importation could not amount to ‘working’ of a patent and found in favour of Natco’s interpretation of manufacture.⁶³⁰

7.4.2 Section 92 of India’s Patent Act, 1970 and the 2005 Amendment: Notification by government

The government of India has had no reason to invoke the section 92 procedure. Section 92 compulsory licences are broadly available for ‘all medicines, without any prior negotiation with patent owners’,⁶³¹ in contrast to section 84 licences.⁶³²

7.4.3 Section 92A of India’s Patent Act, 1970 and the 2005 Amendment: Compulsory licensing for exports

In order to implement the Doha Declaration, India introduced a new section 92A into the 2005 Amendment . The section creates an avenue for compulsory licensing that will allow the manufacture and export of patented pharmaceutical products from India to other countries that lack manufacturing capacity.⁶³³

Section 92A states as follows:

⁶³⁰ See paragraphs 50,51 and 52 of the court’s judgment.

⁶³¹ Love supra note 513.

⁶³² See The Patents Act, No. 39 of 1970, Section 84(6)(iv) (Universal 2005) (amended 2005) (providing that in considering a compulsory license application filed under Section 84, the Controller shall take into account “as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the controller may deem fit”); id. At “Explanation” (stating that “for the purposes of clause (iv), ‘reasonable period’ shall be construed as a period not ordinarily exceeding a period of six months”).

⁶³³ See id. Sec 92(A) (providing that a compulsory license “shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided (that a) compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India”)

- (1) Compulsory licence shall⁶³⁴ be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.⁶³⁵
- (2) The Controller, shall on receipt of an application in the prescribed manner, grant a compulsory licence solely for the manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.’

My initial observation addresses the proper ambit of public health. The Doha Declaration appears to leave room for flexibility in interpreting ‘public health’. The 2003 Decision is limited to the import/export of ‘pharmaceutical products’, which have been defined as ‘any patented product, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration’.

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

Under section 92A(1) it would be absurd for an LDC like Bangladesh to try to import ‘*Viagra*’ or ‘*Plavix*’ under the rubric of the Doha Declaration. Even as ambiguous as the Doha Declaration is, it would be more acceptable if the importation were for an anti-cancer drug that is very expensive in Bangladesh. In the latter case, a WTO panel could most likely be convinced that such a situation can constitute a serious threat to public health.⁶³⁶

⁶³⁴ The term ‘shall’ here is important because it indicates that the compulsory licence will be granted automatically without scrutiny or procedural requirements in India.

⁶³⁵ This amendment also corrected an earlier provision in the Patents (Amendment) Ordinance (Ord. No 7 of 2004) that would have excluded LDCs that did not issue compulsory licenses or where the relevant patent was not existing or valid.

⁶³⁶ To safeguard the interest of countries facing severe health crisis, the WTO should establish an administrative body to determine when a country may issue compulsory licenses of patented pharmaceuticals. See Aileen M. McGill Compulsory Licensing of Patented Pharmaceuticals:” Why a WTO Administrative Body should determine

My second observation is that the above section makes no mention of royalties, but appears to have left the issue to the Controller to ‘fix’ under ‘terms and conditions’. Clause 3 of the 2003 Decision states that ‘adequate’ remuneration must be paid to the patent owner. So the Controller cannot issue a licence under this section without making an order on the amount of royalty that is adequate as regards the patent owner.

Section 92A implements in India’s domestic patent law, a modified version of the framework for implementing a waiver to article 31(f) of the TRIPS Agreement already agreed to by WTO members.⁶³⁷ Most African countries and LDCs with little or no domestic drug manufacturing capacity need to import patented drugs from other countries which have the capacity. In contrast to the TRIPS framework, India’s section 92A is completely silent on any obligation on the Indian government or the compulsory licensee to specify the volume of pharmaceutical products that will be exported, to specially label or mark those products, or to make public any information about the export by posting to a website or other means of publication.⁶³⁸

The Controller, however, has a wide discretion to set the terms and conditions of a section 92A compulsory licence. Consequently, the Controller could in each individual case place a limit on the amount of pharmaceutical product to be manufactured and exported, or require the licensee to specially package and mark its products, etcetera.

In *Natco v Roche, OSI, Pfizer before the Patent Office in Delhi*,⁶³⁹ the Indian generic drug manufacturing company, Natco, filed an application for a compulsory licence to export *Erlotinib* an anti-cancer drug to Nepal under section 92A of the Act. Natco also applied for the issue of a second compulsory licence for the manufacture and export of *Sunitinib*, also an anti-cancer drug. This was the first ever compulsory licence application to be made in India. Section 92A is the provision which implements the Doha Declaration. The issue for the grant of compulsory licence had, however, not yet been decided on the merits when Natco filed an application for interlocutory petition before the Controller of Patents. In that application Natco asserted that

what constitutes a Public Health Crisis under the Doha Declaration”. Wake Forest Intellectual Property Law Journal 10. 1 (2009): 69-97. Also available at http://www.works.bepress.com/aileen_mcgill3

⁶³⁷ See WTO Doha Implementation Decision, supra note 560.

⁶³⁸ Compare WTO Doha Implementation Decision, supra note 560 2(b) with The Patents Act, No. 39 of 1970, Sec 92A (Universal 2005) (amended 2005).

⁶³⁹ See Suit Nos. IA 7397/2011 and No. 1A 9792/2011 Before the High Court of Delhi (The ruling of the courts)

since the application for the grant of compulsory licence had been made under section 92 A of the 1970 Patent Act, the patentee should not be allowed an opportunity to be heard.⁶⁴⁰

In other words, Natco requested the Controller to deny Roche the right actively to represent itself in the compulsory licence proceedings before the court. The Patent Office ruled in favour of the patent owners and held that they indeed had a right to be heard as it was their patent that was the subject of the compulsory licence application.⁶⁴¹ Natco subsequently abandoned all its compulsory licence applications.

Commenting on the above case and section 92(A), Kumar⁶⁴² states as follows:

‘A close reading of section 92 A makes it apparent that the two alternative conditions required to be fulfilled by a party seeking to secure a compulsory license are that:

- (1) such party has been granted a compulsory licence in the country to which it intends to export the products (licensed to be manufactured to them); or
- (2) such party has been allowed (secured permission) to import such product to the said country from India.’

In the Natco compulsory license matter, since Nepal qualified as one of the Least Developed Countries (LDC) under WTO classification, it was not mandatory for Nepal to establish that it had insufficient manufacturing capacities and/or facilities. Additionally, a product patent regime for pharmaceutical products was and is non-existent in Nepal. Therefore, the requirement to grant a license to Natco (in Nepal) to import the requisite drug(s) into Nepal was also not necessary.

7.4.4 Section 91 of India’s Patent Act 1970 and the 2005 Amendment: locking patents

This is the fourth type of compulsory licensing allowed under the Indian Patent Act. The section provides that any person who has the right to use a second patented invention, either as patentee or licensee, may apply to the Controller for the grant of a licence under a first patent on the

⁶⁴⁰ See paragraphs 12, 13 and 14 of the ruling of the court.

⁶⁴¹ See para 17 of the ruling of the court

⁶⁴² Swarup Kumar in his article: ‘Compulsory Licensing Provision Under Trips: A Study Of *Roche Vs Natco* Case In India Vis-À-Vis The Applicability Of The Principle Of Audi Alteram Partem’ (2010) 7(1) SCRIPTed page 136 from pages 143-145.

ground that the person ‘is prevented or hindered without such licence from working the other (second) invention efficiently or to the best advantage possible.’

However, this type of compulsory licensing is not relevant to the topic of this thesis.

7.5 Limitations imposed by parallel imports

7.5.1 Section 107A: Certain acts not to be considered as infringement

Section 107A (b) of the Act provides that ‘importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.’⁶⁴³

Two examples will illustrate the broad scope of this section. Firstly, a pharmaceutical company like Bayer obtains a patent on a pharmaceutical product in India and sells the same product more cheaply outside of India, for example in Botswana. A third party who purchases the product from the patentee (or its agent) in Botswana and imports it into India for re-sale there, would not be liable under section 107A (b) for infringement of the Indian patent.⁶⁴⁴ This result is consistent with the traditional rule of international exhaustion as one in which the patentee has profited from a first sale of the product anywhere in the world.⁶⁴⁵

Secondly, let us consider again the scenario above, but the same product is being sold by a second party who is in no way connected with the patent owner, in an LDC, for example Nepal, that has not yet incorporated the TRIPS Agreement to provide pharmaceutical product patent protection. Even without patent protection in Nepal, the second party is, within the language of section 107A (b), ‘duly authorized under the law to produce and sell or distribute the product.’⁶⁴⁶ In other words, the second party can make and sell the product in Nepal without restriction. A third party who then purchases the product from the second party in Nepal and imports it into

⁶⁴³ . The Patents Act, No. 39 of 1970, Section 107A(b) (Universal 2005) (amended 2005)

⁶⁴⁴ This first hypothetical is consistent with the narrower scope of the pre-2005 version of the parallel imports provision. Prior to the Patents (Amendment) Act of 2005, the provisions read as follows: “importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.” The Patents (Amendment) Act, No. 38 of 2002, Section 107A(b), available at <http://indiacode.nic.in> (emphasis added). The statutory language “who is duly authorised by the patentee to sell or distribute the product” was changed to “who is duly authorised to sell or distribute the product” by the Patents (Amendment) Act, No. 15 of 2005, Section 58(b), (Universal 2005)

⁶⁴⁵ See Janice Mueller, ‘The Tiger Awakens’ supra at p. 609

⁶⁴⁶ The Patents Act, No. 39 of 1970, Section 107A(b) (Universal 2005) (amended 2005)

India for re-sale there, would likewise not be in violation of section 107A(b) for infringement of the Indian patent.

Section 107A was put to the test in *Strix Limited v Maharaja Appliances*.⁶⁴⁷ The case came before the High Court of Delhi and the defendant attempted to take advantage of the defence in section 107A of the Patents Act – the products he was importing were covered by a valid Chinese patent. The court, however, did not go into the underlying jurisprudential issues in interpreting section 107A as the defendant had failed to produce proof of the Chinese patent.

The court held:

‘The Defendant has been unable to show that the Chinese suppliers from whom it is purchasing the infringing product, holds a patent for it. It is not even the Defendants case that the said product per se does not infringe the Plaintiffs patent. The only defense available to the Defendant is that the Plaintiffs patent lacks novelty and its validity is vulnerable on the ground of obviousness. This has not even prima facie been established by the Defendant. It is not possible to agree with the contention that the Plaintiffs patent is a mere trade variant of a known product. The Plaintiff has been able to prima facie show that it has been validly granted the patent which appears to be an inventive step in comparison with the prior art cited by the Defendant, viz., the European Patent.⁶⁴⁸

There is no merit in the contention that in terms of Section 3 (f) of the Act, the patent ought not to have been granted since the invention is a mere re-arrangement of known elements. In the considered view of this court, such a contention cannot be accepted on a mere averment by the Defendant. The Defendant will have to place on record some scientific literature supported by some credible expert opinion to show even prima facie that the Defendants product is a mere re-arrangement of already known products. This burden has not been discharged by the Defendant.⁶⁴⁹

The submission that the Plaintiff has not worked its patent in India is also without merit. It is the Defendants own case that it was purchasing the product from the Plaintiff in the

⁶⁴⁷ Suit No. IA No. 7441 of 2008 (OS), No. 1206 of 2008 (judgment of the court)

⁶⁴⁸ See para 23 of the judgment of the court

⁶⁴⁹ See para 23 of the judgment of the court

year 2005-2006 and when it found that the products were defective, it started importing the product from China. It does not really matter whether the product of the Plaintiff was defective. What is evident is that the Plaintiff did commercially exploit its patent by marketing the product in India since 2005. It is not in dispute that the Defendant was purchasing the said product in India from the Plaintiff.⁶⁵⁰

In the *Niky Tasha* case, the court observed ‘when there is a serious question as to the validity of the design to be tried in the suit and an application for cancellation has been made’ an injunction can be refused as long as damages can provide an adequate remedy. In the considered view of this court, the said decision can also have no application in the instant case. It cannot be said that the challenge to the validity of the patent as raised by the Defendant here is a ‘serious’ one.⁶⁵¹

As regards the applicability of Section 107A of the Act, the Defendant has merely averred that it has written to Chinese supplier to give information on the patent held by it and is awaiting a reply. The Plaintiff cannot be made to wait indefinitely for an injunction just because the defendant is waiting for information from the Chinese supplier. As long as the Defendant is not able to produce any information about the patent held by the Chinese supplier, the court will proceed on the footing that there is no such valid patent held by the Chinese supplier. In any event, it cannot delay the protection that the Plaintiff is entitled to seek on the basis of the patent registered validly granted to it.⁶⁵²

The contention that the Defendant is not a fly-by-night operator and its business turnover is in several crores of rupees is a contention that should work against the Defendant for the simple reason that the Defendant is not expected to import a product without first checking if the Chinese supplier holds a valid patent. The Defendant knew that the Plaintiff held a valid patent for the product that the Defendant was marketing viz., the electric kettle. Even according to the Defendant, it was purchasing this electric kettle from the Plaintiff in the years 2005- 2006. Therefore, there was an obligation on the

⁶⁵⁰ See para 24 of the judgment of the court

⁶⁵¹ See para 25 of the judgment of the court

⁶⁵² See para 26 of the judgment of the court

Defendant, even while it imported the same product from China, to ensure that it was not violating the Plaintiff's patent.⁶⁵³

In the considered view of this court, the Plaintiff is entitled to enforcement and protection of its patent vis-a-vis other manufacturers, sellers and importers. Section 48 of the Act gives the patent holder a right to prevent all other users from making use of the patent or commercially exploiting the patent held by the Plaintiff except with the prior permission of the Plaintiff.⁶⁵⁴

Accordingly, this application succeeds. An interim injunction will issue during the pendency of the suit restraining the Defendant, its agents, servants and all others working for it from manufacturing and/or marketing the Maharaja White line electric kettle Model No.EK172 or otherwise infringing in any manner the Plaintiffs patent No. 192511/95 or any part thereof.⁶⁵⁵

7.6 Conclusion

As stated at the beginning of this chapter, India is of particular importance because of its longstanding role as supplier of low-cost medicines to the developing world. How India would apply its patent law in the face of the TRIPS Agreement would without doubt affect access to medicines far beyond its borders. It was for this reason that many anticipated with dread India's 1 January 2005 deadline for compliance with the TRIPS Agreement.

Since 2005 India has been TRIPs compliant and its generic companies have been unable to manufacture generic versions of new drugs by simply altering the process by which these new drugs are produced.⁶⁵⁶ The recognition of product patents by the Indian government has led to the contraction of local pharmaceutical industry. Smaller companies that remained competitive by being among the first to introduce generic versions of new drugs still under patent in developed countries, have been forced to close down. Without the necessary economies of scale,

⁶⁵³ See para 27 of the judgment of the court

⁶⁵⁴ See para 28 of the judgment of the court

⁶⁵⁵ See para. 29 of the judgment of the court

⁶⁵⁶ Reverse engineering is possible only in countries where the patent law protects processes but not products.

many of these smaller companies could not compete with the well-established generic manufacturing companies such as Aurobindo, Cipla, or Dr Reddy's.⁶⁵⁷

However, the well drafted section 3(d) of the Indian Patents (Amendment) Act 2005 restricted patents on known inventions and the practice of evergreening. Supporters of the section assert that the law is intended to allow genuine improvements and at the same time bar frivolous applications under the cloak of incremental innovation.

Finally, the amendments to the Indian Patents Act, which established the first pharmaceutical product patent regime since 1970, took into account India's role as a prime supplier of essential medicines to the developing world as well as concerns about the effects of pharmaceutical patents on pricing for Indian consumers.⁶⁵⁸

⁶⁵⁷ Some large companies that had developed significant R & D facilities feel that the new regime may provide them an opportunity to grow overseas, while small companies generally seem to have understood that they are not important enough to influence policy-making significantly and must concentrate on surviving either independently or by linking up with bigger domestic or foreign companies. See Anita Ramana, 'Policy Implications of India's Patent Reforms –Patent Applications in the Post-1995 Era', Economics and Political Weekly, May 25, 2002, p 2065.

⁶⁵⁸ Government of India 2007.

Chapter 8

Patents and Access to Essential Medicines: The South African Experience

8.1 Introduction

Both the right to IP and the right to health are articulated in international human rights instruments. Whilst these rights have been declared interdependent, indivisible and interrelated, the South African Constitutional Court cases exemplify the challenge of achieving this aspiration in the context of the divergent economic and political motives and interests that exist between pharmaceutical companies and states. Furthermore, it also serves to highlight the global ramifications of the resulting conflict of rights with regard to the ability of a DC effectively to confront the challenge of access to medicines.

In this chapter I examine the right to health of South African citizens enshrined in international and domestic human rights law, and the obligations this right places on the state. I also consider the role of competition law in curtailing patents rights.

8.2 The effects of conflicts between patents and the right of access to medicines

International human rights instruments have enumerated the right of an author, creator, or inventor to some form of recognition and benefit from his or her intellectual products. Article 27 of the Universal Declaration of Human Rights ('UDHR') states that:

'Everyone has the right to the protection of the moral and material interests resulting from any scientific literary or artistic production of which he is the author. [and further that] Everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancements and benefits.'

From this customary source of law, the right is rearticulated in the International Covenant on Economic, Social and Cultural Rights ('ICESCR') which provides in article 15(1)(c) that state parties must recognise the rights of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is

the author. Like the UDHR, the ICESCR links this obligation to right to ‘enjoy the benefits of scientific progress and its applications.’⁶⁵⁹

Patents are the legal means by which pharmaceutical inventions may be protected. They are the titles conferred by the state that attest to the grant of exclusive rights to the inventor for the exploitation of his/her/its invention.⁶⁶⁰ As such, they serve two functions: an inducement to invent; and an essential factor in scientific and technological progress by providing companies with an advantage over competitors.⁶⁶¹ International and domestic legal regimes defining the nature of IP and the types of protection that accrue to its creators effectively shape the realisation of these rights.⁶⁶²

There is an apparent contradiction between the right of a patentee to exploit his invention and the right of the citizen to medicines when the question of access to medicines arises. The way out of this dilemma is to distinguish IP rights from human rights, and to classify IP rights as a temporary monopoly established for the valid social purpose of encouraging scientific invention and artistic creation.⁶⁶³ In other words, an IP right is a legally protected interest of a lower order than a human right, which implies a superior moral and legal claim. This distinction should not be interpreted to imply that IP rights do not have social value. Indeed, they have a very high value, which justifies the reasonable limitation of article 15 rights to promote innovation and creativity.⁶⁶⁴

Human rights organs have progressively addressed this dilemma, articulating in different stages the human right to essential medicines. The United Nations Commission on Human Rights adopted a resolution in 2001, in which it recognised ‘that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full

⁶⁵⁹ Chapman, A. ‘Approaching Intellectual Property as a Human Right’, Committee on Economic, Social and Cultural Rights, Twenty-fourth session, item 3 of the provisional agenda, E/C.12/2000/12, 3 October 2000, p 2.

