

**A CRITICAL ANALYSIS OF THE TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS AGREEMENT AND HAS
SOUTH AFRICA COMPLIED WITH THIS AGREEMENT WITH
SPECIAL REFERENCE TO PATENTED PHARMACEUTICALS.**

BY

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**A Mini-Thesis submitted in partial fulfillment of the requirements for the degree Magister
Legum in the Faculty of Law, University of the Western Cape.**



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2 NOVEMBER 2006.

DECLARATION

I declare that *A Critical Analysis of the Trade-Related Aspects of Intellectual Property Rights Agreement and Has South Africa Complied with this Agreement with Special Reference to Patented Pharmaceuticals* is my own work, that it has not been submitted before for any degree or examination in any other university, and that all sources I have used or quoted have been indicated and acknowledged as complete references.



Satardien Mogammad Zain

Signed

November 2006

DEDICATIONS

To my beloved mother: We thank you from the depths of our hearts for the sacrifices you have made for your children. May you soar on the wings of angels, may your heart be caressed by tranquillity and may comfort be your shelter.

To my beloved father: To give us the world, would not equate to what you have given us already. It is you who has taught me the one thing that leads me to the answer in everything. 'Always speak the truth, and always seek the truth'.



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GLOSSARY

Compulsory license - An authorization granted usually by the state that permits a third party to make, use, or sell a patented invention without authorization from the patent holder.

Copyright – An exclusive right authorizing the holder thereof to prevent certain actions in relation to the work he or she created (such as copying or reproducing the work).

Dependent patent - A patent which as a matter of law, cannot be worked without falling within the scope of protection of another patent.

Developed countries – Countries that possess a high income per capita and a very high Human Development Index.

Developing countries – Countries with a relatively low standard of living, an undeveloped industrial base, and moderate to low Human Development Index.

Dispute Settlement Body (DSB) – An international dispute settlement mechanism introduced to allow Members of the WTO to effectively and expeditiously settle international disputes that arise between them.

Industrial Designs – A class of intellectual property. It may be described as those elements that are incorporated into mass-produced products, aimed at enhancing the attractiveness of the product by its appearance.

Intellectual Property - An extensive privilege extending the concept of property beyond its material understanding, to include intangible creations and confers a legally protected right upon the creator of the property which empowers the holder to exclusively exercise the right over that property.

Inventive Step - Requires that an invention should not be 'obvious' to a person of sufficient skill in the particular art, before that invention may be protected by a patent.

Least Developed Countries - Countries which according to the United Nations, exhibit the lowest indicators of socio-economic development and with the lowest Human Development Index ratings of all countries in the world.

Most Favoured Nation (MFN) principle – A principle inherent in all WTO agreements providing that any advantage or similar benefit granted to nationals of any country, must similarly and unconditionally be conferred upon the nationals of *all* other WTO members.

National Treatment Principle (NT): A principle inherent in all WTO agreements requiring that Members treat the nationals of co-Members equal to its own, in relation to any benefits conferred.

Novelty - Requires that in order for a patent to be conferred upon an invention, the invention must display an element unknown in the body of knowledge that exists today.

Parallel Importation – A legal mechanism implemented which allows for an importer to find a national market where a certain product is sold at the lowest price, and then import that product into another national market where the product is sold at a higher price.

Patent - An exclusive right granted upon any invention, whether that invention is a product or a process, that provides mankind with a new manner of doing something or that offers a new technical solution to a problem.

Practical Use – Requires that an invention actually possess a function, and achieve a purpose, before a patent may be conferred upon it.

The Doha Declaration of the TRIPS Agreement and Public Health (Doha Declaration) – A document to be read in conjunction with the TRIPS Agreement that declares that the protection of public health and promoting access to medicines is a legitimate basis for Members to circumvent the granting of strict patent protection as demanded by TRIPS.

The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Implementation Agreement) – A document to be read in conjunction with the TRIPS Agreement which allows a Member possessing pharmaceutical manufacturing capabilities, to produce generic medicines of patented pharmaceuticals for, and export them to, those Members lacking manufacturing capacities

The Prior Art - Entails the present body of existing knowledge today.

Trademark – A class of intellectual property. It may be described as a name or a symbol used in trade, which indicates the origin of a certain product and connotes its quality, efficiency and reliability.

Trade-Related Aspects of Intellectual Property (TRIPS) - A multilateral international treaty introduced by the World Trade Organization and came into effect on the 1st June 1995 and attempts to establish minimum standards for the regulation of intellectual property rights within those countries that are Members of the WTO.

TRIPS Flexibilities – A term used to describe the leeway that developing and least developed Members have been granted by virtue of TRIPS, so that they may under certain circumstances, circumvent their TRIPS obligations.

Voluntary License – A license granted voluntarily by the holder of the patent to another so that the other may be entitled to perform those acts granted exclusively to the holder in relation to the patent. The license is usually subject to a royalty.

World Trade Organization (WTO) - A global international organization which sets the rules for the global trading system and resolves disputes between its Member states; all of whom are signatories to its Agreements.



ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
D& LDC	Developing and Least Developed Countries
EU	European Union
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
IP	Intellectual property
IPL	Intellectual Property Law
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
MSF	Médecins sans Frontières
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
US	United States



USPTO United States Patent and Trademark Office (USPTO)

USTR United States Trade Department

WHO World Health Organization

WIPO World Intellectual Property Organization

WTO World Trade Organization



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“There are no islands in the world today, and there are no domestic diseases. We live in a shrinking world. And there are many contact between us. No one is isolated, no one can be smug and sit in his or her corner and say, ‘I’m safe because it is somewhere else’”

Kofi Annan UN Secretary General



“The world’s poor do not resent the rich anywhere nearly as much as what ...parties in the developed world imagine. What they resent is not having any pathways to get rich and to join the flat world and cross that line into the middle class.”

The World is Flat, Thomas L. Friedman



CHAPTER 1: INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) is a multilateral international treaty introduced by the World Trade Organisation (WTO) that came into effect on 1 June 1995.¹ At a basic level it attempts to establish minimum standards for the regulation of intellectual property rights within those countries that are Members of the WTO and signatories to it.² TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and sets certain deadlines for compliance with its provisions. These deadlines vary, depending on the status as well as the capabilities of the individual signatory concerned.³

TRIPS may be called a pioneering work in many ways, as it is the first Intellectual Property Law (IPL) agreement that obliges WTO Members, within a single undertaking, to introduce new standards in several different cases for intellectual property rights.⁴ It is also the first IPL agreement that is included as part of those rules which govern the multilateral trading system.⁵ It therefore merges trade law (and jurisprudence) with intellectual property laws.⁶ TRIPS recognises intellectual property rights as private rights, and has been described as the “...most wide-ranging and far reaching international treaty on the subject of intellectual property to date and marks the most important milestone in the development of international law in this arena”.⁷

Most fundamental on the agenda of TRIPS is the strengthening of the protection of intellectual property rights worldwide. This is to be achieved by implementing legislative models within the national legal regimes of Member countries.

¹ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper* www.pc.gov.au/research/stafres/trips.pdf .

² *Ibid.*

³ *Ibid.*

⁴ Watal *Intellectual Property Rights in the WTO and Developing Countries* (2004).

⁵ *Ibid.*

⁶ *Ibid.*

⁷ *Ibid.*

However, it should be borne in mind that a stronger protection of intellectual property rights obviously has consequences and, sometimes may have severe ramifications for developing and least developed Members of the WTO in several sectors of their national regimes.

Therefore, certain relevant and crucial issues may be raised: “can we say that TRIPS is of mutual benefit?”, “does it represent the interests of Members both weak and strong?”, or “are the objectives of TRIPS as reflected in the Preamble and the text of the Agreement ever going to be realised?”. The answers to these questions rest on certain scenarios which have developed subsequent to the introduction of TRIPS. Developed Members promised that the enhancement of intellectual property rights and global strengthening thereof would promote development, diffuse and disseminate knowledge and technology, and lead to greater foreign direct investment which ultimately leads to economic development.

However, as many authors have advocated and established, the very structure of TRIPS negates the transfer of technology, essential knowledge and development and has up to date only served as a lucrative tool in the hands of developed Members. For instance, as a result of strengthened intellectual property rights and more specifically patents, the US pharmaceutical industry’s global dollar volume in 2004 was \$550 billion, a 7% increase over 2003, which in turn represented a 9% increase over 2002. US sales grew to \$235.4 billion, a growth rate of 8.3% compared with 11.5% growth from 2002 to 2003.⁸ On the other hand, generic manufacturing of pharmaceuticals has dramatically decreased in developing and least developed countries due to them having to give higher priority to intellectual property protection, and this has resulted in these countries purchasing pharmaceuticals at excessive prices beyond their capabilities.

Responses to the concerns raised, state that the problems faced by these countries do not lie within TRIPS. Rather, the root of the problems lies within the poor infrastructure within these countries.

⁸ <http://en.wikipedia.org/wiki/Pharmaceutical>. (Accessed on 9 October 2006).

So what is the position of the TRIPS Agreement and is it welcomed? How does it affect developing and least developed countries?

1.1 The Aims of this Research

This thesis serves a dual purpose. The first leg is to embark on an investigation into TRIPS, critically analyzing the provisions of the Agreement. The important aim here is to analyze and discover whether TRIPS is sensitive to weaker countries. In this area, a brief discussion will ensue on whether strengthened patent laws in Member regimes has brought benefits or concerns to developing and least developed countries in relation to the accessibility of essential pharmaceuticals. The second leg of this thesis is to probe within the legislative framework of South Africa and determine whether South Africa, as a “developing country”, has complied with the demands as expressed by TRIPS. This investigation will be with specific reference to South African patent law. The Agreement will be analyzed and will subsequently be compared to South African case law and legislation in order to arrive at an answer.

1.2 Methodology of Research

The method employed in undertaking this research is by way of a review of the relevant literature. At the core of this thesis is an in-depth critical analysis of relevant TRIPS provisions. Reliance will be placed on the text of TRIPS and shall be compared to South African law and policy in the field of patents. Statutes, books, scholarly articles and foreign laws will also be looked at. Internet based resources will also provide a valuable contribution toward finding clarity on the issues highlighted in this thesis.

1.3 Summary of Chapters

This research consists of the following six chapters:

Chapter One

Chapter One serves as a general introduction to the TRIPS Agreement and its foreseeable difficulties, while also highlighting the aims and methodology of this research.

Chapter Two

Chapter Two provides the reader with an understanding of the notion of intellectual property and its nature, through defining and explaining the concept. A limited number of the separate classes of intellectual property will then be briefly examined. Thereafter, a critical perspective of the concept of intellectual property will be discussed, reviewing the very justifications for protection thereof. This will provide the reader with clarity, when the protection of patented pharmaceuticals is examined in Chapter Four.

Chapter Three

Chapter Three commences with an overview of the TRIPS Agreement, focusing on its structure, its Preamble and the general obligations imposed upon Members. The objectives of the TRIPS Agreement will then be analysed, looking at the measures provided for the effective enforcement of intellectual property rights in terms of Members' legal systems. Attention will also be paid to the mechanisms provided for the settlement of disputes that arise through the obligations imposed by TRIPS. At the end there is a discussion of how the TRIPS Agreement is to be interpreted in light of the dispute settlement mechanisms provided.

Chapter Four

An analysis is undertaken from a critical perspective on how the strengthening of intellectual property rights impacts on access to pharmaceuticals and health. The measures that Members have adopted to provide solutions for the problems posed, and the success that these mechanisms have achieved will be examined. Conclusions are drawn, and recommendations made as to how poorer countries may utilize the “flexibilities”⁹ under the TRIPS Agreement in order to gain stronger bargaining power in other spheres of TRIPS.

Chapter Five

Chapter Five entails an analysis of South African law and whether the South African Government has complied with its obligations under TRIPS with strict reference to patent law. The Chapter also includes an in-depth discussion of the pharmaceutical court battle between the Pharmaceutical Manufacturer’s Association and the South African Government, predicting what the outcome of the case would have been (if a judgement was reached). A discussion of South Africa’s *Medicines and Related Substances Amendment Act* will also be discussed and analysed, and thereafter certain recommendations will be made in this regard.

Chapter Six

In Chapter Six, conclusions will be drawn and recommendations proposed, as to how developing and least developed Members can employ their ‘TRIPS granted’ rights so that they may provide easier access to pharmaceuticals for their people. How developing and least developed countries can employ all possible mechanisms within their national regimes to achieve this goal will also be discussed.

⁹ “Flexibilities” entails the leeway that Members have to avoid conferring TRIPS protection on certain products or services in certain circumstances.

It must be noted that whilst researching and writing this mini-thesis, it became evident that the TRIPS Agreement *does* indeed pose problems for developing and least developed countries, and that these problems may only be overcome if these countries are legislatively proactive, and strongly participate in future TRIPS negotiations.



CHAPTER 2 UNDERSTANDING INTELLECTUAL PROPERTY

This chapter commences by allowing the reader to understand the notion of intellectual property and its nature, through the definition and explanation of the term. A limited number of the separate classes of intellectual property will then be briefly investigated. Thereafter a critical perspective of the concept of intellectual property will be undertaken.

2.1 The Definition of Intellectual Property

Article 2 (viii) of the Convention Establishing the World Intellectual Property Organisation (1970) defines intellectual property as including the rights relating to:

- “literary, artistic and scientific works,
- performances of performing artists, phonograms and broadcasts,
- inventions in all fields of human endeavour,
- scientific discoveries,
- industrial designs,
- trademarks, service marks, and commercial norms and designations,
- and protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.”¹⁰

The WTO defines intellectual property as:

“...rights given to people over the creation of their minds and creators can be given the right to prevent others from using their inventions, designs or other creations”.¹¹

¹⁰ Ricketson *Intellectual Property Cases, Materials and Commentary* (1994) at p5.

¹¹ www.wto.org.

The term ‘intellectual property’ may be explained as an extensive privilege extending the concept of property beyond its material understanding to include intangible creations.¹² It confers a legally protected right upon a creator of (intellectual) property, empowering the holder to exclusively exercise the right over that property.¹³ In essence, it is a “product of the mind”.¹⁴

To better understand this concept, it may be described as a “cluster of legal doctrines” that regulate the use of different sorts of ideas and symbols.¹⁵ The worth of the intellectual property right is to be found not in the particular idea or technology, but in the ability of the “right holder” to prevent (through law) the exploitation of that idea by third parties.¹⁶ In the extreme, these rights may be described as monopolies, mandated by statute, which enable right holders to prevent others from exploiting the invention without their authority.¹⁷

Importantly, intellectual property rights are conferred upon the creator of the property in relation to the *particular form* in which the idea was expressed and not in relation to the idea itself.¹⁸ Therefore, only the expression of the idea receives protection. Should the idea exist independently without it being expressed in some form, then no protection will be afforded.

2.2 The Classes of Intellectual Property

We have seen that intellectual property rights may be viewed or understood as a ‘cluster of legal doctrines’ that regulate the use of different sorts of ideas as manifested in an expressed form. These doctrines branch outward, regulating different categories of intellectual property rights, each category protecting mental property of a distinctive

¹² www.en.wikipedia.org.

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ William Fisher *The Theory of Intellectual Property* www.law.harvard.edu

¹⁶ Simensky *Intellectual Property in the Global Marketplace* 2 ed. (1999) Vol. 1 at p5.

¹⁷ *Ibid.*

¹⁸ *Ibid.*

nature. Copyrights, Patents, Trademarks and Industrial Designs are such categories of intellectual property rights. These are not the only categories of intellectual property, but generally form the main classes. To cover all individual categories of intellectual property is beyond the stated scope of this thesis, and it is not necessary to do so. The main categories as described immediately above will however be dealt with in brief.¹⁹

2.2.1 Copyright

All works, if original and fixed in any tangible (physical) means of expression, may become eligible for copyright protection.²⁰ Copyright is a right, conferred upon an author, flowing from the creation of his or her mind (this includes natural and statutory persons).²¹ Copyright protection may be regarded as a ‘bundle of rights’ in relation to mind-created works.²²

Copyright authorises the holder thereof to prevent certain conduct in relation to the relevant work created (the “person” creating the work is usually described as the author and where two or more people create the work they may be described as joint authors). As soon as the work comes into existence the author holds a right to prevent others from reproducing or exploiting the creation in the absence of his authority, and the right subsists for the life of the author plus an additional fifty years.²³

Several categories of material exist that may be protected under copyright law. They include:

- Literary works (books, magazines, poems etc)²⁴;
- Dramatic works (plays, shows etc);

¹⁹ For a comprehensive discussion of all the categories of intellectual property, see for example Cornish and Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* 5 ed. (2003).

²⁰ *Ibid* at p7.

²¹ Dworkin *Blackstone’s Guide to the Copyright, Designs and Patents Act 1988* (1992) at p1.

²² *Ibid*.

²³ *Ibid*.

²⁴ Any work excluding dramatic or musical works which is written, spoken or sung and includes a table or compilation and computer programmes.

- Musical works (songs, musical pieces etc);
- Artistic works (paintings, drawings, maps, architecture etc);
- Sound recordings (cassettes, cd's)
- Broadcasts (television programmes, radio shows etc.);
- Typographical arrangement of published editions (published works); and
- Cinematograph Films (movies, dvd's or music videos).²⁵

A pre-condition to copyright protection is that the work created must express an element of originality in order to receive protection.²⁶ 'Originality' does not demand novelty (as in the case of a patent), but simply evidence that the author has invested his own skill and effort in the work. Therefore, the fact that a work originates from, or is inspired by, a previous work, does not necessarily mean that it lacks originality.²⁷ This may be illustrated by *University of London Press Ltd v University Tutorial Press Ltd*²⁸ where the Court was faced with the argument that no copyright subsisted in mathematics examination papers as the questions resembled those used in previous papers. As a result, no great effort could have been invested in their creation. The Court, however, rejected the argument. It held that because the questions possessed some element of mental thought and were not simply slavish copies, the works were eligible for copyright.

What is, however, of fundamental importance, is that copyright protects only the form in which the idea is *expressed* and not the idea itself. Put differently, the idea must be expressed in material form in order to be eligible for copyright protection. The distinction between an idea and its expression has for a long time been recognised as a fundamental principle of copyright law.²⁹ In *Plix Products v Frank M Winstone*³⁰ Prichard J held that:

²⁵ To embark upon a study of the various categories of copyright exceeds the scope of this thesis. The discussion on the different classes of intellectual property is merely introductory so that the reader may understand the nature of intellectual property.

²⁶ Ricketson *Intellectual Property Cases, Materials and Commentary* 1994 at p90.

²⁷ Dworkin *Blackstone's Guide to the Copyright, Designs and Patents Act 1988* (1992) at p6.

²⁸ [1916] 2 Ch 601.

²⁹ Ricketson *Intellectual Property Cases, Materials and Commentary* (1994) at p108.

“The learned authors of *Copinger and Skone James* (12th Ed paras 2, 103, 179, 156) state unequivocally that the ideas and original thought of the author are not protected – that copyright is concerned only with concrete forms in which ideas are expressed. There is an insistent line of authority that supports this view.”³¹

Copyright in a work should also be distinguished from the ownership of the physical object that records or constitutes the work.³² This may best be explained through a well known example: If a poet writes a poem on another’s fabric, then, in the absence of any special factors, the ownership of the fabric on which the poem is written vests in ‘the other’. However, the copyright in the poem vests in the poet. Therefore ‘the other’ as owner of the fabric may destroy the fabric, or show it to others. However, he cannot in the absence of the poet’s authorisation, reproduce the poem as that would interfere with the poet’s copyright.³³

Significantly, unless reproduction or “derivation” of a work can be established, no protection will be afforded against the independent or coincidental creation of a similar work by another author.³⁴ As mentioned in *Corelli v Gray*³⁵:

“...no absolute monopoly is given to authors analogous to that conferred on inventors of patents – that is to say, if it could be shown as a matter of fact that two precisely similar works were in fact produced wholly independently, I do not think that the author of the work that was published first, would be entitled to restrain the publication by the other author of that author’s independent and original work.”³⁶

Copyright therefore serves a purpose to reward the creator for creating works and for disclosing such works to the public.

³⁰ (1985) 3 IPR 390 (New Zealand High Court) at p418.

³¹ At p418.

³² Dworkin *Blackstone’s Guide to the Copyright, Designs and Patents Act 1988* (1992) at p8.

³³ *Ibid.*

³⁴ Ricketson *Intellectual Property Cases, Materials and Commentary* (1994) at p94.

³⁵ (1913) 2 9 TLR 570.

³⁶ At p571.

Importantly, these rights are limited to some extent and the protected work may be reproduced in cases of “fair dealing”.³⁷ Fair dealing entails that the work is reproduced or exploited for justifiable reasons, without infringing substantially on the rights of the owner of the copyright. This occurs where the work is reproduced for research purposes, private study, criticism or review, or for reporting on current events.³⁸

2.2.2 Patents

A patent may be defined as an exclusive right granted for any invention that provides mankind with a new manner of doing something or that offers a new technical solution to a problem.³⁹ The invention is “disclosed to the public in exchange for a limited period of time to exclude others from using the invention without the owner’s consent”.⁴⁰ In essence a patent entails the inventor showing the public what he invented and how it works. In return a right is conferred upon him to prohibit the public from use of the invention unless he permits it.⁴¹ Therefore, importantly, a patent does not confer a right upon the holder to reproduce or use the invention, but to prevent others from doing so without the required authority.⁴²

Where an invention is patented (the invention usually being a product or a process), that invention cannot be commercially reproduced, used, distributed or sold without the prior authority of the holder of the patent. The holder of the patent may enforce his or her right in a court of law.⁴³ The term of exclusion of use is a period of twenty years from the date of the application of the patent, and in special circumstances, from the

³⁷ www.usinfo.state.gov . (Accessed on 3 August 2006).

³⁸ Dworkin *Blackstone’s Guide to the Copyright, Designs and Patents Act 1988* (1992) at p71.

³⁹ www.wipo.int. For instance, a fireman might invent a contraption that makes the fire hose expel water over a larger surface area with greater velocity, thus making the fire easier and quicker to extinguish. Let us imagine that this was always a problem amongst fireman and until now, a solution was not anticipated. This contraption, subject to other requirements may possibly be eligible for patentability.

⁴⁰ www.osec.gov . (Accessed on 3 August 2006).

⁴¹ *Ibid.*

⁴² *What are Patents, Trademarks, Service Marks, and Copyrights?* www.uspto.gov .

⁴³ www.wipo.int. (Accessed on 4 August 2006).

date of an earlier related application.⁴⁴ This earlier application is referred to as the ‘priority date’.

Importantly, in order for a patent to be granted relative to an invention, certain conditions must prevail. In essence, the invention must be of practical use, display an element of novelty unknown in ‘prior art’⁴⁵, show an inventive step, and must be acceptable as patentable under the applicable law.⁴⁶

Some other defined concepts are also relevant. “Practical use” essentially means that the invention must actually have a function and must achieve a purpose. “Novelty” requires that the invention must display an element unknown in the body of knowledge that exists today (the prior art). Accordingly, the invention must not have been found in any matter (whether in the form of a product, a process, information or anything else) and should not have previously been made available to the public by written or oral description, by use, or in any other manner.⁴⁷

An “inventive step” requires that the invention should not be ‘obvious’ to a person of sufficient skill in the particular art.⁴⁸ Generally, “obviousness” is determined by referring to specific documents (such as patent specifications, learned articles and items in the general press) and to specific instances of use.⁴⁹ Common general knowledge is then referred to in order to explain why the step taken would be obvious (and thus not inventive) from the specific sources that have been cited (that are applicable to that situation).⁵⁰

⁴⁴ www.osec.gov . (Accessed on 3 August 2006).

⁴⁵ The “prior art” is the body of existing knowledge *in the world* as you read this. Therefore, all inventions already discovered today such as cellular phones, video cameras, air-conditioners, spanners, satellites etc, exist in the prior art. Thus, if an inventor invents a vacuum cleaner tomorrow, without any function that is completely novel, then the invention cannot be patented, as it forms part of the “prior art”.