⁶⁶⁰ See Lisa Anderson, The Conflict between intellectual property rights and the right to health of AIDS victims in South Africa. 2002 (Global Politics Network) available at www.globalpolitics.net/essays/Lisa_Anderson.pdf

⁶⁶¹ Salazar, S., (2000) ‘Intellectual Property and the Right to Health’ in World Intellectual Property Organisation WIPO/UNHCR Intellectual Property and Human Rights: A panel Discussion to commemorate the 50th anniversary of the Universal Declaration of Human Rights, Publication NO. 762 (e), Geneva: WIPO, p. 68)

⁶⁶² Chapman, A., E/C.12/2000/12, P.3

⁶⁶³ See Resolution 2001/5. Globalisation and its impact on human rights, New York: United Nations Sub-Commission on the Promotion and Protection of Human Rights; 2001. E/CN.4/Sub.2/Res/2001/5. Where it was pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right “subject to public interest limitations”.

⁶⁶⁴ See P. Cullet supra at p. 144

realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.’⁶⁶⁵

Among a list of measures, it called on states ‘to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them’,⁶⁶⁶ and, clearly with the TRIPS Agreement in mind, ‘to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies’.⁶⁶⁷

The United States was the only government to abstain from this resolution, which was adopted on 23 April 2001 by 52 votes with no votes against.

It has been argued that provisions of the TRIPS Agreement make it more difficult for countries to set IP standards and policies to fit domestic economic conditions, while at the same time protecting the human right to health and life.⁶⁶⁸ Furthermore, some developed countries are using bilateral and regional trade agreements to negotiate even more stringent protection for patents under so-called ‘TRIPS plus’ agreements.⁶⁶⁹

The principal obstacle to public health care imposed by the patent rights conferred by the TRIPS Agreement is manifested in the cost of pharmaceutical drugs. Patented drugs are often considerably more expensive than their generic counterparts, because patent holders -- usually corporations -- have the freedom to price their products at arbitrary, often inflated. Regarding the issue of patent protection for pharmaceutical goods, the WTO emphasizes that the Agreement contains a substantial number of provisions that take account of immediate as well as longer-term health considerations. These provisions include those relating to patentability, the

⁶⁶⁵ Commission on Human Rights resolution 2001/33, Access to medication in the context of pandemics such as HIV/AIDS, UN Doc. E/CN.4/RES/2001/33, 20 April 2001, para. 1.

⁶⁶⁶ Ibid., para. 3(a).

⁶⁶⁷ Ibid., para. 4(b).

⁶⁶⁸ Oxfam Policy Papers (2001), ‘Patent Injustice: How World Trade Rules threaten the health of Poor People’.

⁶⁶⁹ Ibid, p.6

possibility of allowing limited exceptions to exclusive rights, compulsory licensing (article 31),⁶⁷⁰ parallel importation (articles 28 and 6),⁶⁷¹ and the recognition that member countries may adopt necessary measures to protect public health (article 8).^{672 673}

The vehement resistance of the pharmaceutical industry to the efforts of DCs to make full and effective use of these provisions throws the inconsistency between the legal theory and the practical implementation of the TRIPS Agreement into relief.⁶⁷⁴

The pharmaceutical companies assert that DCs have been offered significant reductions in price in line with tiered pricing schemes such as the UNAIDS' 'Accelerated Access to HIV/AIDS Care and Treatment Initiative'.⁶⁷⁵

Advocates of measures compliant with the TRIPS Agreement to ensure affordable medicines have countered that the cost to the pharmaceutical industry of parallel imports and compulsory licensing is sustainable.⁶⁷⁶ Prices in DCs remain significantly higher despite the global disparities, and evidence of significant discounts already available on medicines for Africa imply that they believe it is possible to manage the threat of parallel imports back into the USA or Europe.⁶⁷⁷ On the availability of discounted drugs, they argue that reliance on preferential

⁶⁷⁰ Article 31 of the TRIPS sets out the framework for national laws on use without authorisation of the patent owner and provides broad discretion on government use of compulsory licensing. The general rules are that governments consider cases on their individual merits and that prior to authorising third party use there should be an effort to negotiate a voluntary licence on reasonable commercial terms and must provide for adequate remuneration taking into account the economic value of the authorisation. Another important rule is Article 31(f) which states "use shall be authorised predominantly for the supply of the domestic market." Health care and IP: International Law and Compulsory Licensing' at URL page: <http://www.captch.org/ip/health/cl/cl-ilaw.html>.

⁶⁷¹ Article 28 of the TRIPS gives the patent owner the exclusive right to import a good into a country, that right is subject to Article 6 which concerns the doctrine of 'exhaustion' of intellectual property rights, which relates to the owner of intellectual property cannot control the resale of legally purchased goods.

⁶⁷² Article 8 of the TRIPS Agreement allows for states 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 economic welfare.

⁶⁷³ Secretariat of the WTO, E/C.12/2000/18

⁶⁷⁴ The inconsistency of their stance is further highlighted by the fact that various developed countries have already taken full advantage of the permissive rules of the TRIPS agreement, e.g. compulsory licenses have been extensively used in North America, Japan and Europe for a variety of purpose, furthermore, the US has broad patent rights, it is not obliged to negotiate for licenses and does not authorise any injunctive relief to the patent owner. Love.J. (2001) Access to Medicines and Compliance with the WTO TRIPS Accord: Models for States Practice in Developing Countries.

⁶⁷⁵ This initiative brings together five companies all of which have pledged to supply cut-price anti-retrovirals to developing country governments.

⁶⁷⁶ See Lisa Anderson supra at p.12

⁶⁷⁷ Oxfam policy papers (2001) 'implausible denial why drug giants arguments on patents don't stand up', at URL page:<http://www.Oxfam.org.uk/policypapers/trips2.htm>

pricing or donations renders governments dependent on companies' goodwill, providing an ad hoc disease-specific approach to the problem rather than an /overall solution.⁶⁷⁸

Foreign aid has also played a significant role in making drugs, particularly those for treating HIV infection, available in DCs.⁶⁷⁹ The availability of these and other medicines might decrease substantially if the flow of capital and aid to DCs continues to dwindle⁶⁸⁰ and self-reliant means of ensuring medicine availability remain absent. The time has come for DCs like South Africa to look beyond foreign aid in the quest to increase access to medicines.

In response to the success of the South African government against the pharmaceutical companies attempting to block the implementation of the Medicines Act, campaigners were optimistic as to the future availability of essential medicines, Ellen 't Hoen, MSF's legal advisor, exclaimed: 'Now nothing should stand in the way of countries who want to ensure long term access to affordable medicines.'⁶⁸¹

In order to facilitate access to essential drugs and ensure their effectiveness, the South African government must be able to monitor the use of drugs and supply adequate nutritional and medical infrastructure.⁶⁸² Data on public health expenditure and human resources from a recent National Health Accounts Projects reveal that since 1997 there has been a steady decline in per capita public funding of health care and increased inequity in provincial resources available to the public health sector.⁶⁸³

Richard Friedland, chief executive of Netcare, talking to 'Business Report'⁶⁸⁴ during March 2013, said that the group paid 40 per cent more for medicines in South Africa than overseas. He

⁶⁷⁸ Oxfam policy papers (April 2001) 'Oxfam update on South African Court case: South Africa v the drug giants', at URL page: <http://www.oxfam.org.uk/policy/papers/safrica2.htm>

⁶⁷⁹ Berger M, Murugi I, Buch F, Ijsselmuiden C, Guzman J et al. Strengthening pharmaceutical innovation in Africa: designing strategies for national pharmaceutical innovation: choices for decision makers and countries. African Union, Council on Health Research for Development & The New Partnership for Africa's Development; 2010.

⁶⁸⁰ International Finance Corporation. Impact: annual report 2012. Washington (DC): IFC; 2012. Available from: http://www.ifc.org/wpc/connect/2be4ef804cacfc298e39cff81ee631cc/AR2012_Report_English.Pdf?MOD=AJPERES [accessed 18 March 2014]

⁶⁸¹ 'Drug Companies In South Africa Capitulate Under Barrage of Public Pressure', TAC Press Release 19 April, 2001.

⁶⁸² Thomas, S., Muheki, C., (2000) 'Public Sector Health financing' in South African Health Review, at URL page: <http://www.hst.org.za/sahr/2000/chapter5.htm>

⁶⁸³ Thomas, S., Muheki, C., (2000) 'Public Sector Health financing' in South African Health Review, at URL page: <http://www.hst.org.za/sahr/2000/chapter5.htm>

⁶⁸⁴ See http://www.iol.co.za/business/companies/netcare_calls-for-medicine-price-inquiry-1.1518899

further stated: ‘There is a view that we are subsidizing government drugs procurement, but that’s pushing our costs’. Friedland’s statement supports recent claims by MSF and the Treatment Action Campaign (‘TAC’) that medicine prices in South Africa are among the highest in the world because of the country’s patent laws.

8.3 Are patents ‘constitutional property’?

Bainbridge⁶⁸⁵ defines IP by reference to other, tangible forms of property. He states that:

‘Intellectual property rights⁶⁸⁶ are a form of property which can be dealt with just as with any other property and which can be assigned, mortgaged and licensed. Intellectual property is property in a legal sense: it is something which can be owned and dealt with.’⁶⁸⁷

He also discusses the jurisprudential character of IP, stating that it gives rise to rights and duties. Intellectual property creates property rights, which grant the owner the right to do certain things pertaining to the subject matter.⁶⁸⁸ This right may come into existence automatically upon the creation of the IP to which the right relates.

It is apparent from Bainbridge’s analysis that IP is concerned with rights. He states that in the context of IP, the right to do certain things could be to manufacture articles according to a patent or a design. The correlative duty to the right is a duty owed by all others not to infringe the right.⁶⁸⁹ However, he cautions that certain provisos must be added to this general Rule.⁶⁹⁰ The law strives to reach a balance between conflicting interests in the area of IP in order to reach a

⁶⁸⁵ Bainbridge DI Intellectual Property (1992) 10. Also see May C & Sell SK Intellectual Property Rights- A Critical History (2006) 5 and Alberts W ‘What is Intellectual Property?’ (2007) Nov De Rebus 45-46 at 45. May, Sell and Albert also compare intellectual property to tangible property for a better understanding.

⁶⁸⁶ They are traditionally divided into two categories: copyright and neighbouring rights and industrial property. Copyright and neighbouring rights are rights granted to prevent the reproduction and dissemination of certain group of works ranging from literary, musical, dramatic, choreographic and audio visual work to pantomimes and motion pictures. Industrial property consists of industrial designs, geographical indications, service marks and trade names, trademarks, utility models and patents.

⁶⁸⁷ Bainbridge DI Intellectual Property (1992) 10.

⁶⁸⁸ See also William Fisher, Theories of Intellectual Property 1999, (available at http://www.law.harvard.edu/Academia_Affairs/coursepages/tfisher/iphistory.html) where he stated that “intellectual property” refers to a loose cluster of different sort of ideas and insignia.

⁶⁸⁹ MacQueen, H., Waelde, C. and Laurie, G. (2007): Contemporary Intellectual Property: Law and Policy Oxford University Press. At page 365 the authors stated that patent represent ‘a form of social contract between the patentee and the state, whereby the award of a patent monopoly is given in return for public disclosure of the invention’.

⁶⁹⁰ See Bainbridge D.I Intellectual Property (1992) supra 10

justifiable compromise. Consequently, the duty not to infringe is not overly strict and recognises many exceptions. Intellectual property rights are further limited by their duration.⁶⁹¹

Most IP rights are granted for a limited period which leads Bainbridge to submit that they may be compared to a lease. He proposes that ‘as a rule of thumb, it can be said that the duration of a right is inversely proportional to its power’.

Patents are a category of IP right and are defined as ‘the right granted to an inventor by a State, or by a regional office acting for several States’.⁶⁹² William Fisher also claims that patent law protects inventions and certain forms of discovery.⁶⁹³ A short explanation of the origins of patents is required. This is not intended as a full overview of the history of patents – a general overview of the patent system was undertaken in Chapter 2 – but merely serves as an indication that patent rights should not necessarily automatically be protected as constitutional property in its current form, but that it possibly needs to be reconsidered. Thereafter the requirements for the existence of a valid patent under South African private law are discussed. Finally, the content and limitations on the extent of patent rights are analysed.

Patents are traditionally associated with creativity and /innovation. Shiva⁶⁹⁴ states that patents may be granted to the inventor, who then holds an exclusive right to manufacture, distribute and sell the product which is the subject of the patent. Historically, patents have served three different purposes. The first is what Shiva⁶⁹⁵ terms ‘patents for conquests’;⁶⁹⁶ the second is

⁶⁹¹ See Norrgard, M. (2008): Fundamentals of Intellectual Property Law. Haken School of Economics

⁶⁹² WIPO 1988. See also 35 U.S.C 154 which defines a p as an official document issued (“granted”) by the federal government to the recipient (“patentee”), granting “...the right to exclude others from making, using, or selling the invention throughout the United States.”

⁶⁹³ See William Fisher, Theories of Intellectual Property. supra (above cited)

⁶⁹⁴ Shiva .V. Protect or Plunder? Understanding Intellectual Property Rights (2001) 11.

⁶⁹⁵ Shiva .V. Protect or Plunder supra

⁶⁹⁶ Patents for conquest referred to open letters that were official documents conferring privileges, rights, ranks or titles. These were used for colonisation and the establishing of monopolies. The reason why it is interesting to note previous use of patents for colonisation, is that patents have also been used to ‘steal’ traditional knowledge from traditional peoples. Similar arguments to that of colonising land have been used to justify this ‘theft’ in that knowledge of the traditional peoples was not seen as either valuable or creative. Their knowledge was used by foreign companies (which may be analogised to colonisers) to derive patents and other forms of intellectual property, but no acknowledgement or monetary remuneration was offered to the original holders of the traditional knowledge.

‘patents for inventions’;⁶⁹⁷ and the last, ‘patents for imports’.⁶⁹⁸ However, these different functions have not been separated precisely in law.

Shiva⁶⁹⁹ argues that the original use of patents was not, as is generally assumed, to encourage inventiveness. Historically, patents referred to ‘letters patent’, which is a literal translation of the Latin term *litterae patentes*. These ‘letters patent’ or open letters, were official documents by which sovereign rulers conferred certain rights, privileges or titles. These letters were used to enable colonisation and to establish key monopolies.⁷⁰⁰ Consequently it becomes clear that patents have throughout history been closely associated with colonialism.

Patents are often viewed by western powers as a natural right,⁷⁰¹ akin to property acquired by conquest during the colonial period. The first patent law passed with the aim of stimulating invention was in March 1474, when the Venetian Senate adopted the first general patent law. This law covered ‘new and ingenious’ devices that had not previously been manufactured in the Venetian domain. A distinction was not drawn between invented and imported patents. Accordingly, a patent could be conferred upon a device which had already been manufactured elsewhere, but was ‘new’ to the country or domain.⁷⁰²

Furthermore, patents were previously used to facilitate the transfer of existing technologies from countries that were technologically more advanced. These inventions were ‘borrowed’ for a certain time, and a patent rewarded and protected the person who introduced the invention. This transfer of technology is now seen as ‘piracy’ which could be defeated by a registered patent.⁷⁰³ These days, knowledge is fast becoming more important than land and other tangible assets as an

⁶⁹⁷ Patents for inventions were granted for new and innovative devices as an incentive.

⁶⁹⁸ Patents for imports were granted to persons who introduced new devices that had already been invented in other countries. Persons were still rewarded for making the devices available, even if they did not invent it.

⁶⁹⁹ Shiva V supra at page 11-15

⁷⁰⁰ See Burrell TD South African Patent and Design Law (3rd ed 1999) 3-1 where he confirms that these *litterae patentes* or ‘open letters’ were historically used by the English sovereigns to confer special rights and privileges. The right to a monopoly for inventions was also conferred by means of these ‘open letters’.

⁷⁰¹ The natural rights theory.

⁷⁰² Shiva .V. supra pages 11-13. Also see Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 2-2 for more specific information about the history of patents in South Africa.

⁷⁰³ Shiva .V. supra pages 14-15.

indicator of the wealth of nations. Patents as property are central to the global economy. In a country like the United States – a knowledge based economy – patents are closely guarded.⁷⁰⁴

In 1995 the TRIPS Agreement⁷⁰⁵ was introduced in order to implement patent laws on a global scale.⁷⁰⁶ Although this led to lack of access to essential medicines and new knowledge, there are specific articles in the TRIPS Agreement which aim to counter this trend.⁷⁰⁷

Article 7 of the TRIPS Agreement specifically provides that ‘the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations’.⁷⁰⁸

Article 66(2) specifies that ‘developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base’. This indicates that positive measures are being taken to include LDCs in the transfer of technology, but simultaneously indicates that there is a risk that countries may attempt to stifle the transfer of technology for financial gain. Article 66 (2) also urges developed countries to support the improvement of pharmaceutical research, development, and the lack of production capacity in most DCs. The article also seeks to encourage the local working of patents. Lack of local working of a patent as was in the case of Bayer Pharma vs Natco in India is a good ground for the grant of a compulsory license.⁷⁰⁹

⁷⁰⁴ The economics and cultural importance of this collection of rules is increasingly becoming important. The fortunes of many businesses now depend heavily on intellectual property rights. A growing percentage of legal profession specializes in intellectual property disputes and law makers around the world are busy revising their IP Law. See William Fisher supra (above cited)

⁷⁰⁵ WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (TRIPS Agreement) available at http://www.wipo.int/clea/en/text_html.jsp?lang=en&id=4064 (last accessed 17 March 2013)

⁷⁰⁶ Shiva .V. supra pages 18-20.

⁷⁰⁷ See Articles 1, 7,8, of the TRIPS Agreement

⁷⁰⁸ See Agreement on Trade Related Aspects of Intellectual Property, 33 I L.M 81 (1994) (TRIPS Agreement).