⁴⁶ Certain countries exclude certain matters from patentability. See for instance section 25 (2) of the South African Patent Act 57 of 1978 that excludes discoveries, scientific theories, mathematical methods, computer programs etc.

⁴⁷ Cornish and Llewelyn *Intellectual Property: Patents, Copyright, Trade marks and Allied Rights* 5 ed. (2003) at p175.

⁴⁸ *Ibid* at p193.

⁴⁹ *Ibid* at p197.

⁵⁰ *Ibid* at p193.

2.2.3 Trademarks

A trademark may be identified as any sign or combination of signs, performing the function of distinguishing a product (that originates from one source) from those products which originate from some other source.⁵¹ In simpler terms, a trademark may be described as a name or a symbol used in trade, which indicates the origin of a certain product and connotes its quality, efficiency and reliability.⁵² It serves as warranty that the product has come from a particular manufacturer, and that the product retains its previous quality.⁵³ As a result, another manufacturer cannot associate its goods with that trademark or attempt to mislead the public with a mark that bears such resemblance thereto that it may cause the public to believe the products to be the same. This would constitute unfair trade practice. In this way a trademark prevents others from designating a mark to a product that resembles the protected mark if the use of that similar mark has the likelihood of confusing the public to believe that the goods are similar or that they originate from a common source.

For instance, “Diesel” is a well established trade name. Most consumers are aware of this name and are able to identify the origin of the product or garment by means of the trade name on the product and the colours used. They know the product, and trust its quality. Due to “Diesel” being a protected trade name, another cannot sell his product under this name or any other similar name (for instance “Deezel”), as it has a great likelihood of causing the public to believe that the products of the respective parties have a common source. Should another use such a name, the public might buy another’s garment thinking that the garment originates from the same source as “Diesel”. So in essence, another would be making money off Diesel’s reputation and goodwill. Another is prevented from doing this because where the law confers

⁵¹ www.osec.gov .

⁵² *What are Patents, Trademarks, Service marks, and Copyrights?* www.uspto.gov.

⁵³ *White Kerley’s Law of Trademarks and Trade Names* 12 ed. (1986) at p12.

protection upon a trademark, it accords a monopoly to the trademark owner.⁵⁴ Only he has authority to utilise the mark, and designate that mark to a particular product.⁵⁵

Of further importance is that even the trademark owner himself cannot through use of the trademark or similar mark attempt to mislead the public as to the quality of the product.⁵⁶ It was held in *Kentucky Fried Chicken Corp. v Diversified Packaging Corp.*⁵⁷ that where a trademark owner permits a licensee to negatively alter the quality standards of the product associated with the trademark, the public is misled and the trademark will in turn cease to have utility as an “informational device”. The mark no longer reflects quality and thus ceases in function. As a result, protection seems superfluous.

2.2.4 Industrial Designs

Industrial designs may be identified as those elements that are incorporated into mass-produced products, aimed at enhancing the attractiveness of the product by its appearance.⁵⁸ As practised today, an industrial design involves the design of three-dimensional products, ranging from consumer goods to technologically sophisticated equipment.⁵⁹

Numerous English legal commentators have classified industrial designs into “class A” designs and “class B” designs.⁶⁰ The former are those designs that contain an aesthetic input and where appearance of the product has a strong influence on consumer choice.⁶¹ Such products include furniture, textiles, clothes, china cutlery and household

⁵⁴ Swan *Cases and Materials on the Regulation of International Business and Economic Relations* (2000) at p156.

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

⁵⁷ 549 F. 2d 368, 387 (5th Cir 1977).

⁵⁸ Cornish and Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* 5 ed. (2003) at p535. Note that it is an article’s design that gives the article its visual appeal. Thus, a design will be the particular shape of a cellular phone, and not the phone itself.

⁵⁹ *Ibid.*

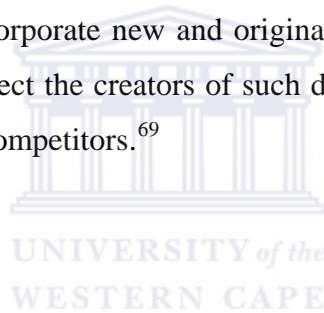
⁶⁰ *Ibid.*

⁶¹ *Ibid.*

appliances.⁶² The latter constitutes those designs that may be referred to as ‘functional designs’.⁶³ Here the product is purchased to perform a function (to do a particular job) and the product’s appearance does not necessarily affect the choice of the consumer (except to the extent that it indicates that the article will render a superior service).⁶⁴ These products include engineering tools, machinery and computer terminals.⁶⁵

Industrial design protection is similar to copyright protection and aims to protect those who are the designers of the ‘ornamental aspects’ of useful articles.⁶⁶ These “ornamental aspects” refer to the features of shape, the configuration or the pattern of the relevant product or article.⁶⁷ Through the protection of an industrial design, only the holder of the right may legitimately reproduce the relevant design.⁶⁸

The rationale for protecting industrial designs is to provide an incentive to produce utilitarian articles that incorporate new and original designs. This is achieved through granting rights which protect the creators of such designs against the unauthorised use of those designs by their competitors.⁶⁹



⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ *Ibid.*

⁶⁵ *Ibid* at p24.

⁶⁶ Simensky *Intellectual Property in the Global Marketplace* 2 ed. (1999) Vol. 1 at p9.

⁶⁷ *Ibid.*

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

2.3 The Concept of Intellectual Property

The issue of whether a state is justified in conferring upon creators a right to exclude all others from the use of their creations has been, and still is, a hotly contested issue.⁷⁰ Once taken for granted as morally legitimate, the rationale for intellectual property rights protection has once again been questioned.⁷¹ Various arguments have been put forward in the spirit of fuelling this debate. Questions have been posed, such as: “Can we *in any case* say that intellectual property is actually property?” and “Should intellectual property, *even if property*, be granted protection?” To entertain questions of this nature requires one to revisit the very notion of intellectual property. In discussing this concept the following may be considered:

“Every man has *Property* in his own *Person*. This no Body has any Right to but himself. The *Labour* of his Body, and the *Work* of his Hands, we may say are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his *Labour* with, and joyned to it something that is his own, and thereby makes it his *Property*.”⁷²

Let us consider the above excerpt against the backdrop of the following:

“According to a common argument, the presence of strong intellectual rights spurs innovation, which leads to higher economic growth and increasing benefits for all. The argument seems coherent...Why then do we argue a “case against intellectual property?” Are we arguing that, while stealing potatoes [physical property] is bad, stealing ideas [mental property] is good? We are not. Economic efficiency, and common sense, argue that ideas should be protected and [be] available for sale, just like any other commodity.

But “intellectual property” has come to mean not only the right to own and sell ideas, but also the right to regulate their use. This creates a socially inefficient monopoly, and what is commonly called intellectual property might be better called “intellectual monopoly.” When you buy a potato you can eat it, throw it away, plant it or make it into a sculpture. Current law allows producers of CDs and books to take this freedom away from you. When you buy a potato you can use the “idea” of a potato embodied in it to make better potatoes or to invent french fries.

⁷⁰ Himma *The Justification of Intellectual Property: Contemporary Philosophical Disputes* Paper 21 2006 at p1. See www.repositories.clilb.org/bclt/lts/21.

⁷¹ *Ibid.*

⁷² Locke *Two Treatises of Government* 2 ed. (1967) at p305.

Current law allows producers of computer software or medical drugs to take this freedom away from you. It is against this distorted extension of intellectual property rights that we argue.”⁷³

This part of our discussion on intellectual property commences in light of the above excerpts and invites the following often posed questions: “For what reason should the State confer rights upon holders of intellectual property?” or “Is society benefited more by the State conferring intellectual property rights upon creators, or could this protection be seen as a deterrent to societal growth (growth being easier achieved in the absence of these rights)?”.

In seeking to provide answers to these questions various theories have been propounded in order to justify the grant of these rights to the creators of works. Most of these theories may be categorised within four approaches.⁷⁴

2.3.1 The Utilitarian Approach

The most popular approach employs the utilitarian argument. When deciding upon the scope of property rights, the main consideration of the lawmaker should be the maximization of net social welfare. In achieving this goal (in the context of intellectual property) the lawmaker should be required to balance the creator’s power of exclusive right to stimulate creation and invention against that right curtailing the public enjoyment of those creations and inventions.⁷⁵ This line of argument may be noted in the essay on copyright law by Landes and Posner.⁷⁶ They argue that, due to the distinctive characteristics of intellectual creations, they are easily susceptible to replication. This susceptibility invites a danger that the creators of these products will be unable to recover their “costs of expression”.⁷⁷ This will in turn deter creators from the future creation of socially invaluable products (which all will benefit from). The

⁷³ Boldrin and Levine *The Case Against Intellectual Property* (2002) at p8.

⁷⁴ Fisher *Theories of Intellectual Property* www.law.harvard.edu

⁷⁵ *Ibid.*

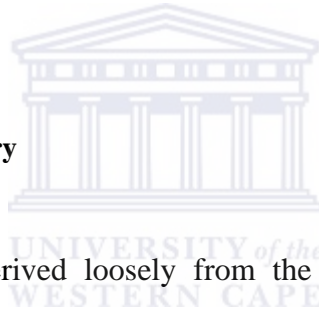
⁷⁶ Landes and Posner *An Economic Analysis of Copyright Law* (1989)
www.cyber.law.harvard.edu/IPCoop/89land1.html.

⁷⁷ *Ibid.*

above outcome can be avoided by allocating to creators an exclusive right to reproduce their creations (for a limited period).⁷⁸

2.3.2 The Labor Theory

The second approach dominating theoretical literature originates from the thought of John Locke.⁷⁹ The approach springs forth from the proposition that a person who labors with ‘unowned’ or ‘common’ resources, acquires a natural property right to the fruits of his efforts. Locke argues that property proceeds from labor and that property is then owned by the one who has labored.⁸⁰ Before an idea is expressed, the idea can only take physical form through the manual labor of the creator.⁸¹ On this basis, the labor of the creator becomes the basis of his ownership of the intellectual work. The state then has a duty to enforce, protect and respect the natural right acquired through that labor.⁸²



2.3.3 The Personality Theory

The third approach is derived loosely from the writings of Immanuel Kant.⁸³ Its premise is that private property rights are crucial to the satisfaction of certain fundamental human desires or needs.⁸⁴ Therefore, policy makers should strive towards creating and making available resources in a manner that best allows individuals to

⁷⁸ *Ibid.* The balance argued by Landes and Posner can clearly be seen. The susceptibility to replication of the work demands protection, but this protection must still allow for the creation to benefit society (not only the creator). Thus, they argue that a right must be conferred, but that that right must be limited.

⁷⁹ Fisher *Theories of Intellectual Property* www.law.harvard.edu

⁸⁰ Weber *A Critique of Intellectual Property Rights* (2002) at p8.

⁸¹ *Ibid.*

⁸² Fisher *Theories of Intellectual Property* www.law.harvard.edu. Nozick, however, extends this concept by arguing that the acquisition of property through labour is only legitimate if, and only if, other persons do not suffer ‘net harm’ through the acquisition of the property. Net harm includes such injuries as a society being left poorer than what it would have been under a regime that did not permit the acquisition of property through labor or a constriction of the set resources available for their use. (See Nozick, R. *Anarchy, State, and Utopia* (1974) at p178).

⁸³ Fisher *Theories of Intellectual Property* www.law.harvard.edu.

⁸⁴ *Ibid.*

satisfy those needs.⁸⁵ From this point of view, the granting of intellectual property rights may be justified on the ground that they prevent the misuse or alteration of works of art through which creators have expressed their will.⁸⁶ Similarly, from this standpoint, intellectual property rights may be justified on the ground that they create conditions (both social and economic) that are conducive to creative intellectual activity, which in turn promotes human flourishing.⁸⁷

2.3.4 The Social Planning Theory

The final approach is not as well known as the others and rests on the premise that property rights (intellectual property rights in particular) should be moulded in a way that encourages the achievement of a just and attractive culture.⁸⁸ The approach coincides to some extent with utilitarianism in its teleological orientation, but deviates in its willingness to “deploy visions of a desirable society richer than the conceptions of ‘social welfare’” as set out by utilitarians.⁸⁹

2.3.5 Economic Perspectives

In the framework of the main theories above, Lamb justifies the protection of intellectual property from a more modern and economic perspective.⁹⁰ He provides practical reasons for the need to protect intellectual property. He argues that due to the piracy of intellectual products, a key result is that the true profit potential belonging to the original creator is never realized.⁹¹ A company suffers disproportionate costs as piracy “steals” profits from those products that possess the greatest investment potential. As a result, the holder of the intellectual property right is confronted with an asymmetric pattern of investment returns with its potential growth rate being

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ Lamb “Economic and Financial Issues in Intellectual Property” in Simensky *Intellectual Property in the Global Market Place* 2 ed. (1999) Vol. 1 Ch 5.

⁹¹ *Ibid.*

dramatically restricted and its downside risks being greatly intensified.⁹² Where the company is a weaker company, “intellectual property theft” results in the company’s survival being continuously threatened.⁹³

Furthermore, the Economic Council of Canada provides cogent arguments in favour of the protection of intellectual property.⁹⁴ It argues that intellectual property rights are policy tools which are used to improve society’s ‘total information’ system in sectors where the production and distribution of knowledge is inadequate. They are incentives which are designed to elicit knowledge creation and knowledge processing. It is also argued that these rights are not protected merely for incentive purposes, but define, validate and protect fundamental rights that already existed.

2.4 Arguments Against Intellectual Property Protection

It is acknowledged that the arguments listed above contain elements of cogence and rest on certain planes of logic and justice. Nevertheless, these arguments may be gainsaid by arguments of equal cogence. A strong case for opposing the concept of intellectual property exists and is premised on a number of negative consequences being identified due to the ownership of intellectual property (such as the retardation of innovation and the exploitation of poorer countries).

“... “intellectual property”... creates a socially inefficient monopoly, and what is commonly called intellectual property might be better called “intellectual monopoly”... Current law allows producers of computer software or medical drugs to take... freedom away from you. It is against this distorted extension of intellectual property rights that we argue.”⁹⁵

Based on the above excerpt, Boldrin suggests in his writings that intellectual property should not be termed as such, but should rather be dubbed ‘intellectual monopoly’ as

⁹² *Ibid.*

⁹³ *Ibid.*

⁹⁴ Economic Council of Canada, *Report on Intellectual Property Rights and Industrial Property*, (1971) Ch 3.

⁹⁵ Boldrin and Levine *The Case Against Intellectual Property* (2002) at p8.

that is essentially what it transpires to be.⁹⁶ He describes intellectual property as a ‘cancer’ and this cancer is presently attacking the most vital centres of the global economy.⁹⁷ The author argues that even though intellectual property protection has been shown to produce certain benefits, these benefits are merely short-term and in the long run they bring greater harm than benefit.⁹⁸ He argues:

“Intellectual monopoly apologists like to portray intellectual property as a cure, a powerful and beneficial medicine alleviating the innovative impotence of competitive markets. If intellectual property is the Viagra of innovation, then it has been prescribed on the basis of the wrong diagnosis to a patient who is not impotent. It may occasionally provide an initial spurt of innovational enthusiasm. Unfortunately, this subsides rather rapidly and is replaced by a rapacious desire to obtain economic satisfaction through the exclusion of as many people as possible from fruitful intellectual intercourse.”⁹⁹

Boldrin argues that intellectual property protection has serious side effects and that no strong evidence exists to show that intellectual property protection invites innovation or beneficial effects.¹⁰⁰ Realistically, intellectual property as it exists today is a disease rather than a cure. He argues that its basis or rationale is not to increase innovation, but to ‘fatten the purse’ of monopolists at the expense of public prosperity.

It is submitted that Boldrin’s argument encapsulates some substance. If, in the pursuit of strengthened intellectual property rights, the goal in mind was to increase innovation, then why are all inventions patented (which produces the opposite effect)? Is it not so, that a patent deters a state from innovation? For instance, if X invents (Y) without a patent being conferred, is it not true that the underdeveloped country Z would have evolved easier if it did not have to pay for use of the invention? To my mind the answer is yes. On the other hand, it is acknowledged that patents will encourage a country to develop its own inventions (in theory), but how does a poor country (in practice) invest in Research and Development (R & D) when most of its money is invested in the use of

⁹⁶ *Ibid.*

⁹⁷ *Ibid.*

⁹⁸ *Ibid.*

⁹⁹ Boldrin and Levine *The Case Against Intellectual Property* (2002) Ch10 at p1.

¹⁰⁰ *Ibid.*

other patents and basic services and amenities? It is further acknowledged that an inventor or creator is entitled to the full use of his property, but can we not curtail the severe ramifications of this entitlement?

Boldrin suggests that intellectual property be eliminated altogether, but because intellectual property may be regarded as a “cancer”, the immediate elimination thereof may bring about damages of an “intolerable magnitude”.¹⁰¹ The abolition of intellectual property must therefore be approached by smaller steps, bringing about gradual reform.¹⁰² He argues:

“On the basis of the present knowledge, progressively, but effectively abolishing intellectual property protection is the only socially responsible thing to do. Evidence has accumulated over the last fifty years leaving little doubt about the damaging effect of current intellectual property laws. At the same time, legal, economic and business know-how has accumulated about how markets for innovation operate without intellectual monopoly. To rule out abolition priori would be as silly now as it would have been to rule out the abolition of tariffs and trade barriers fifty years ago, when the contemporary trade liberalization process began. For a long time the few individuals... that profited from trade barriers argued that these increased the wealth of the nation... It took a while to realise this was not true, and that trade barriers were nothing more than rent-seeking devices, favouring a minority and dramatically hurting the overall economy... The same is now true of patent and copyrights.”¹⁰³

Some authors, such as Vaver, submit that the reasons encouraging intellectual property protection (as listed above) are unconvincing.¹⁰⁴ He rejects the argument that intellectual property encourages the initial creative act. If this was so, then why, in centuries long before the recognition of patents and copyrights, did inventions and

¹⁰¹ Boldrin and Levine *The Case Against Intellectual Property* (2002) Ch10 at p2.

¹⁰² *Ibid.*

¹⁰³ *Ibid.* In my understanding, Boldrin seems to only have a problem with the current nature of intellectual property laws (the laws as they exist today). It seems that initially, due to the exploitation of a creator's work, the creator belonged to a vulnerable class and required protection from the unfair exploitation of his hard labour. This brought about the rights and protection of intellectual property. However, according to Boldrin, these rights have strengthened unreasonably, to the extent that a monopoly has transpired and it is now the consumer that is vulnerable. It seems as if the common saying applies here: ‘ The tables have turned’.

¹⁰⁴ Vaver “Some Agnostic Observations on Intellectual Property” (1991) 6 *Intellectual Property Law Journal (Canada)* 125 at p126.

creations flourish? He also argues that if rights restrict the use and availability of an invention more than it increases it, then the right is unjustifiable. The author commendably finds an inconsistency in the concept of intellectual property. He mentions:

“On the economic plane, patents and copyrights are supposed to encourage work to be disclosed to the public and thus to increase society’s pool of ideas and knowledge. Yet many inventions are kept secret and the law vigorously protects that decision, whether or not disclosure would be more socially useful than secrecy.”¹⁰⁵

To venture into a discussion as to which line of argument is more sustainable, is beyond the scope of this thesis. Nevertheless, if I am to agree that intellectual property provides incentives for development and increases innovation, then why has it been proven that most of the actual creators of intellectual property remain poorly remunerated, whereas the *companies who employ the actual creators* have tasted great benefits?¹⁰⁶ On the other hand, if I am to agree (as argued by Hettinger)¹⁰⁷ that intellectual property is not an individual product, does not exist in a social vacuum and is dependent upon the knowledge of society (therefore society must be compensated), can it not be said that society has already been compensated through other means (such as the creator having to pay taxes, fees at tertiary institutions to learn, fees to patent the product etc.), as argued by some authors?¹⁰⁸

Assessing the various arguments I have come across has compelled me to seek a solution rather than blindly adhering to a certain view. It is to my mind (with all respect), ‘wishful thinking’ to suggest that the notion of intellectual property can be abolished altogether. However, it cannot be denied that the present regime (especially patents) poses some threats that urgently require attention. It seems more probable than not that intellectual property is here to stay, but that does not mean that a tolerable and mutually beneficial regime is unattainable. To my mind, Locke’s theoretical approach

¹⁰⁵ *Ibid* at p128.

¹⁰⁶ Martin *Against Intellectual Property* www.danny.oz.au/free-software/advocacy/against_IP.html.

¹⁰⁷ See *ibid*.

¹⁰⁸ *Ibid*.

has substance and thus a labourer should be entitled to the enjoyment of the fruits of his labour (which extends to intellectual property), but then by the same token (as is common in most property law jurisprudence), that entitlement should be exercised in a manner that is not harmful to the rest of society. As Nozick argues,¹⁰⁹ the acquisition of property is only legitimate if net harm is not suffered. In this light, a right to intellectual property should exist, but the right to enjoyment of the fruits of that property should be exercised in a manner that does not bring about harmful consequences. If this approach is to be employed, then many intellectual property-related concerns might find their long-awaited solution. For instance, if we follow this line of argument, an inventor could have a right to have his pharmaceutical product patented and a right to receive a compensation for use of that product. However, the approach would not allow him to establish a monopoly, as that would cause a shortage of drugs, causing harm to the general public. If a society is entitled to strengthened intellectual property rights, then that same society has a parallel right to evolve, live a higher quality of life and digest knowledge. In essence, what should be achieved is a balance, which allows a creator to benefit handsomely from his work on the one hand, but that simultaneously achieves the vision of humanity's evolution and innovation on the other hand. As Vaver mentions, to the extent that society seeks some semblance of social justice, intellectual property laws, as an important part of that vision, should not escape scrutiny.¹¹⁰

It is thus my submission that Fisher's line of argument is the preferred path to adopt. He mentions:

“Other things being equal, a society whose members are happy is better than one whose members are, by their own lights, less happy. Applied to the field of intellectual property, this guideline urges us to select a combination of rules that will maximize consumer welfare by optimally balancing incentives for creativity with incentives for dissemination and use. That goal must, however, be tempered by other aspirations.”¹¹¹

¹⁰⁹ Nozick *Anarchy, State, and Utopia* (1974) at p178.

¹¹⁰ Vaver “Some Agnostic Observations on Intellectual Property” (1991) 6 *Intellectual Property Law Journal (Canada)* 125 at p126.

¹¹¹ Fisher *Theories of Intellectual Property* www.law.harvard.edu.

“Pursuit of that end in the context of intellectual property, it is generally thought, requires lawmakers to strike an optimal balance between, on the one hand, the power of exclusive rights to create stimulation of inventions and works of art and, on the other hand, the partially offsetting tendency of such rights to curtail widespread public enjoyment of those creations”¹¹²



¹¹² *Ibid.*

CHAPTER 3: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

This chapter commences with an overview of the TRIPS Agreement, focusing on its structure, its Preamble and the general obligations imposed upon Members by virtue of the Agreement (such as the Most-Favoured Nation Principle (MFN)). The objectives of the TRIPS Agreement will then be analysed, looking at the measures provided for the effective enforcement of intellectual property rights in terms of Member legal systems, and also focusing on the mechanisms provided for the settlement of disputes that arise through the obligations imposed by TRIPS. At the end, I will examine how the TRIPS Agreement is to be interpreted according to the dispute settlement mechanisms provided.