⁷⁰⁹ See Mikhalien Kellerman ‘The Constitutional Property Clause and Immaterial Property Interests’ thesis submitted at the University of Stellenbosch. (2011) AT P. 28

The Patents Act 57 of 1978 governs the registration of patents in South Africa.⁷¹⁰ Alberts⁷¹¹ states that the main requirement for the registration of a patent is that it must be for a new invention involving an inventive step. This invention must have the ability to be used or applied in trade, industry or agriculture.⁷¹² He states that a patent grants, among others, the exclusive right to make, use, or import products embodying the invention. The term of a patent is twenty years from the date of application.^{713 714}

A patent granted in South Africa is valid throughout the country for this twenty-year period.⁷¹⁵ Once the term has expired, the invention reverts to the public domain and the public is free to use it. In the case of patents for medicines, this implies that generic substitutes for the medicines may be placed on the market. The original medicine is no longer protected by the patent and the technology falls into the public domain and may be commercially exploited without the patentee's authorisation.⁷¹⁶

Because patent rights are not absolute, the term of a patent limits the extent of the right granted. There are also situations in which inventions are excluded from patentability and these also serve to limit rights.⁷¹⁷ Burrell⁷¹⁸ states that a patent is *prima facie* valid. Therefore, a person who wishes to rely on the invalidity of a patent bears the burden of proof. A court may revoke a patent if it is proven to be invalid.

Section 25(1) of the Patents Act 57 of 1978 describes which inventions are patentable. A patent may be granted for a new invention that involves an inventive step, and is capable of being used in trade, industry, or agriculture.

⁷¹⁰ See Von Seidel M Intellectual Property-The John and Kernick Guide (1998) 15-30 for a basic review of patents.

⁷¹¹ Alberts W 'What is intellectual property?' (2007) Nov De Rebus 45-46 at 45. See also sec 25 of the Patents Act 57 of 1978 and Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 1-26.

⁷¹² See Norrgard M (2008) supra

⁷¹³ Patents Act 57 of 1978 sec 46(1). See also Burrell TD Burrells South African Patent and Design Law (3rd ed 1999), 1-3 and Von Seidel M Intellectual Property – The John & Kernick Guide (1998) 27.

⁷¹⁴ TRIPS Agreement Article 33

⁷¹⁵ Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 1-4.

⁷¹⁶ Alberts W 'What is intellectual property?' (2007) Nov De Rebus 45-46 at 45. See Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 1-1. See further *Letraset Ltd v Helios Ltd 1972 (3) SA 245 (A) at 249* where the court stated that a patent involves a quid pro quo where the quid is the monopoly conferred on the inventor while the quo is the new knowledge that the public may use freely after the patent has expired.

⁷¹⁷ See Articles 27 (2) and 27 (3) of the TRIPS Agreement

⁷¹⁸ Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 1-3. See also *Cape Explosives Co Ltd v Cullen and BSA Explosives Co Ltd 1913 TPD 329 at 331-332*.

Section 25(2) of the Act 57 identifies specific exclusions from the concept of an invention for purposes of patents. These are: a discovery; a scientific theory; a mathematical method; a literary, dramatic, musical or artistic work or any other aesthetic work; a scheme, rule or method for performing a mental act, playing a game, or doing business; a program for a computer; or the presentation of information.⁷¹⁹ Section 25(4)⁷²⁰ identifies further exclusions from patentability, namely, inventions which promote offensive or immoral behaviour;⁷²¹ and any variety of animal or plant, or any essentially biological process for the production of animals or plants that is not a microbiological process.⁷²²

From this it emerges that patents have not always been used for the promotion of creativity, but may be linked to other tools of colonisation.⁷²³ Consequently it cannot be assumed that constitutional property protection should necessarily be granted to all patents in their current form.⁷²⁴ It also becomes clear that there are certain definable rights linked to patents that could be protected under the constitutional property clause.⁷²⁵ The inclusion of immaterial property interests as constitutional property will have two implications: protection and limitation. These two aspects are closely linked, but are also distinct and need to be treated as such. The state is permitted to intervene in property rights in cases of deprivation and expropriation. Provided that the state adheres to these strict requirements, the interference is constitutionally justifiable.⁷²⁶

If an invention complies with the strict requirements set out in the Patents Act 57 of 1978, a patent will be granted. This patent entails the exclusive right to make, use, or import products embodying the invention. These rights could possibly be protected by the constitutional property clause.

There are also certain ‘built-in’ restrictions placed on patents by virtue of the Patents Act 57 of 1978. Some inventions may not be patented at all due to public considerations. The constitutional property clause also imposes certain restrictions via the deprivation and expropriation

⁷¹⁹ Patents Act 57 of 1978 sec 25(2) (a)-(g). See Burrell TD Burrells South African Patent and Design Law (3rd ed 1999) 1-24.

⁷²⁰ Patents Act 57 of 1978.

⁷²¹ Patents Act 57 of 1978 sec 25(4) (a)

⁷²² Patents Act 57 of 1978 sec 25(4) (b)

⁷²³ See Mikhalien Kellerman University of Stellenbosch (2011) supra at p. 28

⁷²⁴ See Mikhalien Kellerman University of Stellenbosch (2011) supra at p. 28

⁷²⁵ See Section 25 of the South African Constitution Act No. 108 of (1996)

⁷²⁶ See Mikhalien Kellerman University of Stellenbosch (2011) supra at p.319

provisions,⁷²⁷ which could be useful in finding a balance between patent protection and the interests in the public domain.

Both foreign law and international law indicate that IP should be recognised as constitutional property. South African courts may consider foreign law but must consider international law. An example of foreign law is the German constitutional law which explicitly accepts patents as constitutional property.⁷²⁸ In international human rights law, IP is protected under the UDHR,⁷²⁹ while the right to IP was entrenched and made a binding right in the ICESCR.⁷³⁰

Finally, in *Laugh it off v SAB International*,⁷³¹ the Constitutional Court explicitly balanced the right of a trademark holder against the right of freedom of expression.⁷³² This is authority for the claim that trademarks may be recognised and protected as constitutional property which would of necessity imply that other IP rights – patents in our case -- should also be recognised and protected.⁷³³

8.4 Section 27 of the Constitution of the Republic of South Africa: The constitutionality of access to medicines

Access to essential medicines as part of the right to the highest attainable standard of health (‘the right to health’) is well founded in international law. The right to health first emerged as a socio-economic right in the WHO constitution (1946)⁷³⁴ and in the UDHR (1948).⁷³⁵ The binding

⁷²⁷ See Section 25 (3) of the South African Constitution Act No. 108 of (1996)

⁷²⁸ See BverfGE 36. 281 [1974] (patent rights) see chapter 5 (immaterial property interests in the constitution)

⁷²⁹ See United Nations Declaration of Human Rights (1948) GA Res 217 A (III), UN Doc A/810 at 7 (1948) <http://www.un.org/en/document/udhr/> (accessed 20 November 2013)

⁷³⁰ See United Nations Covenant on Economic, Social and Cultural Rights (1966) 993 UNTS 3 (1976) (<http://www.2.ohchr.org/english/law/cescr.htm> (accessed 20 November 2013))

⁷³¹ 2006 (1) SA 144 (cc)

⁷³² See paragraph 17 of the judgment of the Constitutional Court

⁷³³ Foreign law and international law indicate that IP should be recognized and protected as constitutional properties. The courts in South Africa may therefore consider these foreign laws (example is German law), but the courts are obliged to follow international laws which the country has ratified.

⁷³⁴ The constitution was adopted by the International Health Conference held in New York from 19th June to 22 July 1946, signed on 22nd July 1946 by representatives of 61 states. (Off.Rec.Wld Hlth Org, 2, 100) and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth and fifty-first World Health Assemblies (resolution WHA 26.37, WHA 29.38, WHA 39.6 and WHA 51.23) CAME INTO FORCE ON 3rd February 1977, 20 Jan 1984, 11 July 1994 and 15 September, 2005 respectively and are incorporated in the present text.

⁷³⁵ UDHR (article 25)

ICESCR⁷³⁶ of 1966 details the progressive realisation of the right to health through four concrete steps including access to health facilities, goods and services. Under the African Charter on Human and Peoples' Rights (1981),⁷³⁷ the authoritative General Comment 14 (2000) further applies the principles of accessibility, availability, appropriateness and assured quality to goods and services, which includes essential medicines 'as defined by the WHO Action Program on Essential Drugs'.⁷³⁸

Access to medical products and technologies as part of the right to health recognised in countries' constitutions or national legislation, is the first country progress indicator for Strategic Objective II (Improved access, quality and use of medical products technologies) of the WHO Medium Term Strategic Plan for 2008-2013.⁷³⁹

The Constitution of the Republic of South Africa is notable for its simplicity and clarity on the right to health. Section 27 of the Constitution protects the right to healthcare and medicines and requires the state to take 'reasonable legislative measures' to realise this right.⁷⁴⁰

Article 2(1) of the ICESCR also provides that 'state parties must take steps...to the maximum of its available resources, with a view to achieving progressively the full realization of the rights.'⁷⁴¹

This provision in section 27 of the South African Constitution has been tested in several cases discussed in this thesis, but of particular interest is the recent case of *Cipla Medpro v Aventis Pharma* (139/12); *Aventis Pharma SA v Cipla Life Sciences* (138/12)[2012] ZASCA 108 (26 July 2012) which concerned two appeals. The opponents in each appeal were one or more companies within the Aventis group ('Aventis') arraigned against one or more companies within the Cipla group ('Cipla').

⁷³⁶ ICESCR (article 12)

⁷³⁷ Adopted on June 27, 1981 (article 16)

⁷³⁸ Available at www.umn.edu/humarts/gencomm/escgencom14.htm

⁷³⁹ Available at www.who.int/medicines/technical.../tbs/medicinesstrategynov8tbs.ppt

⁷⁴⁰ The stipulation of the right to health in the constitution, concerning its equal accessibility, is an indicator of the will of the state regarding its negative duty to protect this right. The state has an obligation to respect and fulfil this right. The obligation to fulfil requires the state to adopt appropriate legislative, administrative, budgetary judicial promotional and other measures towards the full realization of the right to health. See Toebes, B (1999) *The Right to Health as a Human Right in International Law*, London: Intersentia, p 338

⁷⁴¹ Article 2 (1) of the ICESCR

The Treatment Action Campaign ('TAC'), which joined the proceedings as a friend of the court, aligned itself with Cipla's opposition to the grant of an interdict. TAC submitted that the Patents Act must be construed 'through the prism of the Constitution', and that it 'must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby'.⁷⁴²

According to the court, the TAC failed to explain and argue to a logical conclusion, its contention that the legislation should be viewed through the prism of the Constitution.⁷⁴³ The court could not see how section 39(2), or the prism of the Constitution, could come into play to deny the patentee its right to enjoy its patent.⁷⁴⁴

Nugent JA found that the public interest would not have been materially affected, and he could, accordingly, see no proper ground for denying Aventis the relief it sought.

Construing patents through the 'prism of the Constitution', as the TAC sought the court to do, should include giving effect to section 233 of the Constitution in the present context. This provision states that '[w]hen interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law'.⁷⁴⁵

Article 16 of the African Charter on Human and Peoples' Rights ('African Charter')⁷⁴⁶ guarantees every individual the right to enjoy the best attainable state of physical and mental health. State parties are required to take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are ill. The principles and guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter elaborate on the contents of this right by providing that state parties should adopt and implement

⁷⁴² See para. 44 of the judgment of Nugent JA

⁷⁴³ See para 45 of the judgment of Nugent JA

⁷⁴⁴ See para 45 of the judgment of Nugent JA

⁷⁴⁵ See Coenraad Visser, Of liability for Patent Infringement, Public Interest, and Effective Patent Terms: *Cipla v Aventis Pharma* (2012) 24 SA Merc. LJ at p. 7

Relevant international law here includes not only the provisions of the Agreement on TRIPS Agreement but also jurisprudence of the WTO fleshing out the contents of the agreement. "In the present case, Cipla did more than stockpile- it brought CiplaDocetaxel and Cipla Docetaxel solvent onto the market before the expiry of the patent. If this were to countenanced, that would have been in direct conflict with South Africa's obligation under the TRIPS Agreement" See Coenraad Visser supra (footnote above) at p. 7.

⁷⁴⁶ African Charter on Human and Peoples' Rights, OAU Doc. CAB/LEG/67/3/Rev.5; adopted by the Organisation of African Unity, 27 June 1981, entered into force 21 October 1986.

policies that ensure that members of vulnerable and disadvantaged groups have access to medicines.

The guidelines suggest that ‘appropriate legislation and international trade regulation and cooperation should be utilized towards the establishment of scientifically sound pharmaceutical industries in Africa with particular emphasis on local African production for self-reliance in drug industries.’ They explicitly state that ‘this should include utilizing parallel importation and compulsory licensing for medicines where available and applicable, to ensure the availability of drugs and technologies at affordable prices for treatment , care, and prevention of epidemic, occupational and other diseases including malaria, HIV/AIDS tuberculosis and other infectious diseases’.⁷⁴⁷

As stated above, in South Africa the right to access to healthcare services is guaranteed in section 27(1) and 27(2) of the Constitution.⁷⁴⁸ This provision guarantees to everyone the right of access to healthcare services, which includes a right of access to affordable medicines.⁷⁴⁹

As a party to the WTO’s TRIPS Agreement which regulates the international protection of pharmaceutical patents, South Africa is permitted to make use of certain flexibilities -- such as compulsory licensing and parallel importation -- which would allow for improved access to medicines in both the public and private sectors.⁷⁵⁰

8.5 Legislation on access to medicines in South Africa

South Africa has a progressive regulatory framework and the most advanced legislation in Africa for dealing with anti-competitive practices. Although South Africa has relatively weak

⁷⁴⁷ Para 67 (xxix) of Article 16 of the African Charter

⁷⁴⁸ This provision establishes three fundamental principles:

1. The right of access to health should be universal
2. It should be characterized by equality of access
3. It should provide full health coverage.

⁷⁴⁹ See *Minister of Health and Another v New Clicks South Africa (pty) Ltd and Others (Treatment Action Campaign and Another as Amici Curiae)* 2006 (2) SA 311 (CC) para [514] (per Ngcobo J) and para 706 (per Moseneke J).

⁷⁵⁰ Compliance with TRIPS naturally affected the cost of medicines in South Africa, as it eliminated the possibility of generic production during the term of a pharmaceutical patent. This impact was exacerbated, however, by the fact that South Africa failed to take advantage of several flexibilities and opportunities that would limit pharmaceutical patents and help keep drug prices manageable. See Avafia T, Berger J and Hartzenberg T, 2006 “The ability of selected Sub-saharan African countries to utilise TRIPs Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines. A study of producing and importing countries”. TRALAC working paper No 12- Stellenbosch.

provisions on compulsory licences,⁷⁵¹ the flexibilities of the TRIPS Agreement are incorporated in three specific pieces of legislation: the Patents Act;⁷⁵² the Medicines Control and Related Substances Control Amendment Act;⁷⁵³ and the Competition Act.⁷⁵⁴ These Acts have been applied in several instances and in unique fashion to ensure access to medicines. These three enactments are discussed below.

8.5.1 The Patents Act

South Africa's patent law predates the TRIPS Agreement. The Patent Act 57 of 1978 allows a lifespan of twenty years for patents. Compulsory licensing is permissible under patent law.

In 1997, the Patent Act of 1978 was revised by the Intellectual Property Law Amendment Act 38 of 1997 ('IPA 1997') in order to comply with the TRIPS Agreement and facilitate South Africa joining the Patent Cooperation Treaty.⁷⁵⁵

However, the Patent Act as it relates to compulsory licensing can be said to be 'TRIPS-plus' as it allows for greater protection than required under the TRIPS Agreement. Additionally, the patent law permits international exhaustion of patent rights implying that patent rights are considered exhausted if a product under patent is sold anywhere in the world. In 2002, the Act was amended to incorporate the 'Bolar Provision' and subsequently the 2005 amendment extended IPRs to indigenous knowledge systems.

8.5.2 The Medicines and Related Substances Control Amendment Act 90 of 1997

The Medicines and Related Substances Control Act ('MRSCA') 101 of 1965 was amended in the early nineties in order to pave way for the increased access to low-cost drugs. To realise this, the MRSCA amendment Bill was tabled in Parliament in 1997, and passed into law in 1998. Sections 15C and 22C of the MRSCA1997 permit ministerial discretion in the issuing of compulsory licences and parallel trading.

⁷⁵¹ Osewe, Nkrumah and Sakey 2008, Improving Access to HIV/AIDS Medicines in Africa: Trade Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities. Washington, DC World Bank, at p. 16.

⁷⁵² South African Patents Act No. 57 of 1978 as amended by Patents Amendment Act No. 58 of 2002

⁷⁵³ South African Medicines and Related Substances and Control Amendment Act 90 of 1997.

⁷⁵⁴ South African Competition Act No. 89 of 1998

⁷⁵⁵ Kongolo, T. (2002), towards a new fashion of protecting pharmaceutical patents in Africa- Legal Approach, International Review of Industrial Property and Copyright Law II C, Vol. 33, No.2 at p. 192.

The amendment introduces a framework to increase the availability of affordable medicines in South Africa. The provisions of the Act embrace generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines. It was the enforcement of one of these provisions, section 15C,⁷⁵⁶ that led to the well-known trade dispute between the Big Pharma and the South African government which ended in April 2001. The dispute had a significant impact in the run-up to the Doha Declaration seven months later.

It took a further three years before the Act came into full force. Some of this delay was because regulations had to be drafted. In addition, certain minor amendments to the Medicines Act were needed, resulting in the Medicines and Related Substances and Amendment Act 59 of 2002.⁷⁵⁷

The 1997 amendments to the Medicines Act started to come into force on 2 May 2003 and the full package of reform was brought into effect on 2 May 2004 (with certain provisions scheduled to become operative over a period of three months). This was almost seven years after President Mandela signed Act 90 of 1997 into law.⁷⁵⁸

8.5.3 The Competition Act

Under the South African Competition Act it is provided that all people will benefit from an efficient and competitive development-oriented market that balances the interests of producers, consumers, and workers.⁷⁵⁹ The Act further provides support for a market ‘in which consumers have access to, and can freely select, the quality and variety of goods and services they desire’.⁷⁶⁰

Section 1(2)(a) provides that in furtherance of the goal of the Act as stated in the preamble, the Act will be interpreted in a manner which gives effect to its purposes, which include the provision of ‘competitive prices and product choices’,⁷⁶¹ and ‘advancing social and economic

⁷⁵⁶ Section 15C of Medicines Control and Related Substances Act 101 allows the Minister of Health to take necessary measures to import affordable medicines to satisfy national needs.

⁷⁵⁷ To amend the Medicines and Related Substances Act, 1965. Available at www.saflii.org/Za/legis/numact/marsaa200360.pdf

⁷⁵⁸ See Health & Democracy by Hassim, Heywood and Berger 2007, published by Siber Ink: Chapter 14 On Access to essential Medicines at page 452.