3.1 Introduction

Prior to the TRIPS Agreement, existing Conventions regulating intellectual property rights showed weak resistance to piracy and counterfeiting of products in international trade. Previous protection conferred upon holders of intellectual property rights was deemed inadequate and it was this inadequacy that constituted the agenda of the TRIPS negotiations.¹¹³ Consequently, sturdy and persistent political pressure surfaced from developed countries calling for a strengthening of international intellectual property protection.¹¹⁴ The United States and Japan submitted proposals to the Uruguay Round's Preparatory Committee requesting the Uruguay negotiations to cover all trade-related aspects of intellectual property. Due to this persistence, intellectual property protection was on the negotiating agenda for the Uruguay Round of Negotiations of the General Agreement on Tariffs and Trade (GATT), and submissions were forwarded that an inadequate level of intellectual property protection distorts international trade and

¹¹³ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p5.

¹¹⁴ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper* www.pc.gov.au/research/stafres/trips.pdf.

impairs concessions due to piracy.¹¹⁵ It was also claimed that trade problems were arising as a result of the deficiencies in the protection accorded to intellectual property.¹¹⁶

Negotiations had two main aims: The first was to discuss a number of changes in existing Conventions protecting intellectual property and the second aim concerned the better enforcement of intellectual property protection which previously had proved inadequate.¹¹⁷

Initially, during the first phase of negotiations, developing countries refused to negotiate on the subject of intellectual property.¹¹⁸ However, in Montreal, a compromise between developed and developing countries emerged which stipulated that principles of intellectual property protection should be negotiated upon without prejudging who would later administer those rules and principles.¹¹⁹ This compromise has since allowed substantive discussions to take place, leading to the introduction of The Agreement on Trade-Related Aspects of Intellectual Property Rights through the Uruguay Negotiations.¹²⁰

TRIPS is a multilateral international treaty introduced by the World Trade Organisation (WTO) and came into effect on 1 June 1995.¹²¹ The purpose of this legal instrument is to establish minimum standards for the regulation of intellectual property rights within those countries that are Members of the WTO and signatories to it.¹²² The Agreement was negotiated at the end of the Uruguay Round of the GATT and sets out a number of

¹¹⁵ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p5.

¹¹⁶ *Ibid.*

¹¹⁷ *Ibid.*

¹¹⁸ Wolfgang *Strengthening Protection of Intellectual Property in Developing Countries, A Survey of the Literature* 112 World Bank Discussion Papers at p1.

¹¹⁹ *Ibid.*

¹²⁰ *Ibid.*

¹²¹ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper*

www.pc.gov.au/research/stafres/trips.pdf.

¹²² www.wikipedia.org (Accessed on 24 March 2006)

deadlines for compliance with its provisions. These deadlines vary, depending on the status as well as the capabilities of the individual signatory concerned.¹²³

TRIPS is the first IPL agreement obliging WTO members, within a single undertaking, to introduce new standards for several different cases of intellectual property rights.¹²⁴ It is the foremost intellectual property law agreement included as part of the rules which govern the multilateral trading system.¹²⁵ It therefore merges trade law and jurisprudence with intellectual property laws.¹²⁶

3.2 The Structure of TRIPS

The TRIPS Agreement embodies seven different components, exclusive of its Preamble. Parts I and II concern the substantive rules that Members are to implement and apply within their national legal systems. Part III sets out the enforcement obligations of Members and Part IV manages the means for the acquisition and maintenance of intellectual property rights. Part V deals solely with the settlement of disputes between Members under the Agreement and Part VI concerns transitional arrangements. Lastly, Part VII to the Agreement concerns institutional arrangements and other matters. The main contents of the TRIPS Agreement are as follows:

The Preamble which sets out the goals and objectives of the Agreement,

¹²³ J Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper* www.pc.gov.au/research/stafres/trips.pdf . For instance, Developing Members were allowed a “period of grace” to implement the TRIPS Agreement and should fully have complied with TRIPS provisions by 1 January 2000. For Least Developed Members, the extended period of transition was 11 years after the enactment of TRIPS.

¹²⁴ Watal *Intellectual Property Rights in the WTO and Developing Countries* (2004). For instance, Article 16 confers upon the owner of a registered trademark the exclusive right to prevent third parties from using identical or similar signs for goods and services which are identical or similar to those goods and services in respect of which the trademark is registered. However, the use of the identical or similar good or service must lead to confusion, or a likelihood thereof, of the general public. Also, Article 28 confers upon the owner of a patent the exclusive right (if the patent is a product) to prevent third parties from using, producing offering for sale, selling or importing the product for those reasons without the patent holder’s authority.

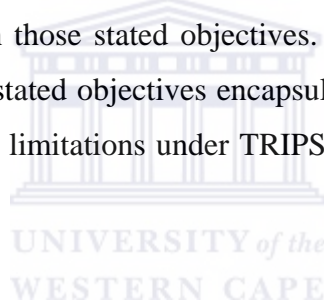
¹²⁵ Watal *Intellectual Property Rights in the WTO and Developing Countries* (2004).

¹²⁶ *Ibid.*

- Part I Contains the general provisions applicable to Members
- Part II Provides for standards concerning the availability, scope and use of intellectual property rights:
- 1) Copyright
 - 2) Trademarks
 - 3) Geographical Indications
 - 4) Industrial Designs
 - 5) Patents
 - 6) Layout Designs of Integrated Circuits
 - 7) Protection of Undisclosed Information
 - 8) Control of Anti-Competitive Practices in Contractual Licences
- Part III Provides provisions for the enforcement of intellectual property rights in Members' legal systems:
- 1) General Obligations
 - 2) Civil and Administrative Procedures and Remedies
 - 3) Provisional Measures
 - 4) Special Requirements Related to Border Measures
 - 5) Criminal Procedures for the Infringement of Intellectual Property Rights
- Part IV Provides for the acquisition and maintenance of intellectual property rights and related inter-partes procedures
- Part V Provides Members with mechanisms to effectively prevent and settle disputes between them
- Part VI Transitional Arrangements

3.3 Analysing TRIPS and its Objectives

The general objectives and underlying policy of the TRIPS Agreement are clearly expressed in the Preamble. The stated focus is mainly on diminishing barriers to, and distortions of, international trade, and promoting satisfactory and effective protection mechanisms for intellectual property rights. Other foci include establishing channels and procedures which allow for the effective enforcement of intellectual property rights in a manner that refrains from simultaneously establishing barriers to legitimate trade. Article 7 supplements the stated objectives by promoting the ‘innovation’ and ‘dissemination’ of technology. Furthermore, I submit that the Article also imposes important conditions upon those stated objectives. On the other hand, it is contended that Article 8 curtails the stated objectives encapsulated in the Preamble and Article 7. These objectives and their limitations under TRIPS are to be discussed later on in this work.



3.3.1 The Preamble

The Preamble of the TRIPS Agreement as is the case with most legal instruments and international Conventions, constitutes an essential component thereof as it articulates the intentions of the instrument itself.¹²⁷ It is a clear communication of the Agreement’s underlying principles, simply embodied in a condensed formula.¹²⁸ The object and purpose of the Preamble, in the eyes of the Appellate Body of the Dispute Settlement Understanding (DSU), is, *inter alia*, to “...promote effective and adequate protection of intellectual property rights...”¹²⁹ on a global, uniform level.

¹²⁷ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p80.

¹²⁸ *Ibid.*

¹²⁹ Appellate Body Report *India –Patents* (US) para 57.

Upon analysis, the first paragraph of the Preamble to the Agreement attempts to strike a balance of some sort between the protection of individual rights and the promotion of international trade. It realises that an inadequate protection of intellectual property rights could prove conducive to distortions in international trade, whereas on the other hand, an excessive protection of those rights could themselves become barriers to trade, which in turn produces a similar effect.¹³⁰ The Preamble therefore expresses that Members have subscribed to the Agreement with a mutual intention to reduce deformations in international trade and to seek an enhancement of the protection of intellectual property rights. However, the delicate balance to be achieved is that an adequate protection of intellectual property rights must not result in the very mechanisms implemented becoming in themselves barriers to trade. Notwithstanding that it seems a difficult task to achieve, this may be seen as one of the core purposes of the Preamble as it purports to balance the entire Agreement.¹³¹

The second and third paragraphs of the Preamble set out further objectives by expressing the desires of the Members to the Agreement. The expressed desires of the Members ultimately represent some of the objectives pursued by TRIPS. It recognises a need to advance and improve the rules and disciplines governing several matters.¹³² These matters include that Members, through TRIPS, intend introducing and implementing new rules which centre on how the basic principles of GATT and other

¹³⁰ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p80.

¹³¹ However, this balance, based on the available evidence, seems only to be achieved within the text of TRIPS. In reality the promises have failed to materialize. Contrary to these promises, the introduction of TRIPS has resulted in increased exports from developed countries and an increase of welfare losses in developing countries. See Correa *Intellectual Property Rights, the WTO and Developing Countries* (2000) at p3.

¹³² These matters are:

- (a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and
- (e) transitional arrangements aiming at the fullest participation in the results of the negotiations.

intellectual property orientated Conventions should be applied. They express the policy consideration that new disciplines be introduced that enhance intellectual property protection, which provide effective mechanisms that promptly permit the enforcement of intellectual property rights. Further, Members desired a body of laws which would allow for “effective and expeditious” procedures through which disputes between governments could be settled. Lastly, novel rules had to be introduced concerning transitional arrangements aiming at the fullest participation in the results of negotiations.

The second paragraph of the Preamble, in essence, represents the very framework of the TRIPS Agreement. This is apparent in that sub-paragraph (b) expresses Part II of the Agreement that sets out the scope, availability and use of rights. Sub-paragraph (c) represents Part III of the Agreement which provides for the effective enforcement of rights. Sub-paragraph (d) summarises Part V of the Agreement providing for dispute prevention and settlement. Lastly, sub-paragraph (e) represents Part VI to the Agreement making provision for transitional arrangements. These paragraphs it might be added also convincingly resemble the initial mandate submitted by the United States and Japan in September 1986.¹³³

The fourth paragraph of the Preamble recognises that intellectual property rights are private law rights (as opposed to public law rights) and therefore, Member states are not obliged to take action against an infringement of an intellectual property right.¹³⁴ Rather, matters of such nature should be resolved between the respective private parties involved.¹³⁵

The fifth and sixth paragraphs of the Preamble express a desire by Members to make provision for Least Developed Countries (LDC) in order to cater for their special needs. Thus, Members recognised a need for flexibility and the need to keep the

¹³³ See Document MIN.DEC (September 20, 1986) pp7-8.

¹³⁴ The significance of this distinction is that a private law right is easier to enforce. The right holder is relieved from having recourse to complicated mechanisms that would have been required in a public law relationship.

¹³⁵ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p80

developmental objectives of these countries in mind.¹³⁶ The last two paragraphs reflect that the Preamble encourages disputes between Members to be resolved through multilateral measures and that a mutually supportive and reciprocal relationship between WTO and the World Intellectual Property Organisation (WIPO) be nurtured. It thus identifies a need to maintain co-operative relations between WIPO and WTO and conveys the message that the latter should employ measures which refrain from encroaching upon the competencies of WIPO.¹³⁷

Upon an analysis of TRIPS, I support the view of Gervais¹³⁸ who states that the Preamble attempts to achieve a point of equilibrium between intellectual property protection and free trade, and also between private rights and the public interest. The attempted balance may be identified in the first and sixth paragraphs to the preamble. It is my further view that the Preamble reflects the very heart of the TRIPS Agreement and echoes the joint consensus and cogent reasoning of the Members, as to why they took the decision to be signatories to the Agreement and embrace its terms.

3.3.2 The Preamble and Articles 7 and 8

It is important that the objectives inherent in the Preamble should be read in conjunction with Articles 7 and 8 of the Agreement.¹³⁹ Measures aimed at the protection and enforcement of intellectual property rights by Members must contribute to those matters mentioned in Article 7, and are limited to them.¹⁴⁰

The measures employed by virtue of Article 7 must contribute to the promotion of technological innovation and to the transfer and circulation of technology.¹⁴¹ Measures

¹³⁶ *Ibid.*

¹³⁷ *Ibid.*

¹³⁸ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p81

¹³⁹ www.iprsonline.org/ictsd/docs/EditorialBridgesYear5N7Sept2001.pdf. (Accessed on 3 May 2006).

¹⁴⁰ Dutfield *Intellectual Property Rights, Trade and Biodiversity* (2000) at p15.