⁷⁵⁹ Preamble to the Competitions Act of South No. 89 (1998)

⁷⁶⁰ Ibid.

⁷⁶¹ Ibid., Section 2(b)

development'.⁷⁶² This enabling competition law has been invoked twice to ensure access to medicines. The first case arose in September 2002 when the TAC lodged a complaint through the AIDS Law Project ('ALP') on behalf of people living with HIV/AIDS ('PLWHS'). The complaint to the Competition Commission was against Glaxo Smithkline (GSK) and Boehringer Ingelheim (BI) for excessive pricing. The two companies were found to have engaged in excessive pricing, anti-competitive behaviour, and a denial of access to an essential facility. A settlement was reached between GSK and the Competition Commission.

The second instance was in February 2005 when the ALP, acting on behalf of the TAC and the Southern African HIV Clinicians' Society, threatened to lodge a complaint with the Competition Commission against Bristol-Meyers Squibb ('BMS') for excessive pricing. A few months after the lodging of the letter of demand, BMS lowered its prices by 80-85 per cent for the public and private sectors.

Although compulsory licences were not issued, this is a clear example that compulsory licences can serve competition law aims when it comes to facilitating the entry of generic medicines into the market, thus resulting in affordability.⁷⁶³

8.6 Competition policy reform: Analysis of the South African situation

Improving access to affordable medicines is a complex issue for DCs and has been tackled in various ways, from strengthening national competition laws to compulsory licensing for drugs.

As the cases before the South African Competition Commission have demonstrated, an aggressive, pro-access competition policy can be a formidable weapon in the country's efforts to ensure access to generics and to achieve economies-of-scale by the inclusion of non-domestic markets.

South African competition law is a model for other DCs in Africa. It is therefore necessary to analyse the application of that law in some depth. Other DCs should consider the wisdom of adopting similar or improved measures in their domestic laws.⁷⁶⁴

⁷⁶² Ellen 't Hoen at page 51

⁷⁶³See Avafia T., Burger J. and Hartzenberg T., 2006 "The Ability of Select Sub-saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries." TRALAC Working Paper No. 12 Stellenbosch.

Section 56(1) of the South African Patents Act 57 of 1978, as amended by the Intellectual Property Laws Amendment Act 38 of 1997, states that: ‘Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory license under the patent.’⁷⁶⁵

Section 56(2) covers four specific circumstances under which any person who can show that patent rights are being abused may apply to the Commissioner in the prescribed manner for a compulsory licence under the patent:

- non-working on a commercial scale or to an adequate extent (within a 3 or 4 year period of filing the patent application or certification of the patent) and there is no satisfactory reason for such non-working (subsection (2)(a));
- demand for the product is not being met to an adequate extent and on reasonable terms (subsection.(2)(c);
- refusal to grant a license on reasonable terms that prejudices an existing or emerging trade or industry and it is in the public interest to grant a license (sub-sec. (2)(d). This provision potentially applies to the issue of pharmaceutical access;
- demand is being met by importation and the price is excessive in relation to the price charged in the countries where the patented article is manufactured (sub-sec. (2) (e)).⁷⁶⁶

The South African Competition Act 89 of 1998 and the Patent Act provide remedies for anti-competitive practices and presumably permit the issuing of open compulsory licences for anti-competitive pricing practices by the pharmaceutical industry. Section 8 of the South African Competition Act prohibits dominant firms from engaging in excessive pricing, refusing access to an essential facility, and engaging in other exclusionary act.

Section 8 states that it is prohibited for a dominant firm⁷⁶⁷ to:

⁷⁶⁴ Ibid

⁷⁶⁵ The State itself may apply for compulsory licenses under the Patents Act Section 4 permits the Minister of State to seek a voluntary license for the use of the patented product for public purposes and in default of such voluntary agreement for the Minister to file application to the commissioner. Section 78, permits the government to go even further and to “acquire” any invention or patent. Under the Constitution, the government could also “take” the patent and pay just compensation.

⁷⁶⁶ See Professor B.K Baker supra at pages 678 to 680

⁷⁶⁷ Section 7 states “A firm is dominant in a market if-(a) it has at least 45% of that market: (b) it has at least 35%, but less than 45%, of that market unless it can show that it does not have market power; or (c) it has less than 35% of that market, but has market power.

- (a) Charge an excessive price to the detriment of consumers;
- (b) Refuse to give a competitor access to an essential facility when it is economically feasible to do so;
- (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; ...’

Section 1 of the Act provides key definitions.⁷⁶⁸

‘(viii) ‘essential facility’ means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers;

(ix) ‘excessive price’ means a price for a good or service which –

(aa) bears no reasonable relation to the economic value of that good or service; and

(bb) is higher than the value referred to in subparagraph (aa);

(x) ‘exclusionary act ’ means an act that impedes or prevents a firm from entering into, or expanding within, a market;

(xii) ‘goods or services’, when used with respect to particular goods or services, includes any other goods or services that are reasonably capable of being substituted for them, taking into account ordinary commercial practice and geographical, technical and temporal constraints; ...’

⁷⁶⁸ Section 1 also provides guidance on interpretation of the Act:

(2) This Act must be interpreted-

- “(a) in a manner that is consistent with the Constitution and gives effect to the purpose set out in section 2; and
- (b) to provide consumers with competitive prices and product choices;
- (c) to promote employment and advance the social and economic welfare of South Africans;
- (d) to expand opportunities for South Africans participation in world markets and recognise the role of foreign competition in the Republic;
- (e) to ensure that small and medium –sized enterprises have an equitable opportunity to participate in the economy; and
- (f) to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.”

The South African Competition Commission identifies three instances in which a pharmaceutical compulsory licence may be issued. Firstly, compulsory licences should be granted whenever it can be shown that there is a gap between the need for the medicine and its accessibility due to excessive pricing.⁷⁶⁹

The second pertains to the refusal to issue voluntary licenses, and this can be viewed as exclusionary, particularly where the anti-competitive effect of non-licensing outweighs any 'technological, efficiency or other pro-competitive gain'.⁷⁷⁰

While, under the third, a compulsory licence should be issued whenever a patent holder's failure to grant voluntary licences denies consumers access to a competitor's product.⁷⁷¹

8.7 The South African draft intellectual property policy

For many years there has been a strong desire to bring the patents law in South Africa into line with the TRIPS Agreement and the Doha Declaration's standard on the interpretation of the TRIPS Agreements on Public Health. Recently, a major step was taken in this direction when the long-anticipated draft National Policy on IP was published on 4 September 2013. Although it could take up to three or more years for the policy to become law in the formal sense, this remains a very welcome development

The main objectives of the new draft policy include: to develop of a framework that should empower all strata of South African society, to contribute to the development and improvement of intellectual property enforcement; to promote research and development and improve national compliance with treaties to which South Africa is a party; to introduce a public health perspective into national intellectual property law; to ensure that intellectual property laws are appropriate to the level of development and innovation in South Africa; and to engender confidence and attract investment, and to promote public education and awareness of intellectual property rights in South Africa.

On patentability, the draft policy states that South Africa should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.

⁷⁶⁹ See Professor K. Baker supra above cited at p. 682

⁷⁷⁰ Ibid

⁷⁷¹ See Professor. K. Baker supra above cited at p. 682

The South African Patents Act already excludes methods of treatment of the human or animal body by surgery or therapy, or of diagnosis practiced on the human or animal body from patentability. The use of the phrase ‘including new uses of known products’ has raised serious concerns in the pharmaceutical sector. Given that the reference to methods of treatment is incorrect, it is unclear whether or not the IP policy intends to exclude the patentability of patents directed at a known compound for use in a new method of treatment.

If that is the case, it means that the current section 25(7) of the Patents Act which specifically provides that a patent may be granted to a known compound for use in a new method of treatment (provided that the new use is inventive) will have to be deleted. An amendment of this nature would clash with both the TRIPS Agreement and the flexibilities highlighted in the Doha Declaration.⁷⁷²

The draft IP policy also states that South Africa should include provisions in its patent law that will facilitate the entry of generic competitors as soon as the patent on a medicine has expired. The draft identifies that section 69(A) of the current South African Patents Act (introduced by an amendment in 2002) already provides for a ‘Bolar’-type provision for obtaining regulatory approval for registration of a patent on medicine prior to the expiry of an existing patent, but it excludes stockpiling. It therefore appears that the draft intends to maintain the status quo as regards the entry of generic medicines into the South African market.

The Minister of Trade and Industry, Rob Davies, whose department was responsible for the draft has given assurances that South Africa will comply with its treaty obligations.⁷⁷³

8.8 Conclusion

While South Africa’s Patents Act 57 of 1978 makes no express reference to the term ‘anti-competitive conduct’, it does make provision for the grant of compulsory licences where ‘the rights in a patent are being abused’.⁷⁷⁴ Amongst other grounds, section 56(2) of the Act recognises that ‘the rights in a patent shall be deemed to be abused if ... [t]he demand for the

⁷⁷² See , Spoor & Fisher, ‘The South African draft IP Policy’: Patent and Health in South Africa 2014-03-10 p.1
See also ‘Whats behind the drug patent furore in South Africa’ Managing Intellectual Property website, February, 2014.

⁷⁷³ See, Spoor & Fisher 2014-03-10 (as indicated above)

⁷⁷⁴ Section 56(1) of the S.A Patents Act

patented article in the Republic is not being met to an adequate extent and on reasonable terms'. However, section 56 has never been invoked in South Africa.

The South African legislative framework has created an enabling environment that ensures access to essential medicines. The granting of voluntary licences to local generic manufacturers resulted from the application of competition law. It can be asserted that the Competition Act is effective in ensuring access to medicines but legislative reform is urgently needed. This is necessary to empower the Competition Commission to grant compulsory licences owing to the current restrictive nature of the Patents Act under which compulsory licences ought to be issued.

It is worth noting, however, that in South Africa unlike in many other African countries, people have a constitutional right both to access health services and to be treated in a way that should improve their health.

Despite these laudable achievements, I think the time is ripe for the government of South Africa and all other relevant agencies involved in the administration of IP, to take urgent steps to implement into law 'The South African Draft National Policy on Intellectual Property' ('draft IPP') which was published on 4 September 2013.⁷⁷⁵

There is urgent need to take full advantage of all flexibilities and public health safeguards available under the TRIPS Agreement, including but not limited to those addressed in the Doha Declaration of 2001.

⁷⁷⁵ On 17 January 2014, Money MSN published a report based on a document that was leaked from the Innovative Pharmaceutical Association South Africa (IPASA), an industry lobby group comprising the local subsidiaries of innovator pharmaceutical companies. The document is a plan for a campaign prepared by U.S based consultancy Public Affairs Engagement, to delay and modify the draft IP Policy. This news report was followed by a press conference by the South African Minister of Health Aaron Motsoaledi. The minister was very critical of the campaign which he said was a calculated attempt by the U.S. to put medicines beyond the reach of the poor in DCs. He said India has already changed its law to control Ever-greening and other devices used to r introduce a patent that has become generic back into registration, to gain an extension of 20 years. He said all what South Africa is trying to do is to catch up with the rest of the world. He said the country is not against intellectual property as "we have already paid them for twenty years". He further stated that the campaign is 'satanic' as the big pharmaceutical companies are looking for "super profits". Out of the more than eight million people who are suffering from AIDS/HIV, more than six million of them are in Sub-sahara Africa. On the issue that investors will run away from the country if the IP Policy is promulgated into law, he stated that there will be noting to invest on if almost all the people in South Africa are dead due to lack of medication. He asked the question, will investors invest on dead people? The IPASA subsequently distanced itself from the campaign, saying that the plan was reviewed and subsequently rejected by IPASA members. See <http://www.spoor.com/home/index.php?ipkArticleID=498>

The consequences of South Africa's current strict patent protection measures are high costs for medicines and the delay in availability of affordable generic medicines.

However, the developments described in this chapter are signs that the human right to essential medicines has advanced as regards both its normative content and its legal recognition. Although, it remains a daunting challenge to coordinate with the international trade regime, bridge the gaps in political will, find incentives for innovation and affordable pricing, and create the availability of adequate human and financial resources to ensure distribution networks. All this needs to be achieved in order for this right to be of practical value for the millions who currently lack access to essential medicines.

CHAPTER 9

Constraints on the implementation of the Doha Declaration and the paragraph-6 decision

9.1 Introduction

A key issue that remained unresolved in Doha was how to ensure that products manufactured under a compulsory licence could be exported to countries without domestic production capacity.

It took over two years of difficult negotiations and deliberations, before the WTO Decision on the Interpretation of Paragraph-6 ('the Paragraph-6 Decision') was announced in 2003. The difficult and cumbersome process specified when countries could import drugs manufactured elsewhere under compulsory licensing.⁷⁷⁶

Despite the affirmations provided by the Doha Declaration, and the Paragraph-6 Decision, a number of difficulties still face DCs seeking to implement them in practice.

9.2 Compulsory licensing and parallel importation

The TRIPS Agreement contains two important measures that can be used to limit patents rights. These measures include the right of a government to grant compulsory licences, and the application of the principle of the exhaustion of IP rights, which allows for parallel importation of patented goods. Although, the Doha Declaration and the Paragraph-6 Decision interpreting the paragraph-6 problem of the Doha Declaration clarify the right of DCs to engage in compulsory licensing and parallel importation, doubt as to their use in practice persists.

Many DCs hesitate to use compulsory licensing because of its economic and political repercussions. Countries that have followed the compulsory licensing route have seen a decrease in foreign direct investment which is vital for the economic development of many DCs.

⁷⁷⁶ WTO: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August, 2001 (<http://www.who.int/medicines/areas/policy/WT/L540>, 2 September 2003).

‘Parallel trading’ or ‘parallel importation’ is a problem that manifests when a buyer purchases products at below market price and subsequently exports the products to another market where they are higher priced.⁷⁷⁷ The concept underlying parallel trading is based on the principle of the exhaustion of rights. This principle is premised on the fact that where the patent holder has been rewarded through the first sale or distribution of the product, he or she no longer has the right to control the use or the resale of the product.⁷⁷⁸

The sale of a patented product, unless notification is given, gives the purchaser a licence under the patent to exercise all the normal rights of an owner, including the right to resell the product.⁷⁷⁹ Article 6 of the TRIPS Agreement allows each member country the freedom to incorporate the principle of international exhaustion of rights, the underlying justification for parallel trading, in its legislation.⁷⁸⁰

Parallel imports are of particular importance for public health interests as the pharmaceutical industry generally sets prices of medicines differently in different parts of the world. Parallel trading prevents market segmentation and price discrimination by patent holders on a regional or international scale.⁷⁸¹ Parallel imports are not a means by which to ignore the patentee’s right to remuneration (which accrues with the first sale of the product), but a means of ensuring that patents work ‘to the mutual advantage of producers and users of technological knowledge’ (art 7 of the TRIPS Agreement) in a global economy.⁷⁸²

⁷⁷⁷ See Bryan C. Mercurio, TRIPS, Patents and Access To Life-Saving Drugs in the Developing World, 8 Marq. Intell. Prop. L.Rev. 211, 242-245.

⁷⁷⁸ See Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options 2000 at pp81-82.

⁷⁷⁹ See Cornish ‘Intellectual Property’ 1989 at p.2000

⁷⁸⁰ See Carlos M. Correa supra at p.83

⁷⁸¹ Article 6, of the TRIPS Agreement, provides that the exhaustion issue may not be subject to dispute settlement. Since ‘exhaustion’ is not a specifically defined term, it appears that each WTO member is permitted to adopt the definition it reasonably considers appropriate. This definition might include exhaustion by first sale under compulsory licence. See Frederick M. Abbott The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO. Journal of International Economic Law (2002) 469-505 at p.495

⁷⁸² See Carlos M. Correa supra at p.86

Developed countries and their corporations discourage parallel imports on the ground that if parallel trading were to be permitted, companies would charge a uniform price worldwide. This would result in an increase in the price that may be charged in low-income countries,.⁷⁸³

In South Africa 39 pharmaceutical companies sued the Mandela administration challenging the new legislation⁷⁸⁴ which allowed parallel importation of medicines which a patent holder had sold more cheaply in another country.⁷⁸⁵

9.3 Data exclusivity and regulatory approval

Data exclusivity measures prevent generic manufacturers from using existing clinical research to gain regulatory approval for their medicines. This, in turn, forces them to conduct duplicate clinical trials or to wait for the ‘data monopoly’ period to end.⁷⁸⁶

In the absence of data exclusivity measures, when a generic manufacturer applies to register and sell a version of a previously-registered medicine, it need only provide data showing that its product is equivalent to the original.⁷⁸⁷ The drug regulatory authority relies on the clinical trial data provided by the original manufacturer to evaluate the safety and efficacy of the generic drug.

The introduction of data exclusivity provisions essentially creates a new system for granting monopolies by blocking registration of generic medicines until the data exclusivity period has run its course, even if the patent monopoly has already expired or been overcome, for example by the use of a compulsory licence. Under these terms generic competition is stifled not only for

⁷⁸³ The pharmaceutical industry is highly critical of parallel importation because it limits companies’ ability to charge whatever a local market will bear. It also potentially reduces profits in high-price countries, but only if consumers can lawfully obtain cheaper sources of supply with a lower profit margin elsewhere. To allay these risks most developed countries have imposed significant restrictions on parallel importation of medicines. For example, the US prohibits the practice completely except for consumer’s personal supply of medicines purchased abroad. See Brook K. Baker *Arthritic Flexibilities For Accessing Medicines* supra at p. 661

⁷⁸⁴ Article 15 C (A) of the Medicines Act authorized the minister of health to prescribe “conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public.

⁷⁸⁵ *Pharmaceutical Manufacturers Association v. President of the Republic of S. Africa* supra

⁷⁸⁶ For an extended analysis of Article 39.3 and the options developing have to permit registration of bio-equivalent products, see Carlos M. Correa, *Protection of Data Submitted For the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement (2002)*, available at <http://www.southcentre.org/publications/protection/protection.pdf>. (last visited Apr. 6, 2014).

⁷⁸⁷ Perez, M (2004, October) *Intellectual Property and Pharmaceutical data exclusivity in the context of innovation and market access*.

Retrieved from http://www.Iprsonline.org/unctadictsd/Bellagio/docs/pugatch_Bellagio3pdf

old medicines no longer under patent protection, but also for new medicines that do not warrant patent protection.

Data exclusivity prevents the registration of generic versions of a medicine for many years. Compelling generic manufacturers to repeat the required clinical trials is not only extremely costly and time consuming, but also arguably unethical and wasteful as it forces duplication of clinical trials for patients and animals in order to prove something that is already known.⁷⁸⁸

9.4 The ‘Bolar provisions’: Early application

National legislation generally requires medicines to be registered by a country’s national drug regulatory authority before it is placed on the market. Although this process is important to ensure the safety and efficacy of drugs that are marketed, it can result in delays in generic medicines becoming available unless appropriate provisions are included in legislation.