¹⁴¹ TRIPS express this objective in both Article 7 and the Preamble to the Agreement. It further protects and ensures achievement of this objective in Article 40. Where licensing practices or conditions pertaining to intellectual property rights, which restrain competition, impede the transfer and dissemination of technology, Members may specify in their legislation those practices that constitute an abuse of intellectual

employed should further be of benefit to both the producers of technological knowledge as well as to the consumers thereof.¹⁴² Article 7 lastly stipulates that intellectual property rights must be enforced and protected in a manner that is, firstly, conducive to social and economic welfare, and then secondly, to a balance of rights and obligations.

In light of the above it may be argued that Article 7 should be interpreted so that the objectives of TRIPS stated in the Preamble are *subject* to: (1) achievement of the objectives resulting in the innovation and dissemination of technology;¹⁴³ (2) mutually benefiting creators and consumers of technology; and (3) balancing the rights and obligations of Members. As a result it can be seen that Article 7 adds additional objectives to be achieved by TRIPS, by stipulating that the measures used to achieve the “preamble goals” should also achieve “Article 7 goals”.

Dutfield writes that Article 7 means that Members are now required to design a national regime that best serves their needs in terms of public welfare and the interests of producers and consumers of technological knowledge.¹⁴⁴ He writes however that satisfying Article 7 will by no means be an easy task. Members will no doubt face difficulty in ensuring that the rights and obligations of creator and user are well balanced in support of the social, economic and developmental objectives that Members intend their regimes to pursue.¹⁴⁵

Gervais correctly makes the apt observation that because the objectives set out in Article 7 are incorporated into the *text* of TRIPS and not its Preamble, it results in a

property rights having an adverse effect on competition in the relevant market. Thus, in order to prevent the objective of transfer of technology from being impeded, Members may control or prevent such abusive practices.

¹⁴² In light of this stipulation, it can again be seen that the TRIPS Agreement purports to achieve balances. The protection of intellectual property must be to the benefit of the creator thereof on the one hand, but also to the user thereof on the other hand.

¹⁴³ Correa however submits that proof is absent that world-wide intellectual property rights’ protection will increase technology flow to developing countries. See Correa *Intellectual Property Rights, the WTO and Developing Countries* (2000) at p24.

¹⁴⁴ Dutfield *Intellectual Property Rights, Trade and Biodiversity* (2000) at p15.

¹⁴⁵ *Ibid.*

heightened status of these objectives.¹⁴⁶ He further makes the far-reaching and potentially significant point that the reference to social and economic welfare and to a balance of rights and obligations under Article 7, could justify exceptions to exclusive rights where the holder has failed to participate in social and economic development.¹⁴⁷ In conclusion, the manner in which Article 7 is drafted reflects that the balance of rights and obligations of ‘right holders’ are to be assessed in a manner that uses well-established rules of intellectual property law.¹⁴⁸

Whereas Article 7 purports to extend the objectives stated in the Preamble, Article 8 seems to limit these objectives. This Article is essentially a policy statement and seems to provide broader grounds for exceptions than those provided by Article 7.¹⁴⁹ It affords Members the leeway to introduce laws at a national or municipal level which protect public health and nutrition, and which promotes public interest in such sectors that are of *vital* importance to socio-economic and technological development.¹⁵⁰ However, the laws introduced in terms of Article 8 are required to be consistent with the provisions of TRIPS (such as: *inter alia*, the National Treatment and MFN principles, which will be discussed later). Article 8:2 grants Members a right to implement *appropriate* measures to prevent the abuse of intellectual property rights by their holders, or to prevent practices which unreasonably restrain trade or which adversely affect the international transfer of technology. In light of these reservations of rights, it may therefore be expected that the objectives of TRIPS to protect intellectual property rights are limited to the extent that the protection thereof should not lead to an abuse of those rights, or an unreasonable restraint on trade, or an adverse hindrance of technological transfer.

¹⁴⁶ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p116.

¹⁴⁷ *Ibid.*

¹⁴⁸ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p117.

¹⁴⁹ *Ibid* at p121.

¹⁵⁰ It is unsure whether the word “vital” in the text of Article 8 provides an additional limitation on the use of the Article. A distinction however rests between a matter of “importance” and a matter of “vital importance”, and thus a likelihood exists that a tribunal might interpret this provision in light of the letter of the Article. Therefore, it seems possible that this might be a greater limitation on the use of Article 8. It might also be added that proving a matter of “vital importance” imposes a greater burden upon the Member wishing to activate the Article.

However, the measures implemented under Article 8 must be appropriate, necessary, and should be in conformity with the rest of the Agreement. Also, a mere ‘restraint’ of trade, or a mere ‘hindrance’ of technological transfer, is insufficient for activation of Article 8 and illustrates that the requirements of Article 8:2 establish difficult criteria for the application thereof.

3.3.3 The Status of Articles 7 and 8

Articles 7 and 8 of TRIPS were selected to have special importance in the Doha Ministerial Declaration.¹⁵¹ Paragraph 19 of the Declaration records that “... the TRIPS council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS agreement and shall take fully into account the development dimension”.¹⁵² Gervais is of the correct view that the impact of this could result in a Panel considering more deeply how these provisions should be interpreted in the context of the TRIPS Agreement as a whole.¹⁵³ In light of the above discussion, it is argued that Articles 7 and 8 should be interpreted to constitute the *threshold of the Agreement* and that all measures taken under TRIPS to protect and promote intellectual property rights be subject to these Articles. If this interpretation is adopted, only then will the balance sought in the Preamble to the Agreement be achieved, and only then will TRIPS be of mutual benefit to both those Members who have called for higher intellectual property protection on the one hand, and those Members who may be labelled as the consumers of intellectual property and called for lesser protection on the other hand. In this respect, therefore, the underlying policy debate within the context of TRIPS parallels the debate on the broader level at the WTO. A debate which emphasises upon the tensions between developed and developing states and the management of their competing but sometimes complicated interests.

¹⁵¹ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p122.

¹⁵² Section B of Part One of the Doha Ministerial Conference Declaration.

¹⁵³ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p122. Article 1 provides that Members may, but are not be obliged to, implement more extensive protection than required by TRIPS.

3.4 Part I: General Obligations

3.4.1 Basic Principles

Part I of TRIPS encompasses the general provisions and basic principles of the Agreement. It sets out the nature and scope of the relevant obligations of its Members.¹⁵⁴ Article 1 states boldly that Members are to “give effect” to the provisions of TRIPS. “Giving effect” restates the basic international legal obligation of *pactum sunt servanda* (parties should honour their agreements) and provides a broad mandate which entails that the scope of the Article is not merely limited to changes of a legislative nature.¹⁵⁵ It extends to intergovernmental arrangements and, therefore, Members that are parties to arrangements of this nature must employ reasonable measures to ensure consistency between such arrangements and the Agreement.¹⁵⁶

By providing that Members have the option, but are not obliged to, introduce more extensive protection than that introduced by TRIPS, the Agreement indicates that its rules supply the bare minimum protection and thus provide a base line for intellectual property protection.¹⁵⁷ It establishes the minimum requirements to be honoured by a Member. Therefore in terms of the Agreement a Member may raise its level of protection to the so-called “TRIPS-plus”¹⁵⁸ level, but may not however decrease its intellectual property rights protection to a level that falls short of satisfying the requirements under TRIPS. In terms of Article 1:1 Members are also afforded the liberty to freely implement their own mechanisms that result in compliance with the demands of TRIPS. They are therefore free to independently determine what the most

¹⁵⁴ Article 1.

¹⁵⁵ http://www.iprsonline.org/unctadictsd/docs/RB_1.2_update.pdf. (Accessed on 8 May 2006).

¹⁵⁶ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p81.

¹⁵⁷ http://www.unctad.org/en/docs/edmmisc232add18_en.pdf. (Accessed on 11 June 2006).

¹⁵⁸ This term is not defined in TRIPS but is widely used by authors in this area. The “TRIPS-plus” term is used to refer to protection of intellectual property rights on a level higher than that required by TRIPS. This is allowed in Article 1 of the Agreement.

effective scheme would be to meet their obligations under TRIPS, within the context of their own legal systems.¹⁵⁹

Article 2 of the Agreement incorporates the Paris Convention of 1967, and calls for Member compliance with Articles 1 to 12 and 19 thereof in respect of Parts II, III and IV of the TRIPS Agreement. Articles 1 to 12 and 19 constitute the substantive provisions of the Paris Convention.¹⁶⁰ What transpires is that, due to the application of Article 2, Members are bound by the Paris Convention notwithstanding a failure by them to pledge to this Convention previously.¹⁶¹ In *United States – Section 211 Omnibus Appropriations Act of 1998* the Appellate Body mentioned that all “WTO members, whether they are countries of the Paris Union or not, are obliged...to implement those provisions of the Paris Convention (1967) that are incorporated into the TRIPS Agreement”.¹⁶² Thus, those necessary measures must be employed by Members to bring their national legislation into conformity with the demands of the Paris Convention regardless of previous membership thereof.¹⁶³ Article 2:2 further provides that nothing from Parts I to IV of the Agreement shall negate those duties imposed upon Members towards each other by virtue of the Paris, Berne and Rome Conventions and the Treaty on Intellectual Property in Respect of Integrated Circuits respectively. In effect, by virtue of Article 2:2, Members who are parties to the mentioned Conventions are prohibited from circumventing their obligations under these Agreements on the basis of the TRIPS Agreement. Thus no argument used in light of TRIPS could sustain the derogation of a duty under any of these other Agreements.¹⁶⁴ The implication of Article 2:2 can be illustrated by the following excerpt:

¹⁵⁹ Appellate Body Report *India-Patents (US)*, at para 59.

¹⁶⁰ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p95.

¹⁶¹ The application of external Conventions is scattered throughout the TRIPS Agreement. For instance, Article 9 requires Members to comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. Article 14 provides that the provisions of Article 18 of the Rome Convention apply in all respects to the rights of performers and producers of phonograms. Furthermore, Article 16 provides that Article 6bis of the Paris Convention is to apply in all respects to trademark services.

¹⁶² Appellate Body Report *United States – Section 211 Omnibus Appropriations Act of 1998* at para 125.

¹⁶³ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p95.

¹⁶⁴ *Ibid* at p81.

“This would mean that, by virtue of the conclusion of the WTO Agreement, e.g. Berne Union Members, cannot derogate from existing obligations between each other under the Berne Convention. For example, the fact that Article 9.1 of the TRIPS Agreement incorporates into that Agreement Articles 1-21 of the Berne Convention with the exception of Article *6bis* does not mean that the Berne Union Members would henceforth be exonerated from this obligation to guarantee moral rights under the Berne Convention.”¹⁶⁵

To interpret the above paragraph: the Arbitration decision tries to explain (by way of example) that because *TRIPS* Members are not required to honour Article *6bis* of the Berne Convention in terms of TRIPS Article 9:1, does not mean that parties to the Berne Convention (who are also Members of the TRIPS Agreement) need no longer honour Article *6bis* of the Berne Convention. This echoes the import of Article 2:2.

3.4.2 The National Treatment Principle

The National Treatment Principle (Article 3) and the MFN Principle (Article 4) of TRIPS seek to introduce an element of fairness and non-discrimination to aspects of intellectual property related to trade, on both a national and international level.

Article 3 of TRIPS mandates Members to observe the principle of “National Treatment” which has been described by the WTO Appellate Body as one of the cornerstones of the world trading system.¹⁶⁶ By virtue thereof a Member must treat the nationals of co-Members in a manner that is equal to the treatment given to that Member’s own nationals, in relation to the protection of intellectual property rights. Therefore in summary, Article 3 calls upon Member A to afford the same intellectual property rights protection to the nationals of Member B that Member A would have afforded to its own nationals. The implication of this principle, in light of TRIPS, lies in the restriction that a Member should refrain from giving special protection to its domestic innovators or innovations which it fails to afford to foreign ones.¹⁶⁷

¹⁶⁵ Decision by the Arbitrators *EC-Bananas (Ecuador) (Article 22.6 – EC)*, at para 149.