It often takes as long as a year from the expiry of a patent before its generic alternative is available on the market. During this period, the previous patent holder still enjoys an effective monopoly. Delay is due largely to the drug registration process and can be minimised by completing the registration process during the life of the patent, so that generic alternatives are already registered and can be sold immediately once the patent expires. However, beginning the registration process during the life of the patent may be a violation of the patent, because the law normally prevents anyone from using a patented product without the express authorisation of the patent holder.

This problem can be overcome by including an early-working exception in patent legislation. An early-working provision allows generic manufacturers to register a generic version of a medicine during the life of the patent of the original version. This is often termed the ‘Bolar exception’ based on the case *Roche Products v Bolar Pharmaceuticals*⁷⁸⁹ decided by the USA Court of Appeals for the Federal Circuit (CAFC) in 1984.

⁷⁸⁸ See Professor Brook.K.Baker , Arthritic flexibilities for accessing medicines: Analysis of WTO action regarding paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. P. 708.

⁷⁸⁹ *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d. 858(Fed. Cir. 1984)

Early-working provisions under India's Patents Act have recently become a major focus of litigation between generic producers and patent holders in India. In 2010 the drug company Bayer Corporation sought to prevent a generic manufacturer, Cipla, from seeking marketing approval for a generic cancer medicine still under patent. Bayer Corporation had sought an order to refuse marketing approval for the generic version. The Delhi High Court found in favor of Cipla,⁷⁹⁰ and the Supreme Court refused Bayer's petition for leave to appeal.⁷⁹¹

Under TRIPS-plus measures, a patent owner must consent to marketing approval for a generic version during the patent term.

9.5 The need for national laws on compulsory licensing

The Paris Convention for the Protection of Industrial Property ('Paris Convention') plainly states that 'each country of the union have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent', for example, failure to work. From the wording of article 31 of the TRIPS Agreement on Compulsory Licensing, it is clear that members are free to determine several reasons specified in their national laws for the grant of compulsory licensing for pharmaceutical patents.

However, many DCs lack the legislative provisions which would allow them to take advantage of the flexibilities available under the TRIPS Agreement and the Doha Declaration. National legislation is important because many provisions are permitted only if written into law. It is important to note that many DCs and LDCs have stricter IP protection than is minimally required by the TRIPS Agreement.⁷⁹²

9.6 Research and development

Diseases such as malaria, tuberculosis, cholera, polio and many other infectious diseases continue to threaten the health of millions of people living in DCs. Most of the drugs currently

⁷⁹⁰ Journal of Intellectual Property Rights Vol.5, May 2010, pp 187-196

⁷⁹¹ *Bayer v the Union of India and Cipla* (High Court:MANU/DE/1756/2009) Supreme Court:DC 6540/2010); And see:<http://genericpharmaceuticals.blogspot.com/2010/12/india-supreme-court-dismiss-bayer.html>;
<http://patentsnmore.wordpress.com/2010/01/18/india-patent-linkage-with-regulatory-approval/>.

⁷⁹² Druce N: *supra*

available to treat these diseases insufficiently effective, inaccessible, or unaffordable. Profits from the sale of drugs have been the driving force for drug development by pharmaceutical firms. Because the majority of the infectious disease in the world are most prevalent in DCs and the majority of the people living in these countries have inadequate purchasing power, the markets for these drugs are not attractive to profit-driven pharmaceutical companies. These companies are therefore reluctant to become actively involved in the development of drugs to address diseases affecting people living in DCs.

Despite extensive research to discover new, effective and cheap drugs to combat the diseases facing DCs, it is not yet realistic to fully develop leads and drug candidates from natural products. As a result sick people in DCs continue to rely on traditional medicines. Lack of human and technological resources, poor economies, and unavailable managerial skills are the major constraints facing R&D for new drugs in DCs.

9.7 Ambiguities in the terms of the Doha Declaration

Perhaps the biggest concern raised by compulsory licensing is the ambiguity of its terms introduced in the Doha Declaration. At face value, the compulsory licensing provisions contain a number of vague terms that are intended to broaden the scope of medical aid that can be provided by not limiting compulsory licences to specific circumstances. The problem is that the scope of eligible diseases, drugs, and nations are undefined.⁷⁹³

This lack of specificity was intended to give LDCs flexibility to decide for themselves what constitutes a public health emergency and minimise delay in accessing essential drugs.⁷⁹⁴ However, it may actually create more controversy because, in theory, any nation can declare a public health emergency for questionable reasons in order to assign compulsory licences for a patented drug.⁷⁹⁵

Indeed, the vague terms in the Declaration have led to many questionable actions by WTO members which have hindered access to medicines for those in need. The revisions of the TRIPS

⁷⁹³ See, Implementation Decision, Supra note 30

⁷⁹⁴ See Id.

⁷⁹⁵ "In the present state a nation could feasibly identify depression as a public health problem and issue a compulsory license on Prozac". See Visual Gupta, A Mathematical Approach to Benefit-Detriment Analysis As a Solution To Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement, 13 *Cardozo J. Int'l & Comp. L.* 631 (2005)

Agreement under the Doha Declaration allow WTO members to override patent laws ‘in the case of a national emergency or other circumstances of extreme urgency.’⁷⁹⁶

Furthermore, the TRIPS Agreement requires countries utilising compulsory licences to pay ‘adequate remuneration’ without specifying how this is to be calculated.⁷⁹⁷

Perhaps, lists of valid diseases, drugs, and nations that are assessed and updated annually by a non-partisan body can overcome these problems.⁷⁹⁸

As ‘emergencies’ and the ‘adequate remuneration’⁷⁹⁹ to patent holders’ are defined under the discretion of a member government, there have been cases where members have abused the use of compulsory licences.

In 2002, shortly after Pfizer received approval to launch *Viagra* into the Egyptian market, the Egyptian government, pressured by the popular local manufacturers, issued a compulsory licence for the generic manufacture of *Viagra*.⁸⁰⁰ *Viagra*, a drug to treat erectile dysfunction, is important but certainly not a drug used for ‘public health emergencies’. From an economic point of view, the positive health effects through compulsory licensing should outweigh the financial losses for pharmaceutical companies. This was not the case for Pfizer and *Viagra* in Egypt. After being informed of Egypt’s compulsory licence for *Viagra*, Pfizer halted plans to build a manufacturing facility in Egypt.⁸⁰¹ The *Viagra* case also discouraged other pharmaceutical

⁷⁹⁶ World Trade Organisation. (2003, Sept 1). Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health. Retrieved from http://www.wto.org/English/tratop_E/TRIPS_e/implem_para6_e.htm

⁷⁹⁷ See Implementation Decision, Supra Note 30 at para.3 (“adequate remuneration shall be paid taking into account the economic value of the importing member”). See also Bryan C. Mercurio, TRIPS, Patents and Access to Life Saving Drugs in Developing World, 8 Marq. Intell. Prop.L.Rep. 211, 242-244 (Reasoning that the ambiguous provision for “adequate remuneration” invites future disputes).

⁷⁹⁸ See Vishual Gupta, A Mathematical Approach To Benefit-Detriment Analysis As a Solution To Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement, 13 Cardozo J. Int’l & Comp. L. 631 (2005), at 649-659 (proposing a socio-economic analysis that balances detriment to developed countries against the aggregate health benefit). The WHO has also gathered and organised enormous amount of world health statistics for the purpose of assisting policy makers. See also WHO, Using Indicators To Measure Country Pharmaceutical Situations, WHO/TCM/2006.2(2006), At <http://www.who.int/entity/medicines/publications/WHOTCM2006.2A.pdf>

⁷⁹⁹ See Bryan C. Mercurio, TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World, 8 Marq. Intell. Prop. L. Rev. 211, 242-44, where he is of the view that the ‘ambiguous provision for “adequate remuneration” invites future disputes’.

⁸⁰⁰ Bird, R.C, & Cahoy, D.R ((2008). The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach. Page 19. Retrieved from http://www.personal.psu.edu/faculty/d/r/drc13/index_files/CL_and_FDI.pdf

⁸⁰¹ Id.

companies from investing in Egypt's market. As a result, Egypt's foreign direct investment dropped from \$1 104 million in 1997 to \$428 million in 2002.⁸⁰²

To safeguard the interest of countries facing severe health crises, the WTO should establish an administrative body to determine when a country may issue compulsory licences for patented pharmaceuticals⁸⁰³ and to determine what would constitute adequate remuneration.

9.8 The undermining of public health protection through bilateral and regional trade agreements

The problem for developing countries is not whether compulsory licensing of pharmaceuticals is legal, because it is clearly legal. It is the political problem whether they will face sanctions from the United States government for doing things that they have a legal right to do, but which the United States government does not like.⁸⁰⁴

Along with the above barriers to implementing the flexibilities in the TRIPS Agreement, there is substantial concern among public health advocates as to the spread of the so-called 'TRIPS-plus' measures.⁸⁰⁵ Seeking to increase economic growth through trade, governments in DCs and LDCs have agreed to such measures in exchange for access to potentially lucrative export markets for key sectors such as agriculture and textiles. For the public health community, however, provisions to protect access to medicines have been bargained away.

The scope for compulsory licensing has been a particular focus of TRIPS-plus restrictions, narrowing the circumstances when parties are permitted to use this mechanism. Under negotiations for a Free Trade Agreement of the Americas ('FTAA'), for example, it is proposed that compulsory licensing would only be permitted when the patent on a product has expired or

⁸⁰² Asfour, A. FDI in Egypt during 5 years. Retrieved from <http://74.125.95.132/search?q=cache:1np7Q6v20WQJ:www.uneca-a.org/francais/un/S%C3%A9minaires%2520et%2520r%C3%A9unions/FDI%/2520in%250in%250Egypt%2520during%25205%2520years.doc+FDI+Egypt&cd=2&hl=en&ct=clnk&gl=ca>

⁸⁰³ See, Aileen M. McGill. "Compulsory Licenses of Patented Pharmaceuticals: Why a WTO Administrative Body should determine what constitutes a Public Health Crises under the Doha Declaration". Wake Forest Intellectual Property Law Journal 10.1 (2009) : 69-97

Available at: http://works.bepress.com/aileen_mcgill/3

⁸⁰⁴ See Letter from James Love to Ambassador Susan C. Schwab dated 12th December, 2006, asking the US Government not to interfere with the Thai Government's decision to issue a government –use-order on patents covering the AIDS drug efavirenz. Annex 8 of this thesis.

⁸⁰⁵ Access to medicines is a core element of the basic human rights to health. However, TRIPS-plus rules, and FTA's between the USA and developing countries threaten to undermine poor people's rights to medicines.

in situations of ‘national emergency’, with a body independent of the WTO to be set up to rule on disputes.⁸⁰⁶

TRIPS-plus measures also include provisions dealing with data exclusivity, enabling large pharmaceutical companies to prevent or delay generic competition. While the TRIPS Agreement already provides for protection of such data, many bilateral and regional agreements extend both the scope and duration of such protection.

Other restrictions include extending the protection of data disclosed through grant-marketing procedures (versus data-undisclosed procedures covered by the TRIPS Agreement), extending data protection past patent expiry to offset time lost during marketing approval, and/or prohibiting reliance on existing test data for both patented and off-patent products by market-approval authorities. These more stringent protections raise concern in that they reduce the capacity of a country to issue or use compulsory licensing for unpatented drugs. If required to await expiry of data exclusivity, a country is in effect unable to make effective use of a licence.⁸⁰⁷

A related form of patent extension is ‘evergreening,’ a term which refers to patent protection of *inventions*, as opposed to *medicines* which may in fact have multiple patents. ‘New use’ for existing compounds, or a change in dosage or form, can serve as a basis for applying for an extension of the patent protection period, thus preventing the production of generic versions of the drug.

While not permitted under the TRIPS Agreement, many free trade agreements (‘FTAs’) include ‘new use’ clauses. Even if an application for ‘new use’ fails, the process of application can create considerable delays, especially when applicants become embroiled in disputes over a potential patent violation.⁸⁰⁸

In addition to trade agreements, TRIPS-plus requirements may be introduced through bilateral investment agreements (‘BITs’) and investment chapters in FTAs. There is an increased use of

⁸⁰⁶ Human Rights Watch: The FTA, access to HIV/AIDS treatment, and human rights. Briefing paper (<http://www.hrw.org/press/2002/10/ftaa1029-bck.htm>) 29 October 2002

⁸⁰⁷ MSF: Data exclusivity in international trade agreements : What consequences for access to medicines? Technical Brief 2004 (<http://www.citizen.org/documents/DataExclusivityMay04.pdf>)

⁸⁰⁸ MSF: A guide to the post-2005 World: supra

investment agreements by developed countries to undermine those provisions of the TRIPS Agreement which provide exceptions and flexibilities for DCs.

The available flexibilities under the TRIPS Agreement to protect public health, in short, face erosion by the negotiation and conclusion of TRIPS-plus measures.

9.9 Trade in counterfeit drugs

To date the most dangerous threat to public health is the trade in counterfeit drugs. This is because people will not be able to distinguish a counterfeit drug from an original drug based on its physical appearance. There is, therefore, an urgent need for regional cooperative arrangements between countries to fight the scourge of counterfeit drugs.

During the Tokyo Rounds between 1973 and 1979, trade in counterfeit goods had started to emerge as a serious threat to access to essential medicines. Attempts to agree on some common rules to eradicate this trade failed at the end of the round, but efforts to include a specific discipline within the GATT framework continued. Further efforts were made within the GATT but all failed to achieve a binding obligation to eliminate the trade in counterfeit drugs and pirated goods. There was resistance to the establishment new norms. Certain countries felt that no additional standard was necessary or that it would impede legitimate trade. Others held the view that the WIPO rather than the GATT, was the appropriate forum for the treatment of these issues.⁸⁰⁹ Yet others have argued that over-broad counterfeiting laws could restrict the availability of generic medicines.⁸¹⁰

Market segmentation, by which drug companies seek to maintain a higher profit margin in private sector sales while discount prices are available to public sector NGOs, has been identified as one of the causes of the trade in counterfeit drugs.⁸¹¹

The WHO has in the past recommended legislative reforms to enhance enforcement powers for drug regulatory authorities and strategies to reduce corruption and criminal activities. Efforts

⁸⁰⁹ See Daniel Gervais, *The TRIPS Agreement Drafting History and Analysis: The genesis of GATT (1998)* at pages 8-9

⁸¹⁰ Oxfam (2011) Briefing Paper, *Eye on the Ball Medicine regulation – not IP enforcement – can best deliver quality medicines.*

⁸¹¹ See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 *Yale Journal of Health Policy, Law & Ethics* 193 (2005) at pages 270-271

have also been made to promote the enforcement in FTA negotiations with the European Union and in relation to the draft of the Anti-Counterfeiting Trade Agreement ('ACTA').⁸¹²

9.10 Conclusion

The big pharmaceutical industries based in developed countries were not happy with the provisions of the TRIPS Agreement negotiated during the Uruguay Round. The USA pharmaceutical companies have, as shown above, lobbied the USTR and other sectors of the USA government (including Congress) intensively to incorporate higher levels of industry protection in bilateral and regional FTAs. These so-called TRIPS-plus measures vary in different agreements, and the main objectives have been stated above.

These restrictive provisions significantly strengthen the position of these pharmaceutical companies and thereby erect barriers to the introduction of generic pharmaceutical products.

The text of article 30 of the TRIPS Agreement certainly evidences sufficient flexibility to justify limited exceptions designed to address the public-health needs of the developing world, including those arising for poor countries that are unable to make effective use of compulsory licences because they lack meaningful capacity to manufacture medicines locally.

I have emphasised that the Doha Declaration has not served countries most in need of inexpensive medicines. The condition of patients in LDC and DCs has deteriorated. Many countries have seen a dramatic drop in foreign direct investment ('FDI') as a result of extensive compulsory licensing of patented pharmaceutical products, making LDCs hesitant to invoke the terms of the Doha Declaration for fear of similar losses in FDI.

I further stressed the need for the WTO to establish an administrative body to determine when a country may issue a compulsory licence for patented pharmaceutical products.

Finally, in order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement need to be incorporated in national legislation. There is equally the need to ensure that the international commitments, including regional and bilateral arrangements,

⁸¹² The Anti-Counterfeiting Trade Agreement (ACTA) has been criticized of imposing limits on price – reducing generic competition and jeopardizing the free flow of legitimate medicines across borders.

do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine.

CHAPTER 10

Conclusions and Recommendations

The 2009 report of the UN Special Rapporteur on the Right to Health and Access to Medicines concluded:⁸¹³

‘The framework of the right to health makes it clear that medicines must be available, accessible, acceptable and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTA’S (free trade agreements) have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfill the right to health.’

10.1 Introduction

This thesis has assessed compulsory patent licensing and access to essential medicines in DCs after the Doha Declaration of 2001.

In doing so, I have considered how the introduction of patents into pharmaceutical products and processes provided drug companies with monopolies over the production and marketing of medicines and allowed them to fix prices at high rates to maximise profits. The TRIPS Agreement (which represents the marriage between IP and international trade law) came under severe criticism for facilitating the extension of these patents around the world. I also discussed how these criticisms led to calls for the amendment of the TRIPS Agreement which many felt was too heavily weighted in favour of private rights and commercial interests, and against public interest.

⁸¹³ Human Rights Council (2009) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover to the Human Rights Council, 11th session, A/HRC/11/12 31 March 2009; See also: Human Rights Council Resolution 12/27 of 22 October 2009:

Para 10: TRIPS “does not and should not prevent members from taking measures now and in the future to protect public health and (...) that the Agreement can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections.”

Para 12: “Encourages all States to apply measures and procedures to enforce intellectual property rights in a manner that avoids the creation of barriers to legitimate trade of medicines, and to provide for safeguards against abuse of such measures and procedures.”

These agitations eventually led to the Fourth Ministerial Conference of the WTO held in Doha in 2001 (The Doha Declaration).

The Declaration made it clear that all countries have the right to grant compulsory licences and to determine the circumstances under which a compulsory licence may be granted. For DCs with insufficient domestic manufacturing capacity, the potential usefulness of these rights was severely limited by article 31(f) of the TRIPS Agreement. The WTO General Council was therefore instructed to find an ‘expeditious solution to the problem...before the end of 2002.’

On 30 August 2003, the WTO General Council addressed this problem with an interim waiver for article 31(f) and (h) of the TRIPS Agreement (the Paragraph-6 Decision).⁸¹⁴ Paragraph two of the Council’s Decision waives article 31(f) so that countries with manufacturing capacity may export products manufactured under compulsory licences. However, as we saw in Chapter 5 above, certain conditions must be fulfilled before importing countries can take advantage of the system. This General Council’s decision does not, however, offer an economically feasible solution for DCs.

On 6 December 2005, WTO members approved changes to the WTO’s TRIPS Agreement making the Paragraph-6 Decision permanent.⁸¹⁵ This will be formally built into the TRIPS Agreement when two thirds of WTO members have accepted the change. They originally set themselves until 1 December 2007 to do this. The General Council extended the deadline to 31 December 2009, then to 30 November 2011, and then to 31 December 2013. Once two thirds of members have formally accepted it, the amendment will take effect in those members and will replace the Paragraph-6 Decision for them. For each of the remaining members the waiver will continue to apply until that member accepts the amendment and it takes effect.

Following this recap, I will present my findings and conclusions. Thereafter I shall make recommendations on how access to medicines can be secured in the developing world. In closing I shall make suggestions for further research.

⁸¹⁴ World Trade Organisation [internet]. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: General Council Decision of 30 August 2003 (WT/L/540). Geneva : WTO; 2013, Available from: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

⁸¹⁵ World Trade Organisation Amendment of the TRIPS Agreement: General Council decision of 6 December 2005 (WT/L/641). Geneva: WTO; Available from: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [5th March, 2013] Incorporates the provision of the implementation decision as an amendment to the TRIPS Agreement and enters into force once accepted by two thirds of all WTO members.

10.2 Findings and Conclusions

10.2.1 Patents and Medicines

There is a special relationship between patents and medicines.⁸¹⁶ This has been found to be true worldwide.⁸¹⁷ From my research it has emerged that in no other field of technology do patents play as significant a role as in the field of pharmaceuticals.⁸¹⁸ Without patent protection many medicines would simply not have been developed.⁸¹⁹ Three important factors justify the importance of patents in the pharmaceutical industry:

- * the extremely high cost of the R&D involved in the production of new medicines;⁸²⁰
- * the indispensability of medicines and our willingness to pay any price for them;⁸²¹
- * the cost to the pharmaceutical industry and the benefit to the developing world of reverse engineering that makes replication of new medicines easy and cheap (ie generic manufacture).⁸²²

⁸¹⁶ “There is no faster way to kill access to the latest life-saving drugs for people in India than to avoid offering patent protection”. John Gilardi 2006 (Novartis spokesman)

See Adam Beaumont, NGOs Attack Novartis Over Drug Access, SWISSINFO, Oct. 12, 2006, http://www.swissinfo.org/eng/In_depth/detail/NGOs_attack_Novartis_over_drug_access.html?siteSect=107&sid=7159190&cKey=11607714785000 (quoting John Gilardi Novartis spokesman)

⁸¹⁷ See Feroz Ali Khader, *The Law of Patents- with a special focus on pharmaceutical patents* (2008). See preface to the student edition of 2009 at p. xii.

⁸¹⁸ In the pharmaceutical sector, the private sector health industry finds them indispensable. See Philippe Cullet supra at p. 141 and also see Ida Madieha Azmi and Rokiah Alavi, ‘TRIPS, patents, technology transfer, foreign direct investment and the pharmaceutical industry in Malaysia’, *Journal of World Intellectual Property* 4, 2001, p. 948, concerning Malaysia.

⁸¹⁹ The pharmaceutical industry and its government supporters justify patents on medicines on the ground that R & D of pharmaceutical drugs is extremely expensive.

⁸²⁰ See the Business Line in India Published on April 30 2014 Titled ‘Respect For Intellectual Property Rights leads to Innovation, Investment’. In an interview with Aesha Datta of Business Line Jasper Macslarraw, Executive Director of US Chamber of Commerce’s Global Intellectual Property Center stated as follows:

‘In the absence of IP rights millions of people suffering around the world won’t have access to cures because the capacity to pursue this kind of research will be disrupted’

⁸²¹ ‘Your life may depend on a patent’. According to several public health advocates and organisations, this statement is not an exaggeration. See MEDICINS SANS FRONTIERES, *A MATTER OF LIFE & DEATH: THE ROLE OF PATENTS IN ACCESS TO ESSENTIAL MEDICINES* (Nov.2001) available at http://www.doctorswithout_borders.org/publications/reports/2001/doha_11-2001.pdf (stating that people in developing countries are dying because patents are interfering with access to life-saving medicines); Seth Shulman, *In Africa, Patents Kill*, *TECH. REV.*, April 2001, available at <http://www.technologyreview.com/Biotech/12348/> (discussion the impact of Western drug patents on African AIDS patients).

10.2.2 The Doha Declaration

The Doha Declaration represents a decisive step forward by acknowledging in the WTO context that the introduction of patents in the health sector has a significant impact on access to medicines. However, the declaration neither amends the TRIPS Agreement nor provides a basis for DCs to link their patent and health legislation. To date, however, the WTO is far from providing a comprehensive response to the needs of DCs in the field of health in general.⁸²³

There is also the unfulfilled promise of an increase in R&D in exchange for a higher level of IP protection -- an expectation that formed part of the bargain when countries were negotiating the TRIPS Agreement.⁸²⁴ The Declaration has also failed to address the problems confronting DCs when threatened with trade sanctions and deprivation of other benefits outside the framework of the WTO.⁸²⁵ There is also lack of specific requirements for determining eligibility for compulsory licensing.

With respect to LDCs, paragraph 7 allowed them not to grant or enforce pharmaceutical product patents until 2016,⁸²⁶ and this has now been extended to 2021. However, the Paragraph 7-action did not represent any significant improvement for the great majority of the member countries. As a result, the problems faced by LDCs in gaining access to the pharmaceuticals they need are likely to require further consideration by the WTO members if the objectives sought by the Doha Declaration are to be realised.

At most, the Declaration provides a temporary respite in some limited areas. The Declaration fails to answer more fundamental questions on the scope of patentability and the twenty-year

⁸²² See Feroz Ali Khader, *The Law of Patents- with a special focus on pharmaceutical patents* (2008). See preface to the student edition of 2009 at p. xii.

⁸²³ The adoption of this Declaration and, subsequently, of a Decision aimed at facilitating the importation of medicines by developing countries without manufacturing capacity in pharmaceuticals, was an attempt to ensure, through the effective use of the permitted flexibilities, some balance in the implementation of the TRIPS Agreement and, in particular, that public health be given priority in case of conflict with intellectual property rules. See Carlos M supra 'Implications of bilateral free trade agreements on access to medicines' bulletin of the WHO May 2006 p. 400

⁸²⁴ The fact is that the TRIPS Agreement does not encourage R & D on diseases of particular relevance to DCs. See Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner At The WTO*. *Journal of International Economic Law* (2002) 469-505 at p.484

⁸²⁵ See Frederick M. Abbott supra (note 747 above) at p. 484

⁸²⁶ 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. Decision of the Council for TRIPS of 27 June 2002 (IP/C/25). Available from: http://www.wto.org/English/tratop_e/trips_e/art66_1_e.htm

duration for patents in the pharmaceutical sector. There is no indication from the Declaration that future rounds of trade negotiation will lead to a relaxation of requirements set by the TRIPS Agreement in the public health sector. Judging from the aggression evidenced by the USA pharmaceutical industry through its relentless use of TRIPS-plus and data exclusivity measures, the only indication is that a further strengthening of patent rules is about to take place.⁸²⁷

The TRIPS Agreement provides for minimum standards and not maximum levels of patent protection. This has allowed the USA and the EU to link higher levels of protection to bilateral and regional FTAs.⁸²⁸ The developed nations, and the USA in particular, are shifting platforms, adding layers, and thereby further reducing any impact the system established under the Council's Decision might have.⁸²⁹

Recently, in a letter dated 10 April 2014 and signed by a bipartisan group of 32 members of the House of Representatives, the USTR is requested to elevate Canada to the special 301 'Priority Watch List' for 'violation of [its] international obligations' in not granting enough patents on 'innovative medicines'. According to the members of Congress who signed the letter, Canada is in violation of its obligations under the TRIPS Agreement.⁸³⁰

Furthermore, in a recent interview with *Business Line of India*, Jasper Macslarraw the Executive Director of USA trade chamber, indicated that the USA is threatening to take action against India for failing to protect IP rights, especially those relating to pharmaceuticals.⁸³¹ The USA's

⁸²⁷ It seems unrealistic to expect the standards of intellectual property protection to become less restrictive. The international patent system is flexible enough as it allows countries to implement its provisions in a way and manner to advance socioeconomic welfare of its citizens. The recent decision of the Indian Supreme Court in *Novartis v. Union of India* in 2013 supports this view. See *Novartis AG v. Union of India, SC Civil Appeal Nos. 2706-2716 of 2013. Supreme Court of India; 2013. Available from <http://www.globalhealthrights.org/asia/novartis-v-union-of-india-2> (accessed 5th February 2014)*

⁸²⁸ The wave of FTAs referred to in chapter 9 above represents a drastic setback in this respect, since they not only erode such flexibilities but impose a number of additional obligations on states that can further restrict their access to medicines. See Carlos M. Correa 'Implications of bilateral free trade agreements on access to medicines' bulletin of the WHO May 2006 at page 400.

⁸²⁹ See Scott Lucyk, Patents, Politics, and Public Health: Access to Essential Medicines Under the TRIPS Agreement, Ottawa L.Rev. 2006-2007 at p.205

⁸³⁰ See 32 members of US House of Representatives asks USTR to sanction Canada for not granting patents on drugs. Submitted by James Love on 11, April 2014 –at 14-21

Available at http://keionline.org/?option=Com_Content&task=view&Id=4&Itemid=1 (last visited 22nd April, 2014).

⁸³¹ See Business Line of India dated April 30, 2014 titled 'Respect for Intellectual Property Rights leads to Innovation, Investment'. Aesha Datta in an interview with the Executive Director of US Chamber of Commerce's Global Intellectual Property Center. Available at <http://www.thehindubusinessline.com/news/international/ip-leads-to-innovation-investment/article5963414>

pharmaceuticals lobby estimates that it currently loses in excess of \$1,7 billion annually because of India's inadequate IP protection.⁸³²

It should also be noted that the compulsory licensing system established by the WTO General Council's decision of August 2003, does not offer an effective solution as it is not economically feasible for DCs. The concern of finding a suitable source of supply has not been overcome, even though the legal framework for doing so is in place. The decision also does not eradicate the problem of lack of know-how and trade secrets, i.e. the transfer of technology.⁸³³

The system of compulsory licences established by the Paragraph-6 Decision is intended to be used in good faith, for health purposes, and not to gain commercial or industrial advantage.

However, from an international relations perspective, the Doha Declaration and the Paragraph-6 Decision represent an important political victory for DCs in shifting the international debate from trade to public health. These are the most important attempts to date to reform IP protection for the benefit of society. However, the Declaration neither amends the TRIPS Agreement nor provides a basis for DCs to link their patent and health legislation.

10.2.3 Compulsory licensing

It has been a trend running through my thesis that the compulsory licensing mechanism has not been effectively utilised by the DCs for fear of reprisals and sanctions from developed countries like the US. South Africa, and Brazil have used compulsory licensing as a threat in several instances and eventually forced the pharmaceutical companies to settle on favourable terms. In these cases, while the threat of compulsory licences yielded concessions from pharmaceutical companies, the flexibilities have remained untested in practice.⁸³⁴ Brazil's efforts freely to

⁸³² See Pharmaceutical Research and Manufacturers of America, PhRMA 2002. 'Special 301' Submission (2002).

⁸³³ Both the Council's Decision of 2003 and the December, 2005 amendment of the TRIPS Agreement are not faithful to the spirit of the Doha Declaration. They are also not in tune with human right instruments, which guarantee the rights to health and life.

⁸³⁴ See Vanessa Bradford Kerry and Kelly Lee in TRIPS the Doha declaration and Paragraph 6 decision: what are the remaining steps for protecting access to medicines? Globalisation and Health 2007 at p. 4. Also available at <http://www.globalisationandhealth.com/content/3/1/3>

provide ARVs are often cited as an example of how the Doha Declaration has strengthened the position of LMICs.⁸³⁵

The most significant DC use of compulsory licensing to date has been that of the government of Thailand's use of government use orders. This provoked angry response from the media, politicians, and pharmaceutical companies. The fact remains that for DCs and some emerging economies, their use of compulsory licensing is severely penalised leading to loss of FDI. Where developed countries have used the mechanism – as happened with the USA during the anthrax outbreak – no country was able to challenge its use.

However, it is doubtful whether focusing on compulsory licensing as the principal tool to redress the perceived inequalities of the international patent system, presents an appropriate strategy for DCs.⁸³⁶ Under the TRIPS Agreement and in its current state, it is highly unlikely that DCs will have the liberty to use compulsory licensing flexibility to any meaningful extent, even if it is part of their domestic legislation. It may, however, be used as a valuable tool in negotiations with specific pharmaceutical companies as highlighted in the cases of Brazil and South Africa.⁸³⁷ I feel, however, that these should be no more than complimentary measures. The adoption of a strong compulsory licensing regime cannot be a substitute for strong health-related provisions in a member country's domestic legislation.⁸³⁸

India's decision to protect its pharmaceutical industry and the health of the developing world through section 3(d) of its Patent Act, rather than relying solely on compulsory licences, is a solution that should be endorsed by DCs concerned with compliance with the TRIPS

⁸³⁵ See Ciccio L: Patenting Drugs from 1st January 2005: Implications and Problems. Health Policy and Development 2004, 2(2):136-143.

⁸³⁶ See Jayashree Watal Intellectual Property Rights in the WTO and Developing Countries, 2001, p.328. Here the author states that, in cases where know-how which is not disclosed in the patents is required for the exploitation of the patented invention, the cooperation of the right holder has to be ensured, and this can be done only through the conclusion of voluntary licenses or through reverse engineering. Therefore according to him, compulsory licenses may be most effective when the technology is already known and only access is required.

⁸³⁷ Cornish takes a cautious approach in saying that it could neither be measured nor discounted to what extent the threat of applying a compulsory licence enhances the bargaining position of would-be voluntary licensees. See W.R Cornish, Intellectual property: Patents, Copyrights, Trade Marks and Allied Rights, Fourth Edition, p. 295-296.

⁸³⁸ See Jerome Reichman, Catherine Hasenzahl "Non-voluntary licensing of patented inventions", UNCTAD-ICTSD Capacity Building Projects on IPRs, Issue Paper No. 5. Where the paper suggested that policy makers should view the compulsory licenses as but one item in an arsenal of tools that may be used to promote coherent national systems of innovation.

Agreement.⁸³⁹ Even though India's patent laws on the issue of compulsory licences are extremely broad, the country has rarely granted these licences.

10.2.4. Parallel imports

Parallel imports are very important to DCs, particularly in the health sector. Since there is a practice of price discrimination and market segmentation within the pharmaceutical industry, parallel imports can be used to curtail the adverse effect of these practices. Furthermore, they are a viable policy tool for DCs to gain quick access to life-saving drugs and respond rapidly to a health crisis or emergency.⁸⁴⁰

This practice is justified and a legitimate measure under article 8 of the TRIPS Agreement. There is no provision in the TRIPS Agreement prohibiting parallel imports. Article 6 of the TRIPS Agreement specifically allows each member country the freedom to incorporate the principle of international exhaustion of rights. This article 6 is actually the underlying justification for the practice.⁸⁴¹ Parallel imports can therefore be undertaken in the following situations:

- where the patented product has already been marketed in another country by the patent-holder; or
- the product is already sold under a compulsory licence; or

⁸³⁹ Some DCs have already recognised the powerful implications of section 3(d) of India's Patent Act and have begun modelling their laws on India's. See Gireesh Chandra Prasad, Copycats Popping Patent Law Pill, ECON. TIMES Aug. 13, 2007, http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare_Biotech/Pharmaceuticals/Copycats_popping_patent_law_pill/articleshow/2276358.cms ("More than 10 countries in the Asia – Pacific region are planning to adopt the much-debated provision which makes it difficult for drug makers to get patent protection for anything less than breakthroughs in pharmaceutical research. The provision describes what sort of pharmaceutical substance is worthy of a patent. The idea is to prevent companies from blocking the entry of cheaper rival products by passing off old medicines in new bottles as patent-worthy inventions.")

⁸⁴⁰ The line of argument by the big pharmaceuticals that Article 28 of the TRIPS Agreement, effectively overrides Article 6 in each members internal law since it imposes an obligation to protect against infringing imports cannot be justified. See Frederick M. Abbott The Doha Declaration On The TRIPS Agreement: Lighting A Dark Corner At The WTO. *Journal of Int'l Economic Law* (2002) 469-505 at p.485

⁸⁴¹ See Carlos M. Correa, Implications of bilateral free trade agreements on access to medicines. *Bulletin of the World Health Organisation*, May 2006, 84 (5). At page 400.

- the product is being marketed in another country through legal means without the authorisation of the patent holder, ie in LDCs or importing countries where the product is not patented (a good example is a generic producer of medicines like Cipla in India).⁸⁴²

In South Africa, section 15C(A) of the Medicines Act authorises the Minister of Health to prescribe ‘conditions for the supply of more affordable medicines in certain circumstances

so as to protect the health of the public’. The Minister ‘in particular may...determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put on the market by the owner of the medicine, or with his or her consent.’ This is an example of parallel import exception in South Africa but is limited to medicines.⁸⁴³ Despite these limitations, this provision has been challenged by foreign pharmaceutical firms and the USA government.⁸⁴⁴

10.2.5 The threat of counterfeit drugs

The benefits of essential medicines outweigh the risks of counterfeit drugs.⁸⁴⁵ Outterson states that empirical evidence tends to show that the threat to counterfeit medicines is overstated for the following reasons:⁸⁴⁶

First, narrowing counterfeit drugs to non-functional copies that lack the active ingredient. He cites authority claiming that the majority of the non-functional counterfeit drugs are produced locally.⁸⁴⁷

Secondly, he points out that counterfeit drugs should be distinguished from functional, generic copies of patented drugs.⁸⁴⁸

⁸⁴² See Carlos M. Correa, *Intellectual Property Rights the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000).

⁸⁴³ See Carlos M. Correa, *Intellectual Property Rights the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (2000) at pp 87-88.

⁸⁴⁴ *Big Pharma vs Nelson Mandela supra*

⁸⁴⁵ See Do Hyung Kim *Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developing Countries*. Hauser Global Law School Program Feb 2007 at p.5

⁸⁴⁶ See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drugs Markets*, 5 *Yale J. Health Policy, Law & Ethics* 193 (2005) at 268-71.