¹⁶⁶ Appellate Body Report *United States – Section 211 Omnibus Appropriations Act of 1998*, at para 238.

¹⁶⁷ Lal Das *The World Trade Organisation A Guide to the Framework for International Trade* (2000) at p359.

Article 3 has close relations to the National Treatment principle in GATT and other WIPO Conventions; however it uses a different legal formula and possesses different legal characteristics.¹⁶⁸ Nevertheless, in essence the general principles remain the same.¹⁶⁹ Significantly however, relative to Article 3, the Panel of the DSB has drawn its boundaries of scope and application. It held that as expressed in the footnote of Article 3, the principle does not apply to intellectual property rights generally, rather only to those matters affecting the use of intellectual property rights as specifically addressed within the TRIPS Agreement.¹⁷⁰ The question whether Article 3 allows for new classes of subject matter to fall within the National Treatment obligation, therefore remains unanswered.¹⁷¹ Geller opines that the answer to this question is “...critical for knowing how far TRIPS panels may go in resolving disputes between W.T.O members, as well as the principles that might guide them on the way”.¹⁷²

3.4.3 The MFN Principle

The twin to Article 3, is Article 4.¹⁷³ It advocates the Most Favoured Nation principle, which introduces a new element to the international intellectual property framework.¹⁷⁴ The principle which is well established in the multilateral trade arena, provides that any advantage or similar benefit granted to nationals of any country (regardless whether that country is a WTO member or not), must similarly and unconditionally be conferred upon the nationals of *all* other WTO Members. Therefore, Member A must refrain from granting additional benefits to Member B (with regard to the protection of its intellectual property rights), unless Member A confers that same benefit

¹⁶⁸ http://www.unctad.org/en/docs/edmmisc232add18_en.pdf. (Accessed on 11 June 2006).

¹⁶⁹ *Ibid.*

¹⁷⁰ Panel Report on *Indonesia – Autos*, para 14.275-14.276.

¹⁷¹ Goldstein *International Copyright Principles, Law and Practice* (2001) at p 79.

¹⁷² Geller *Intellectual Property in the Global Market Place: Impact of TRIPS Dispute Settlements* (1995) 29 Int'l Law. 99 at p105.

¹⁷³ Bhala *International Trade Law: Theory and Practice* 2 ed. (2000) at p1176.

¹⁷⁴ Goldstein *International Copyright Principles, Law and Practice* (2001) at p85.

unconditionally to all other Members of TRIPS.¹⁷⁵ Article 4 thus purports to ensure uniformity and fairness in the multilateral trading sphere, extending that fairness to intellectual property on an international level.¹⁷⁶

3.5 The Enforcement of Intellectual Property Rights

TRIPS emphasises the enforcement of intellectual property rights legislation under the Agreement.¹⁷⁷ Enforcement of intellectual property rights is regulated by Part III of the Agreement and allows for this by setting out general principles applicable to enforcement, domestic procedures for enforcement, and remedies which make enforcement a greater probability.¹⁷⁸ Enforcement measures under TRIPS have been described by Revesz to be perhaps the most significant contribution of TRIPS to the promotion of intellectual property rights.¹⁷⁹ Gervais describes Part III as one of the major achievements of the WTO negotiations.¹⁸⁰ I would agree that without provision for the enforcement of intellectual property rights, these rights would be insignificant and the system would be worthless.

Viewing these enforcement measures provided by TRIPS contextually, Article 41 enunciates the general enforcement obligations incumbent upon Members.¹⁸¹ Articles 42 to 50 set out the civil and administrative procedures and the remedies that should be afforded to intellectual property right holders (right holders) by Members.¹⁸² Articles 51 to 60 provides for the border control of intellectual property counterfeiting and

¹⁷⁵ By use of the word “unconditionally” in Article 4, it is understood that even if a similar benefit is conferred upon others, but the benefit granted is subject to a condition, then the principle nevertheless remains violated.

¹⁷⁶ What is interesting to see, however, is that the MFN principle requires only that a Member treat all *foreign* creative goods equally, allowing it to favour the creative goods of its own nationals if it wishes. See Goldstein *International Copyright Principles, Law and Practice* (2001) at p79.

¹⁷⁷ Lal Das *The World Trade Organisation A Guide to the Framework for International Trade* (2000) at p 359.

¹⁷⁸ *A More Detailed Overview of the Trade-Related Aspects of Intellectual Property Agreement* www.wto.org .

¹⁷⁹ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper* www.pc.gov.au/research/stafres/trips.pdf.

¹⁸⁰ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p81.

¹⁸¹ www.delpak.cec.eu.int/WHATSNEW/Guidelines.pdf. (Accessed on 7 July 2006).

¹⁸² *Ibid.*

Article 61 calls upon Members to institute criminal procedures and remedies in matters of wilful commercial trademark counterfeiting or copyright piracy.¹⁸³ Lastly, Articles 62 and 63 provide for the establishment of multilateral consultation and dispute settlement.¹⁸⁴

In this light the new enforcement provisions under TRIPS contain two distinct aspects.¹⁸⁵ One which affords guidelines for effective domestic enforcement of TRIPS requirements, and the other which provides Members with a channel for settling disputes among themselves.¹⁸⁶

3.5.1 Section 1 of Part III

As mentioned, Section One of Part III provides for the general obligations to be honoured by Members in respect of the enforcement of rights. It adopts an approach of obligating Members to set up administrative and judicial machinery within their jurisdictions which will enable the holders of intellectual property rights to effectively protect their interests.¹⁸⁷ In terms of Article 41:1 Members are required to incorporate the enforcement procedures provided by TRIPS into their own national legal systems, which must in turn allow the nationals of fellow Members to take effective action against conduct which constitutes an infringement of their rights.¹⁸⁸ Members are further required by Article 41:1 to enact laws which provide right holders with

¹⁸³ *Ibid.*

¹⁸⁴ *Ibid.*

¹⁸⁵ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper*
www.pc.gov.au/research/stafres/trips.pdf

¹⁸⁶ *Ibid.*

¹⁸⁷ http://www.unctad.org/en/docs/edmmisc232add18_en.pdf. (Accessed on 11 June 2006).

¹⁸⁸ Just as TRIPS provides for the protection of intellectual property rights on the one hand, it also allows Members to provide limited exceptions to these rights on the other. Generally the exceptions are permitted as long as they do not conflict with the normal exploitation of the right or unreasonably prejudice the legitimate interests of the holder. For instance, Article 13 permits exceptions to copyright, as long as the legitimate interests of the copyright holder are not unreasonably prejudiced or the exceptions do not conflict with the normal exploitation of the work. Article 17 permits exceptions to trademarks provided that the exceptions take account of the legitimate interests of the owner of the trademark and of third parties. Article 30 also allows exceptions to patent rights as long as the exceptions do not conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner and third persons.

remedies that allow speed prevention and deterrence of further infringement. However, it is observed that the Article also purports to dictate that the procedures implemented be constructed in a manner that prevents the abuse of these very procedures. The reason for this is that while *bona fide* disputes do exist, the procedures must not allow the “infringer” to delay or avoid legal action taken against them.¹⁸⁹ Of significant importance is that Article 41:1 lastly demands that the remedies provided by Members’ legal systems should steer clear of establishing obstacles to legitimate trade.

Article 41:2 sets out the principle that the implementation by Members of enforcement procedures under TRIPS should be “fair and equitable” and should further refrain from being “unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays”.¹⁹⁰ The Panel explained the concept of this Article in the *Canada – Patent Term* Report. In this Report, the Panel found that Canada unnecessarily complicated enforcement procedures and effectively violated Article 41:2 by requiring an applicant to resort to delays such as abandonment, reinstatement, non-payment of fees and non-response to a patent examiner’s report. The Panel further mentioned that:

“ By their very nature, the delays, which are not tied to any valid reason related to the examination and grant process, would be inconsistent with the general principle that procedures not entail ‘unwarranted delays’ as expressed in Article 41.2...”¹⁹¹

The effect, and importance, of Article 41:2 is that enforcement procedures involving the violation of intellectual property shall not be subject to any procedure that complicates enforcement beyond what is the norm in the country concerned.¹⁹²

Article 41:3 rather boldly moves to the point of dictating to a Member’s judicial authority.¹⁹³ It instructs judicial officers to take a decision based only on evidence that

¹⁸⁹ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p288.

¹⁹⁰ To me it seems that Article 41:2 is in some respect a confirmation of Article 41:1 in that Members wanted to better secure access to effective remedies. Looking at the two Articles together, the first requires speedy remedies, and the second requires that remedies should not be of unnecessary delay. Thus Article 41:2 is just the other side of the ‘Article’ 41:1 coin.

¹⁹¹ Panel Report *Canada – Patent Term*, at para 6.117.

¹⁹² Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p 288.

is disputable by the parties. This seems to coincide with the well-established *audi alteram partem* principle which demands that the other party be heard. The decision should further be in writing, with reasons, and should be given to the parties to the dispute within a reasonable time frame. This provision may allow for a better understanding of a Member's judicial system and is possibly required where an appeal is desired.¹⁹⁴ Furthermore, Article 41:4 demands that Members provide opportunities for review of findings except where the finding entailed an acquittal in a criminal case.

A discussion of Article 41:5 may commence by saying that it clarifies what Part III does *not* purport to achieve. The Article establishes two fundamental principles.¹⁹⁵ The first principle is that Part III of the Agreement does not require a Member to create a separate judicial system for the enforcement of TRIPS obligations. Rather, the enforcement measures required may legitimately be incorporated into the Member's judicial system that provides for the enforcement of law in general. Neither does Part III affect a Member's capacity to enforce its own law in general. The second fundamental principle of Article 41:5 is that Part III does not impose an obligation upon Members "with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general".¹⁹⁶ Effectively, if a Member generally lacks competence or resources in the administration of its civil legal system, it is then not obliged to afford special attention to matters of TRIPS enforcement.¹⁹⁷

3.5.2 Subsequent sections of Part III

Sections 2 to 5 of Part III makes intellectual property rights enforceable by providing *inter alia*, for matters concerning civil procedure and remedies, provisional measures,

¹⁹³ With regard to civil proceedings, a Member's judicial authority is also allowed to place an onus upon the defendant to prove that he/she did not infringe another's right. See Article 34 which allows this in respect of patent processes.

¹⁹⁴ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p288.

¹⁹⁵ F. Abbott *Course on Dispute Settlement in International Trade, Investment and Intellectual Property* UNCTAD/EDM/Misc. 232/Add.18 (2003) at p29.

¹⁹⁶ *Ibid.*

¹⁹⁷ *Ibid.*

border control measures and criminal procedures and sanctions for the infringement of rights. Articles 42 to 49 establish basic principles for the performance of civil proceedings to enforce intellectual property rights, such as through actions brought by right holders to enjoin infringement.¹⁹⁸ The rules provided are well established in developed legal systems, and include rights that are equally favourable to both the defendant and complainant.¹⁹⁹ Generally, the principles dictate that Members offer satisfactory remedial mechanisms, and allow parties to present and question and test evidence in proceedings.²⁰⁰ They ultimately provide for flexibility in enforcement.²⁰¹

Article 50 at its crux instructs Members to provide its judicial authorities with the competence to order effective provisional measures that prevent: intellectual property infringement and the entry of infringing goods into their “channels of commerce”.²⁰² These authorities must be empowered to adopt provisional measures *even in the absence* of the “alleged infringer” where the court deems this fit or where delay would result in irreparable harm to the right holder.²⁰³ However, where this has occurred, the affected party must be given prompt notice thereof (after execution by the latest), and must be given a right to have the decision reviewed.²⁰⁴

Members are also instructed to empower their customs authorities with a competence to suspend the release of alleged “infringing goods” when ordered by a relevant ‘competent authority’ to do so. These ‘competent authorities’ may be either administrative or judicial in nature. However, the order will be given by the ‘competent authority’ only where an application in writing was lodged by the right holder to the relevant authority, and the right holder has valid grounds for suspecting an importation of products that violates its rights.²⁰⁵

¹⁹⁸ *Ibid* at p30.

¹⁹⁹ *Ibid.*

²⁰⁰ *Ibid.*

²⁰¹ *Ibid* at p31.