⁸⁴⁷ See Outterson, *supra* (above note) at pp 269-70

⁸⁴⁸ *Id* at pp 268-71

Finally, he reasons that as drug prices fall, there will be less incentive for criminals to produce counterfeit drugs because of unattractive profit margin.⁸⁴⁹

He further argues that patented drugs, not cheap generics, are the target of counterfeits, so increased availability of low-cost generic drugs would actually dissuade counterfeiting.⁸⁵⁰

10.2.6 The interface between access to medicines, intellectual property (patents) and human rights

Should IP rights prevail over the right of access to essential medicines? In chapter 8 I indicated that patents can be classified as constitutional property. In the same chapter, I stated that the United Nations Sub-Commission on the Promotion and Protection of Human Rights has pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right 'subject to public interest limitations'.⁸⁵¹

In Chapters 3 and 8, it was shown that access to medicines is a fundamental component of the human right to health.⁸⁵²

In *Laugh-it-off v SAB International*,⁸⁵³ the South African Constitutional Court also explicitly balanced IP rights against the various fundamental rights enshrined in the Bill of Rights of the South African Constitution.⁸⁵⁴ Although, the Constitutional Court was prepared to recognise and protect trademarks as constitutional property, on the facts of the case freedom of expression constituted a more important right than the economic rights of a trademark and therefore the right to freedom of expression received greater protection than the property right in trademarks.⁸⁵⁵

⁸⁴⁹ See Id at pp270-71

⁸⁵⁰ See Id

⁸⁵¹ Resolution 2001/5. Globalisation and its impact on human rights. New York: United Nations Sub-Commission on the Promotion and Protection of Human Rights; 2001. E/CN.4/Sub.2/Res/2001/5.

⁸⁵² See e.g. Commission on Human Rights, Resolution 2001/33, Access to medicines in the context of pandemics such as HIV/AIDS', in Report on the 57th Session, 19 March-27 April 2001, UN Doc.E/2001/23-e/cn/2001/167

⁸⁵³ *Laugh it off v SAB International* 2006 (1) SA 144 (CC)

⁸⁵⁴ The case bordered on the interface between human right of freedom of expression Section 16 (1) of the constitution of South Africa and the intellectual property right attached to a trademark as envisaged by Section 34 (1) of the Trademarks Act 194 of 1993.

⁸⁵⁵ See *Laugh it off v SAB International* supra

In this context, it appears that within the framework of the WTO's Dispute Settlement Understanding, the right of access to essential medicines provides powerful arguments for states that have been victimised and sanctioned for infringing IP rights in patents. In such a scenario, member states can defend their actions by claiming that 'by taking actions to guarantee a minimum access to essential medicines, they are just complying with another international obligation'.⁸⁵⁶

10.2.7. Access and innovation⁸⁵⁷

The current pharmaceutical innovation system depends largely on patent protection for financing and priority setting. This global trend in R&D has had a disproportionately heavy impact on the needs of people in DCs. There is an urgent need for a policy agenda to tackle the fundamental question of how to create incentives for R&D that do not create access barriers to medicines.⁸⁵⁸

Public health practitioners, groups, and government officials viewed the TRIPS Agreement⁸⁵⁹ as a mistake as it was devoted to achieving an increase in the price of drugs as the primary or only instrument to promote global medical R&D.⁸⁶⁰

At the core of the issue is the fact that the financing of innovation depends on the ability to charge high prices. The stronger the monopoly, the greater the opportunity to charge high

⁸⁵⁶ See F.M Abbott, 'The TRIPS Agreement' p. 38, suggesting that measures adopted by developing countries and least developed countries to address public health should be presumed to be consistent with TRIPS and that any member challenging them should bear the burden of proof.

⁸⁵⁷ Innovation has been traditionally perceived as the domain of the research-based originator companies. However, generic medicine companies often spend significant sums on innovation-improving formulations, enhancing delivery systems and finding solutions to patent compliance issues. In 2007, 7% of revenues from the generics medicine industry were spent on research and development alone. Furthermore, sector investments in manufacturing and development facilities have created a solid base of employment (150,000 direct employees in the EU, according to EGA). Yielding societal benefits that go beyond the realms of health care.

See Generic Medicines: Essential Contributors to the long term health of society: Author Alan Sheppard, Principal, Global Generics, Thought Leadership, IMS Health. Generic Bulletin 2008

⁸⁵⁸ By striking the right balance between the interests of innovators and wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

⁸⁵⁹ During the negotiations of the TRIPS Agreement there was no international public debate on IP and health. Commercial interests were strongly represented and they played a crucial role in drafting the text and lobbying for its support. For these reasons, TRIPS was therefore negotiated as a treaty to protect IP rather than a treaty for R & D. See James Packard Love 'Drug Development Incentives to Improve Access to Essential Medicines', available at <http://www.cptech.org/ip/health/rnd/love-who052006.pdf>, last visited 24th April, 2014)

⁸⁶⁰ See the 2006 report by the US Government Accountability Office (GAO). The report analysed pharmaceutical drug development and the recent decline in the number of new drug applications (NDA). The report concluded that 'current patent law discouraged drug companies from developing new drugs by allowing them to make excessive profits through minor changes to existing pharmaceuticals'. Available at www.gao.gov/new/items/d06656.pdf

prices.⁸⁶¹ But the societal cost of patent monopolies is high, and for DCs it is too high. Policy makers have therefore shifted their focus to examining how effective the IP system is in encouraging the development of the much needed drugs.

They argue that private R&D incentives should not be linked to the price of drugs at all, and that the rewards for innovation should be more closely linked to evidence that these products are able to improve health.⁸⁶² They stress that trade agreements should include public sector funding for R&D, use of innovation prizes, and other innovative ways to improve R&D. Future agreements should further include real efforts at priority setting and adequate investment in treatments for illnesses that disproportionately impact on the health of poor in DCs.⁸⁶³ It is therefore necessary to discuss the progress made by the World Health Organisation's ⁸⁶⁴World Health Assembly ('WHA') through the Commission on Intellectual Property and Public Health ('the CIPIH') and the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property ('the IGWG').

10.2.7.1 Commission on Intellectual Property Innovation and Public Health (CIPIH)

⁸⁶¹ Trips forced countries to give up the diversity and flexibility in intellectual property law and practices that existed pre-Trips. For example by introducing a minimum 20 years patent term and obliging patents in all fields of technologies, it was no longer possible to exclude medicines and food from patenting. It also introduced requirements for test data protection that, in practice, have created additional forms of monopoly by creating exclusive rights to the data needed to obtain marketing approval.

⁸⁶² See Globalisation and access to drugs. Perspectives on the WTO/TRIPS Agreement, second edition. DAP Series No.7. Revised January 1999. Geneva: World Health Organisation; 1999. This study was produced pursuant to a resolution adopted by the World Health Assembly at its 49th session requesting the Director-General to report on the impact of the work of the WTO with respect to national drug policies and essential drugs (WHA49.14, Revised drug strategy, 20-25 May 1996). Available from: http://whqlibdoc.who.int/hq/1998/WHO_dap_98.9_Revised.pdf

⁸⁶³ See James love, Director Knowledge and Ecology International, Politics and Intellectual Property Rights and Access to Medicines posted may 29, 2007 available at www.huffingtonpost.com/jameslove/the_politics_of_intellect_ben.pdf

⁸⁶⁴ The Report of the WHO Commission recommends a broad range of policy changes needed to improve all stages of drug production and use. It calls on industrialised countries to allocate more resources to R & D on the health needs of DCs, create new ways of better sharing information, strengthen health delivery systems, and promote public-private partnerships.

With respect to the Doha Declaration and paragraph 6 decision specifically, the report calls for adaptations to national legislation and institutions to allow TRIPS flexibilities to be used, for public health reasons with respect to data exclusivity rules. That the paragraph 6 decision should be kept under review and appropriate changes considered necessary to achieve a workable solutions be made, if necessary.

See Commission on Intellectual Property Rights, Innovation and Public Health: Public health, Innovation and Intellectual Property Rights. In Final Report Geneva: WHO: 2006.

The CIPIH was established by the World Health Assembly in 2003. The operative part of the text establishing the Commission reads as follows: ‘to collect data and proposals for the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanism for the creation of new medicines and other products against diseases that disproportionately affect developing countries.’⁸⁶⁵

The work of the Commission focuses on the intersection between IP, innovation, and public health.

At 196 of the report, the Commission made the following observation:

‘Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. However, the fact that a patent can be obtained may contribute little or nothing to innovation if the market is too small or scientific and technological capability is inadequate. Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding.’⁸⁶⁶

The CIPIH has shown that so long as health R&D depends on patent monopolies for its financing, prices are likely to remain a barrier to access. There are currently interesting experiments taking place and proposals being discussed towards moving away from patent monopolies as the main source of financing medical R&D.⁸⁶⁷

10.2.7.2 The Intergovernmental Working Group on Public Health Innovation and Intellectual Property (‘IGWG’)

In order to improve access to medicines, vaccines, and diagnostics for people living in DCs, the WHA agreed to establish an Inter-Governmental Working Group to draw up a global strategy

⁸⁶⁵ See www.who.int/bulletin/volumes/84/5/CIPIH_report/en

⁸⁶⁶ See Available at www.who.int/intellectual_property

⁸⁶⁷ See Ellen F.M. ‘t Hoen *The Global Politics of Pharmaceutical Monopoly Power* (2009) at p. 92

and plan of action based on the recommendations of the CIPIH. The aim of the IGWG is to negotiate and put in place a plan of action for priority setting and the financing of essential health R&D.⁸⁶⁸ These multilateral negotiations on IP, health, access and innovation started in 2006 at the WHO.

The IGWG and its effective global strategy has been described as the most successful attempt since the Doha Declaration at finding a resolution to real health needs.⁸⁶⁹

The Director-General of the WHO was asked at the 60th WHA in 2007 to:

‘Encourage the development of proposals for health-needs driven research and development for discussion at the Intergovernmental Working Group that includes a range of incentive mechanisms including also addressing the linkage of the cost of research and development and the price of medicines vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries.’⁸⁷⁰

The IGWG’s Global Strategy was adopted by the WHA in May 2008. The IGWG is a forceful call for change. The strategy includes the following proposals:

- To promote the use of compulsory licensing to encourage competition in the pharmaceutical generics market.
- To intensify efforts to ensure the rejection of TRIPS-plus measures in trade agreements.
- To encourage the development of new incentive mechanisms, such as prizes and government involvement in R&D priority- setting.
- To encourage the introduction of Patent pools for upstream and downstream technologies towards an improvement in access and innovation.⁸⁷¹

⁸⁶⁸ See Ellen F.M ‘t Hoen The Global Politics of Pharmaceutical Monopoly Power (2009) at p. 92

⁸⁶⁹ See Ellen F.M ‘t Hoen, The Global Politics of Pharmaceutical Monopoly Power (2009) at p. 93

⁸⁷⁰ See World Health Assembly (WHA) 2007 , Fifth Report of Committee B WHA 60/64

⁸⁷¹ See Ellen ‘t Hoen supra at p. 92

The Global Strategy also paved the way for more fundamental changes in two other key areas.

First, it considered the possibility of intergovernmental discussions on an essential health and biomedical R&D treaty to change the current rules governing medical R&D.⁸⁷²

Secondly, WHA Resolution 60.30 calls for the development of proposals for health-needs driven R&D, and also the need to address ‘de-linkage of the costs of R&D and the price of health products.’ De-linking paying for the cost of R&D from the price of the product would break the vicious circle financing R&D through high drug prices.⁸⁷³

It is important to note that while these fundamental changes in how future global R&D is to be funded will not yield results overnight, alternatives such as the Novartis R&D Fund proposal,⁸⁷⁴ the Medical Innovation Prize Act 2005,⁸⁷⁵ Not-for-profit drug development,⁸⁷⁶ patent pools, and the Hubbard and Love R&D treaty are also receiving serious consideration. Resisting the use of monopolies as the single most important incentive for health R&D, will steer medical research in the right direction.

10.2.8 Patent pools

⁸⁷² See Ellen ‘t Hoen supra at p. 92-93

⁸⁷³ See Ellen ‘t Hoen supra at pages 92-93. Also see Intergovernmental Working Group (IGWG) Outcome document at 14.00 hours, Saturday 3 May 2008, Draft global strategy on public health, innovation and intellectual property.

⁸⁷⁴ This is a proposal to create a global fund for R & D for neglected diseases to support not-for-profit innovation. The proposal focuses on neglected diseases only and is limited in the sense that it does not suggest fundamental changes to the global R & D system. See Ellen t’ Hoen supra at p. 94

⁸⁷⁵ On 26 January 2005, Representative Saunders introduced HR 417 – a bill ‘[t]o provide incentives for investment in research and development (R & D) for new medicines, to enhance access to new medicines, and for other purposes’. The bill contains a new paradigm for drug development (the Medical Innovation Prize Fund), that would reward the development of new drugs without introducing artificial scarcity for new inventions, like the patent system does (see James Packard Love ‘Drug Development Incentives to Improve Access to Essential Medicines’ (see above note 571)

⁸⁷⁶ This is a business model experiment for R & D, in respect of neglected diseases. It finances R & D upfront and offers the outcome of its research on a non exclusive basis to generic producers.

A patent pool is constituted when two or more owners put their patents together in such a way that authorisation for use can be granted for all the patents in the pool as a single package.⁸⁷⁷ Patent pools are not new and have been established in several fields of technology.⁸⁷⁸ It is also possible to manage pharmaceutical patents through this type of patent pooling arrangement. Third parties like generic manufacturers can also use the pool by paying royalties.

Joanne Clarke et al, have outlined six benefits of the patent pool mechanism. The mechanism:

- eliminates blocking patents;
- reduces licensing transaction costs;
- manages multiple owners and stacking of patents;
- has the potential to facilitate downstream innovations and developments;
- has the potential to encompass non-patent technology and know-how; and
- has the potential to facilitate technology transfer and a sustainable scaling-up of capacity and access in developing countries.⁸⁷⁹

In 2010, UNITAID (an international drug purchasing facility), established a medicines patent pool as a legal entity ('MPP'). The initial focus of the medicines patent pool is to increase access to newer ARVs. However, the pool also aims to promote reduction in the price of existing ARVS and to stimulate the production of newer first and second-line ARVs by increasing the number of generic producers. The USA National Institute of Health was the first patent holder to join the MPP when it licensed the life prolonging ARV *Dunavir* in October 2010.

Kenya followed suit when Gilead Sciences entered into a licensing agreement, first with Medchem in July 2001, and then with Aurobindo in October of the same year. These are positive steps towards improving access to affordable medicines.

10.2.9 The impact of tariffs on access to medicines

⁸⁷⁷ Nicol D, Nielsen J. Opening the dam: patent pools, innovation and access to essential medicines. In: Pogge T, Rimmer M, Rubenstein K, editors. Incentives for global public health: patent law and access to essential medicines. New York: Cambridge University Press; 2010. Pp. 235-62

⁸⁷⁸ See Joanne Clarke et al, Patent Pools: A Solution to the problems of Access to Biotechnology Patents? At 10 (December 5, 2000) available at <http://www.uspto.gov/web/offices/pa/dapp/opla/patentpool.pdf>

⁸⁷⁹ See Joanne Clarke et al, Patent Pools: A solution to the problems of Access to Biotechnology Patents? At 10 (December 5, 2000) available at <http://www.uspto.gov/web/offices/pa/dapp/opla/patentpool.pdf>

‘Any solution that may result from the current process in the TRIPs Council will not provide the universal panacea of solutions for the problem of access to medicines. As the EC have already emphasised, improving access to medicines requires a mix of complementary measures in different areas.... The discussion within the TRIPs Council should not overshadow these (other) aspects and efforts to make medicines available at affordable prices in a number of international fora...’⁸⁸⁰

The leading objective of the Doha Declaration is to make medicines less costly and more accessible to the poor and needy. Although there are many ways in which this could be achieved, the most important one within the WTO’s jurisdiction is through tariff reduction. These tariffs (also termed import duties) are often a part of the price mark-up that occurs between medicine prices on the international market and medicine prices at the pharmacy in DCs. This mark-up has been measured at over 100 per cent in some cases.⁸⁸¹

Amir Attaran has stated that:

‘Last of all there is a pragmatic point about pharmaceutical tariffs. It is woefully counterproductive that companies might deeply discount a pharmaceutical, only to have the price driven up by an import tariff, yet this is the case in many poor countries now.’⁸⁸²

Unfortunately, many DCs do not publish their tariff rates for finished medicines or the active ingredients of the medicines. This means that data are difficult to obtain and that custom agents can charge illicit tariffs. In South Africa, which indeed publishes its tariff rates, the government lists (but does not necessarily charge) a bound tariff rate of between ten to fifteen per cent on imports of medicines containing *zidovudine* (used for HIV/AIDS), medicines containing *pyrazinamine* or *ethambutol* (for tuberculosis), and the raw material of quinine (malaria).⁸⁸³

⁸⁸⁰ Draft Communication from the European Communities and their Member States to the TRIPs Council. Concept Paper for Approaches Relating to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, at para. 4.

⁸⁸¹ See Jean Madden, *Medicine Prices: A New Approach to Measurement*, WORLD HEALTH ORG. & HEALTH ACTION INT’L 3 (2003) available at http://www.haiweb.org/medicineprices/Synthesis_paper_20030625.pdf

⁸⁸² See The Doha Declaration on the TRIPs Agreement and Public Health, *Access to Pharmaceuticals, and Options under WTO Law* 2002 *Fordham Intell. Prop. Media & Ent. L.J.* (2001-2002) 859 at 882.

⁸⁸³ Bound tariff rates are reported by the countries to the WTO pursuant to Article II of the General Agreement on Tariffs and Trade. (GATT) Each country’s rates are reported in Part 1, Section II of Concessions. See Art. 2.1. For schedules, see Goods Schedules: Members’ Commitments, http://www.wto.org/english/tratop_e/schedules_e/safrica.zip.

Each of these is, according to the WHO, an ‘essential medicine’ for a leading disease of poverty.⁸⁸⁴

Developing countries should therefore agree to eliminate medicine tariffs as part of their contribution to making medicines affordable. It is important to note that the long-term economic benefits to poor countries of improved health certainly outweigh the one-off revenues that tariffs generate. The WTO’S authority to facilitate a multilateral agreement to this effect is found in articles II and XXVIII*bis* of the GATT, which aim at tariff reductions generally.⁸⁸⁵

Finally, although these are GATT issues and must not be treated as ancillary to the issues arising under the TRIPS Agreement, they are of equal, if not of greater, importance to the Doha Declaration’s goal of pharmaceutical access.⁸⁸⁶ Whilst the risk of arbitrage hinders the expansion of pharmaceutical discounts and donation programmes, tariffs make medicines unnecessarily costly and could be more easily managed and controlled than arbitrage.⁸⁸⁷ It is necessary for the TRIPS Council to take action and remit these GATT issues to the Ministerial or General Council. The Doha Declaration mandate cannot be solved by the TRIPS Council alone: other WTO jurisdictions must also be actively involved.⁸⁸⁸

10.2.10 The role of international and multilateral donors in access to medicines

Improving access to affordable medicines in DCs means increased funding and more efforts in the R&D for medicines. As a result of fiscal constraints, many DCs rely on donor funding for purchasing important on-patent medicines.⁸⁸⁹ Funding mechanisms, such as the Global Fund, PEPFAR and UNITAID, and donors such as the World Bank and the European Commission,

⁸⁸⁴ WORLD HEALTH ORGANISATION, THE WHO MODEL LIST OF ESSENTIAL MEDICINES 7, 9-10 (13th ed., 2003), available at http://www.who.int/medicines/organisation/par/edl/expcom13/eml13_en.pdf

⁸⁸⁵ See Amir Attaran, The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals and Options Under the WTO Law 2002. 12 Fordham Intellectual Property Media & Ent. L.J 859 2001-2002 at p. 883

⁸⁸⁶ See 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 & Ent. L.J 859 2001-2002 at p. 883

⁸⁸⁷ See Mercurio, TRIPS, Patents, and Access To Life-Saving Drugs in the Developing World, 8 Marq. Intell. Prop. L.Rev. 211, at p. 245 where he stated that ‘technically arbitrage is the more general term, and parallel trade is the narrower term used to describe arbitrage intellectual property. (Here arbitrage is considered synonymous to parallel trading.

⁸⁸⁸ See Amir Attaran *supra* at p.883

⁸⁸⁹ Most DCs are unable to provide their citizens with a basic package of essential health services. In this context most DCs rely on donors to finance their health sector. See AMASA –Literature review WG3 available <http://www.amasa-project.eu/literature-review-wg3>

have opened up much needed avenues to finance the procurement of health commodities, including ARVs.

In the past most donor aid was allocated to disease-specific projects instead of a broad-based investment in health systems, infrastructure, and human resources. Although there have been immense benefits, there is also a need for an increase in the duration/currency of the loans.

In general, all of these funding mechanisms have played a significant role in making drugs available in DCs and LDCs, particularly those for the treatment of HIV infections. Although, they have to some extent encouraged the use of the Doha Declaration through their procurement policies, these funding mechanisms still require greater economic support and political will.

The availability of medicines might decrease substantially if the flow of capital and aid to DCs and LDCs continues to dwindle⁸⁹⁰ and there remains no self-reliant means of ensuring access to much needed drugs. The time has therefore come for the developing world to look beyond foreign aid to increase its access to medicines.

10.3 Recommendations

The Doha Declaration is rightly viewed as a remarkable document in the WTO'S history of conscientising the trading world to health and development. The Declaration also represents a major step forward in that it acknowledges that the introduction of patents in the health sector has significant negative impact on access to medicines. The question that one may then ask is: 'How can the more than 1,7 billion people who have little or no access, gain access to the much needed essential medicines?'⁸⁹¹ I intend to answer this question by making the following recommendations.

- The amendment to the TRIPS Agreement as it currently applies should not be adopted. Instead, negotiations should commence towards a far more simplified procedure.⁸⁹²

⁸⁹⁰International Finance Corporation. Impact: annual report 2012. Washington (DC): IFC; 2012. Available from: http://www.ifc.org/wps/wcm/connect/2be4ef804cacfc298e39cff81ee631cc/AR2012_Report_English.pdf?MOD=AJPERES (accessed 11th April, 2014)

⁸⁹¹ See R. C. Bird, "Developing Nations and Compulsory License: Maximising Access to Essential Medicines while Minimising Investment Side Effects," *Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 209-222.

⁸⁹² Instead of relying on a highly conditioned , limited and procedurally burdensome Article 31(f) solution, DCs and other WTO members should revisit the much more simplified option under Article 30 of the TRIPS Agreement. See Prof Brook. K. Baker 'Arthritic Flexibilites For Accessing Medicines' supra at p. 713

Rwanda was the first country to use the paragraph-6 procedure to import 260 000 packets of *TriAvir* from Canada over a period of two years.⁸⁹³ Rwanda relied on the World Bank model forms to register notification under paragraph 2(a) of the Paragraph-6 Decision on the Implementation of paragraph 6 of the Doha Declaration.⁸⁹⁴ There was a delay in granting of compulsory licences, difficulties in coordination, and heavy financial losses on both sides.⁸⁹⁵

Ghana also worked with the University of Toronto-based Access to Drugs Initiative ('ADI') to take advantage of the WTO decision. ADI hoped that Ghana would be the first country to use the system and offered technical assistance in filing for a compulsory licence. However, the entire exercise failed and had to be abandoned.⁸⁹⁶

As of the time of writing no other country has taken steps to use the system.

- The problem at hand requires the WTO to undertake all steps within its jurisdiction, not just those within the TRIPS Agreement, particularly where evidence suggests that giving effect to the TRIPS Agreement and international patent rules alone, will hold uncertain, and probably slight, benefits for pharmaceutical access in poor countries. An equal, or possibly greater, impact could be realised by facilitating current practices to make medicines available cheaply for poor countries, and in particular, discounts and donations which are currently complicated by legal uncertainty under the GATT. Accordingly, the Doha Declaration requires comprehensive attention to the WTO Agreements and at a minimum the TRIPS Agreement and the GATT together.⁸⁹⁷
- Patent pools may be an attractive way for patent-holding companies to avoid the proliferation of compulsory licences and the associated public relations problems that arise from IP conflicts, to gain access to new markets (through the licensee), and to

⁸⁹³ Notification under para 2(A) of the Decision of 30 August, 2003 on the implementation of paragraph 6 of the TRIPS Agreement and Public Health-Canada, Oct, 5 2007 (IP/N/10/CAN/1)

⁸⁹⁴ Canadian Access to Medicines Regime, Ch 23, Statutes of Canada (2004).

⁸⁹⁵ For the disappointing story of the first attempt to use the Waiver, see P.E Goodwin, "Right Idea, Wrong Result-Canada's Access to Medicines Regime," American Journal of Law & Medicines 34, no. 4 (2008): 567-584.

⁸⁹⁶ For more information, see, <http://www.cptech.org/blogs/drugdevelopment/2006/11/noah-novogrodsky-on-compulsorylicensing>

⁸⁹⁷ See Amir Attaran supra at p.883

improve the overall public image of the company.⁸⁹⁸ A the patent pool is constituted when two or more patent owners pool their patents in a way that allows authorisation for use to be granted for all patents in the pool as a single package.⁸⁹⁹

- As pointed out in Chapter 2, globalisation accounts for a major part of the problem of high drug prices in DCs. I also feel the solution lies at the global level, in a new agreement on sharing the costs and benefits of medical R&D for humankind. The clear tensions between profit and public interest are not readily resolved.⁹⁰⁰ For pharmaceutical companies seeking world markets, the globalisation of IPRs is seen as essential for recouping investment to develop and market new drugs.⁹⁰¹ The time is ripe for the WTO to show that globalisation can be equitable for rich and poor alike. The Doha Declaration recognises a collective obligation to access medicines for all; private markets alone cannot meet the access-to-medicines goal. The world community seeks to address a ‘public good’ problem with a ‘private market’ solution.⁹⁰² Measures can and need to be taken urgently to ensure lower prices for medicines and other health care products, to steer medical research in the direction of the greatest need and to prevent unnecessary loss of lives.
- The formation of regional trade agreements (‘RTAs’) in the sub-Saharan and other parts of the African region will not only facilitate the eventual establishment of an African economic community, but will also enable the continent to obtain compulsory licences from patent pools to meet its public health demands. Through a regional collaborative arrangement, African countries can obtain licences from the pool to meet the health needs of their populations, especially in relation to the epidemic of HIV infection. When a

⁸⁹⁸ See, Joanne Clarke et al, Patent Pools: A solution to the problem of Access to Biotechnology patents? At 10 (Dec, 2000) available at <http://www.usptogov/web/offices/pa/dapp/opla/patentpool.pdf>

⁸⁹⁹ Nicol D, Nielson J. Opening the dam: patent pools, innovation and access to essential medicines. In: Pogge T, Rimmer M, Rubenstein K, editors. Incentives for global public health: patent law and access to essential medicines. Newyork: Cambridge University Press; 2010. pp. 235-62.

⁹⁰⁰ Most informed observers agree that investing in pharmaceutical R & D is a very risky business, which is the principal justification offered for strong pharmaceutical patents. See K.M Lybecker and E. Fowler, “Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules,” *Journal of Law, Medicines & Ethics* 37, no. 2 (2009): 222-240 See .A. O. Sykes, “TRIPS, Pharmaceuticals, Developing Countries, and the Doha ‘Solution,’” *Chicago Journal of International Law* 3, no. 1 (2002): 47-68.

⁹⁰¹ See Adams CP, Brantner VV: Estimating the cost of new drug development: is it really 802 million dollars? *Health Affairs* 2006 25(2): 420-8.

⁹⁰² DiMasi J, Hansen R, Grabowski H: The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 2003, 22: 151-85.

voluntary licence cannot be obtained, an African RTA can enable a single compulsory license for local production or importation to meet its internal needs and the needs of other countries party to the RTA.

As part of its mandate, the TRIPS Council stipulated that if a developing or least developed WTO member country is part of an RTA within the context of the WTO, goods produced in or imported under a compulsory licence to that country can be exported to other DCs or to least developed member countries in the RTA that share the health problem the goods are intended to alleviate, provided that half of the parties to the RTA are recognised as LDCs by the United Nations.^{903 904} This provision allows DCs to aggregate their markets to make the creation of a local pharmaceutical industry more attractive.⁹⁰⁵ More than half of the countries in Africa are currently recognised by the United Nations as LDCs.

An African RTA will therefore make it possible under WTO law to issue compulsory licences for the importation of drugs that can circulate without trade or legal barriers within the continent. Although, the immediate establishment of an African community⁹⁰⁶ might not be a popular idea, steps can be taken to unify the existing eight regional economic communities on the continent.

I further urge DC governments to pursue programs of cooperation that will permit them to take advantage of economies of scale in purchasing, as well as in the production of pharmaceutical products. Many DCs have begun to advocate local pharmaceutical

⁹⁰³ World Trade Organisation (internet). Implementation of paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health: General Council Decision of 30 August 2003 (WT/L/540). Geneva WTO; 2013. Available from: http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm (accessed 28 February 2014)

⁹⁰⁴ World Trade Organisation (internet). Amendment of the TRIPS Agreement: General Council decision of 6 December 2005 (WT/L/641). Geneva: WTO; 2013. Available from: http://www.wto.org/english/tratop_e/trips_e/.htm (accessed 28 February 2014)

⁹⁰⁵ See Yu PK. Access to medicines, BRICS alliances, and collective action. *Am J Law Med* 2008; 34:345-94 PMID:18697697

⁹⁰⁶ From its establishment in 1963 the Organisation of African Unity (OAU), identified the need for the economic integration of the African continent as a prerequisite for economic development. The 1980 Lagos plan of action for the development of Africa, was followed by the 1991 treaty on the establishment of the African Economic Community (also referred to as the Abuja treaty), proposed the creation of regional economic communities (RECs) as the basis for an African integration, with a timetable for regional and then continental integration to follow.

The Abuja treaty proposed for the setting up of an African Economic Community in 34 years (by 2028) through a gradual process involving 6 stages. See *The Role of Regional Economic Communities (RECs) as the Building Blocks of the African Union*. July, 21 2004 prepared by the South African Department of Foreign Affairs. Available at www.dfa.gov.za/docs/2003/au0815.htm

production as a mechanism to address lack of access and ensure supply capabilities. It is also seen as a means of stimulating employment, reducing importation and loss of foreign exchange, gaining foreign exchange through exports, as well as increasing national prestige.⁹⁰⁷

- A ‘bigger-picture’ solution is possible if the RTA can also implement an arrangement to permit exports under article 24 of the GATT. Under this arrangement, it will be preferable for a member country of the RTA to obtain a compulsory licence and then export the drugs it manufactures or imports to its neighbours with similar health needs. The Southern African Development Community (‘SADC’) or the Economic Community of West African States (‘ECOWAS’) are examples of potential platforms to do this.⁹⁰⁸ The RTA member countries need to incorporate an exception into their national laws based on article 24 of the GATT. Article 24 of the GATT provides an important exception to article 1 of the GATT (the MFN clause) by permitting countries to enter into preferential free trade agreements (‘PFTAs’) in terms of which a group of member countries of the WTO extends tariff concessions to each other that they do not extend to other members.
- Developed countries, particularly the USA and members of the EU, should affirm their commitment not to exert bilateral or regional pressure on DC members to forego their rights to adopt effective compulsory licensing and parallel importation measures and other measures to promote public health permitted under the TRIPS Agreement, or to pressurise or compel them to adopt measures and standards beyond their obligations under the TRIPS Agreement.⁹⁰⁹

⁹⁰⁷ However, opponents of local pharmaceutical production contend that it may result in less access to medicines, since economies of scale may be lost if more countries start manufacturing their own medicines.

⁹⁰⁸ For example Ghana was able to incorporate an exemption into its law based upon Article 24 of the 1947 GATT. Thus Ghana could further develop its limited generic manufacturing capacity to serve whole West African Region, especially Nigeria, a country with a large HIV+population.

⁹⁰⁹ The issue of access to medicines to meet critical public health needs arose during outbreak of anthrax in the U.S. in 2001. Once again the outbreak of Tamiflu prompted debates about the importance of protecting intellectual property rights versus protecting public health. While compulsory licensing was not issued in both cases, these cases demonstrate that developing countries are not alone in their vulnerability to public health hazards. During the period of the outbreak of anthrax the U.S. government expressed its commitment to public health, including references to the Doha Declaration as one of four principal negotiating objectives for IPRS in the 2002 Trade Promotion Authorisation Act.

- LMICs like India, Brazil, China and Thailand with substantial pharmaceutical markets, should lead the way in establishing the use of the flexibilities available under the TRIPS Agreement to protect public health.⁹¹⁰ India, through section 3(d) of its Patents (Amendment Act) Act 2005 has already taken a brave step in this regard, although more could still be done.
- Finally, article 31(k)⁹¹¹ can be used as an exception to the limitations under article 31(f) and the Paragraph-6 Decision of the TRIPs Council.⁹¹² A generic manufacturing company (based in South Africa, India, China, etc) holding a compulsory licence can manufacture drugs on a large scale for export to DCs or LDCs. This is possible especially when a non-special and non-paragraph-6 compulsory licence have been granted in the importing country. One good example is the predominantly-for-the-domestic-market exception in article 31(k) where a patent holder has been found to have anti-competitively⁹¹³ abused its patents by excessive pricing or otherwise, in the manufacturing country.⁹¹⁴

10.4 Suggestions for further research

⁹¹⁰ In 2001 China and India alone accounted for over 20 percent of pharmaceutical imports into Africa. See IMS Health [Internet]. Africa: a ripe opportunity. Understanding the pharmaceutical market opportunity and developing sustainable business models in Africa. London: IMS Health; 2012. Available from: http://www.imshealth.com/Global/Content/Insights/Featured%20Topics/Emerging%20Markets/IMS_Africa_Opportunity_Whitepaper.pdf [accessed January 28 2014]

⁹¹¹ '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 a judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorisation if and when the conditions which led to such an authorisation are likely to recur.'

⁹¹² While an action sounding in anticompetitive conduct under article 31 (k) will require some judicial or administrative process. See note 4, at article 31 (k).

⁹¹³ The TRIPS Agreement does not provide the definition of 'anti-competitive' practice. Article 1 of the TRIPS Agreement allows member states to provide their own appropriate interpretations and Article 8(2) of the TRIPS Agreement also allows member states to prevent abuse of IP rights by patent holders which unreasonably restrain trade. Therefore in accordance with the above provisions actions by generic producers in this respect can be justified.

⁹¹⁴ For this recommendation see B.K. Baker, 'Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', 14 Indiana International and Comparative Law Review (2004) p. 613 at p.664

Compulsory licensing of pharmaceutical patents continues to be important in addressing the access to medicines problem. It is therefore recommended that further research be undertaken by those who have an interest in this area of study by considering the following two crucial issues.

- How, effectively can the patent buy-out mechanism accelerate access to essential medicines in DCs?
- How, from a human rights perspective, can ‘the exclusion of patents from medicines’ improve access to essential medicines in DCs?

These two crucial issues are briefly highlighted below.

10.4.1 Patent buy-out mechanism

Professor Kevin Outterson, a leading authority on international public health law, proposed this solution in a recent article.⁹¹⁵ This article suggests an alternative solution to improve access to drugs in light of the recent lack of success with compulsory licensing. The idea is to establish a systematic buy-out mechanism, limited to a specific market, for the patent rights to identified essential drugs.⁹¹⁶ Outterson argues that this will not only circumvent the controversial issue of compulsory licensing, it will also provide medicines at production cost.

He outlines a three-step process for this buy-out mechanism.

- The purchaser acquires the patent and the exclusive marketing rights in a geographical area.
- The purchaser offers an open, non-exclusive, no-royalty licence to any legitimate generic manufacturer subject to limited geographic area.
- The patent owner is compensated under a buy-out formula which mimics the lost R&D cost recovery from lost sales.⁹¹⁷

⁹¹⁵See Kevin Outterson, Patents Buy-Outs for Global Diseases Innovations for Low-and Middle-Income Countries, 32 Am. J.L & Med. 159 (2006)

⁹¹⁶See Kevin Outterson, Patents Buy-Outs for Global Diseases Innovations for Low-and Middle-Income Countries, 32 Am. J.L & Med. 159 (2006).

⁹¹⁷ See Kevin Outterson supra at p. 171

10.4.2 Excluding the patenting of medicines

In order to ensure more effective measures to protect public health and promote access to medicines, countries should be given the option offered by the flexibility of excluding patents from medicines or certain categories of medicines in their national laws. Such exclusions or exemptions can be justified under article 27(2) and 27(3) of the TRIPS Agreement.⁹¹⁸

Article 27 (2), which deals with patentable subject matter, provides as follows:

‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.’

This provision can be further clarified by allowing members to exclude from patentability medicines of certain categories – such as life-saving medicines or medicines used to treat poverty-related diseases.

Further, article 27(3),⁹¹⁹ which also deals with patentable subject matter, provides as follows:

‘Members may exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes...’.

This provision can be amended by including categories of medicines to the list of subject matter that can be excluded from patents.

⁹¹⁸ Agreement on Trade Related Aspects of Intellectual Property Rights, (1994) (TRIPS Agreement)

⁹¹⁹ TRIPS Agreement

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