²⁰² Article 50:1 (a).

²⁰³ Article 50:2.

²⁰⁴ Article 50:4.

²⁰⁵ Article 51.

Unique to the TRIPS Agreement, Part III also provides for *criminal* penalties where violations of intellectual property rights have been found to exist.²⁰⁶ By virtue of Article 61, Members are to make remedies available which include imprisonment and fines, which must be consistent with the penalties applied to crimes of a “corresponding gravity”. Whereas the Article allows for criminal procedures and penalties to be applied in any case of intellectual property right infringement, they *must* however apply where “wilful” commercial trademark counterfeiting or copyright piracy has occurred.²⁰⁷

3.6 Dispute Settlement

As mentioned earlier, the new enforcement provisions under TRIPS contain two distinct aspects.²⁰⁸ One of those aspects affords guidelines to Members for effective domestic enforcement of TRIPS.²⁰⁹ This aspect as we have seen, is to be found under Part III of TRIPS. The other aspect mentioned, was that it provides Members with a channel for settling disputes among fellow Members.²¹⁰ This is to be found under Part V of the TRIPS Agreement.

Firstly, Part V requires an element of transparency in the national laws of a Member and therefore, decisions taken in respect of its TRIPS obligations are to be published in a national language, so that other Members and right holders may become acquainted with them.²¹¹ However, the transparency requirement should not be extended to the point that it requires Members to disclose matters which are of a confidential nature, that are contrary to the public interest, or that are to the detriment of particular legitimate commercial interests.²¹²

²⁰⁶ Article 61.

²⁰⁷ It is clear from the wording of section 61 that an intention to infringe has to exist in order for sanctions to be imposed and thus unintentional infringement shall constitute a legitimate defense.

²⁰⁸ Revesz *Trade Related Aspects of Intellectual Property Rights – Staff Research Paper*
www.pc.gov.au/research/stafres/trips.pdf.

²⁰⁹ *Ibid.*

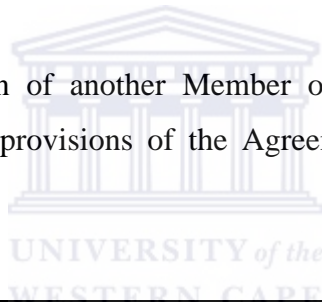
²¹⁰ *Ibid.*

²¹¹ Article 63:1.

²¹² Article 63:4. Note that a difference exists between the Dispute Settlement Understanding and the Dispute Settlement Body. The former entails the body of laws (or the Agreement) which is applied to

Article 64 provides Members with an effective mechanism to settle intellectual property related disputes that arise among them. The Article incorporates the provisions of GATT and stipulates that Articles XXII and XXIII of the GATT 1994 shall apply to TRIPS in the manner elaborated and applied by the Dispute Settlement Understanding²¹³(DSU).²¹⁴ However, the application of GATT articles to TRIPS entail some slight ‘modifications’.²¹⁵ A Member of GATT may initiate an action in the DSU if a benefit under the Agreement is being nullified or impaired, or when the satisfaction of an objective under the Agreement is being obstructed due to a Member failing to discharge its obligations.²¹⁶ However, under TRIPS Members were denied two alternative conditions under Article XXIII [subparagraphs 1 (b) and (c)] of GATT which were causes for action under other Agreements.²¹⁷ These conditions relate to the nullification or impairment of benefits or an obstruction to the achievement of any objective of the Agreement due to:

“(i) the application of another Member of any measure, whether or not it conflicts with the provisions of the Agreement [Article XIII.1 (b) of GATT 1994] or



dispute settlements among Members, whereas the latter refers to the actual judicial body that solves the disputes which arise among Members.

²¹³ A discussion dealing with the Dispute Settlement Understanding and its procedures is a matter which falls outside the scope of this paper. However, it suffices to say that the major aspects of the DSU are: (1) Consultation, (2) The Panel Process, (3) The Appellate Process and (4) The Implementation Process. Consultations commence first. If consultations are not mutually satisfying within 60 days, or if a Member refuses to consult, then the complaining Member may request that a Panel be established. The Member accused may block the establishment of a Panel, but should the Dispute Settlement Body meet for a second time, it can then no longer block the appointment. Article 6.2 of the DSU provides that the request must be in writing, must indicate whether consultations were held, identify the issues and must also summarise the legal basis of the complaint. Should the request be properly lodged, the Panel then has up to a period of 45 days to establish itself and 6 months to reach a decision. If either the complainant Member or the defendant Member is dissatisfied with the report, then either, or both, may appeal against the finding. The Appellate Body may uphold, alter or reverse the finding of the Panel. The Appellate Body must arrive at a finding within 60 days after filing of the appeal, or within 90 days at most. After this, the finding must be implemented by the Member within reasonable time and if it fails to do so, then eventually, retaliatory action may be taken against the non-compliant Member.

²¹⁴ Article 64:1.

²¹⁵ Lal Das *The World Trade Organisation A Guide to the Framework for International Trade* (2000) at p389.

²¹⁶ *Ibid.*

²¹⁷ These alternative actions were denied under TRIPS until 1 January 2000, i.e. “...for a period of five years from the date of entry into force of the WTO Agreement”. (Article 64:2).

(ii) the existence of any other situation [Article XIII.1 (c) of GATT 1994].”²¹⁸

However, these alternatives were only denied until 1 January 2000 and are therefore currently available to TRIPS Members.

3.6.1 Matters Confronting the Dispute Settlement Body (DSB) with Regard to TRIPS

Due to the ‘minimum standards’ nature of TRIPS, the Agreement is regarded as having a unique position within the WTO dispute settlement system.²¹⁹ In effect, the DSB has limited experience with dispute settlement under TRIPS.²²⁰ In the *India – Patent Protection* case, the Panel mentioned that the TRIPS Agreement boasts a “*sui generis*” (unique) status.²²¹ However, this “*sui generis*” nature of TRIPS is regarded as a potential problem for the DSU, opening up the Agreement to various and divergent possible interpretations under national laws.²²² What has been of guidance to the DSB when interpreting TRIPS however is the constant reference to the provisions of the Vienna Convention on the Law of Treaties which provides for methods of WTO Agreement interpretation.²²³

A matter worthy of consideration is that Abbott²²⁴ foresees two basic types of issue regarding the enforcement provisions that are to be faced by the DSB. The first deals with complaints that Members have failed to adopt laws and establish administrative procedures that satisfactorily satisfy enforcement requirements. The second involves complaints that even though Members have adopted the relevant laws, they have failed to operate them in a manner that is effective.²²⁵

²¹⁸ Lal Das *The World Trade Organisation A Guide to the Framework for International Trade* (2000) at p390.

²¹⁹ Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p343.

²²⁰ Watal *Intellectual Property Rights in the WTO and Developing Countries* (2000) at p66.

²²¹ At para 5.19.

²²² Gervais *The TRIPS Agreement, Drafting History and Analysis* 2 ed. (2003) at p343.

²²³ *Ibid.*

²²⁴ F. Abbott *Course on Dispute Settlement in International Trade, Investment and Intellectual Property* UNCTAD/EDM/Misc. 232/Add.18 (2003) at p32.

²²⁵ *Ibid.*

Another fundamental question to be faced by the DSB is how much discretion should be afforded to Members to follow their own customs in matters of enforcement.²²⁶ Of even greater difficulty, is how the DSB will evaluate claims that Members are failing to implement their enforcement obligations.²²⁷ Further confusion is brought about by Article 45:1, which expressly acknowledges that Members need not afford special attention to intellectual property rights enforcement as compared with their general law regime.²²⁸

In light of these issues, Abbott suggests that a claim involving enforcement provisions be approached by the DSB in a manner that considers the “flexible nature” of the TRIPS Agreement.²²⁹ He further provides an answer to the problems identified, by writing these commendable words:

“IPR [Intellectual Property Rights] holders are required to have access to courts or appropriate administrative authorities, and to be afforded basic due process protection. It is not required that right holders be placed in a special category outside the normal civil legal channels. While certain specific requirements must be met, e.g., in respect to the availability of provisional measures, these measures may be those applicable in all civil procedures.... Developing Members with limited enforcement capacity need not specially allocate resources to IPRs enforcement compared to general law enforcement.”²³⁰

Therefore, in support of the above it may be said that in arriving at a finding of such a nature, the DSB is appointed with a role by TRIPS, under Article 41:5, to examine the civil legal channels of the relevant Member and then compare these to its own procedures on TRIPS enforcement. What is important to note here is that the DSB should not compare one Member’s enforcement measures to *another’s* in order to measure enforcement compliance, but rather to the developing Member’s *own* general law enforcement. This is the ‘flexibility’ of TRIPS. Should the two enforcement

²²⁶ F. Abbott *Course on Dispute Settlement in International Trade, Investment and Intellectual Property* UNCTAD/EDM/Misc. 232/Add.18 (2003) at p33.

²²⁷ *Ibid.*

²²⁸ *Ibid.*

²²⁹ F. Abbott *Course on Dispute Settlement in International Trade, Investment and Intellectual Property* UNCTAD/EDM/Misc. 232/Add.18 (2003) at p 33.

²³⁰ *Ibid.*

systems be of parallel significance and efficacy under the developing Member's laws, I fail to see how the DSB would find a situation of non-compliance with TRIPS enforcement measures, even where the developing Member's enforcement implementations are of a less effective nature when compared to those of other Members. This, in my submission, should be the view of the DSB, as long as the efficacy of the measures corresponds with the efficacy of the general laws of that Member, and the measures are in compliance with the rest of the Agreement.

Importantly, it is interesting to note the following words, and I am in full agreement with them. The DSB should "... acknowledge that the TRIPS Agreement allows substantial discretion to members to implement its norms in accordance with national and regional public policy preferences, and taking into account social interests...The WTO DSB is not designed or intended to serve as a civil appellate court for the review of private disputes; it is rather a forum for the settlement of intergovernmental disputes that warrant multilateral attention".²³¹

3.7 The Approach for Interpreting TRIPS?

After all the goals, principles and enforcement laws have been outlined and discussed above, the question arises: How are these goals, principles and laws under TRIPS to be interpreted? Ample authority on the topic is lacking; however, the 'mailbox' case involving India, the US and the EC provides brief answers.²³² The Panel declared that "... the TRIPS Agreement must be interpreted in good faith in light of (i) the ordinary meaning of its terms, (ii) the context and (iii) its object and purpose".²³³

Through the eyes of the Panel, the 'good faith' requirement mentioned in the 'mailbox case', requires the protection of legitimate expectations derived from the protection of

²³¹ Abbott "The Enduring Enigma Of TRIPS: A Challenge For The World Economic System" (1998) 1 *Journal of International Economic Law* 497 at p514.

²³² Panel Report *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* December 1997.

²³³ At para 7.22

intellectual property rights provided for in the Agreement.²³⁴ When interpreting the Agreement, legitimate expectations of WTO Members under TRIPS must be duly considered, including the standards of interpretation previously developed by Panels in the GATT framework, particularly those laying down the principle of the ‘protection of the conditions of competition’ flowing from multilateral trade agreements.²³⁵

Furthermore, interpretation of TRIPS should be guided by Articles 31 and 32 of the Vienna Convention on the Law of Treaties 1969, as well as Articles 3:2 and 19:2 of the DSU, without diminishing the rights and obligations provided under other WTO agreements.²³⁶ These are the limited guidelines laid down by the DSB and will probably increase as time progresses.

Ultimately, it is submitted that for TRIPS to prove successful in the future, the Agreement has to be interpreted in light of the above, but having Article 7 as a threshold. Interpretation of all the provisions of the TRIPS Agreement *must* bring beneficial results to both producers and consumers of intellectual property. An interpretation of TRIPS must not only flow from the letter of the relevant Article, but that Article must further be interpreted in a manner that ultimately disseminates technology, enforces and protects rights in a manner that is conducive to social and economic welfare, and that balances rights and obligations. If this method of interpretation is adopted, only then will the balance sought in the Preamble to the Agreement be achieved, and only then will TRIPS be of mutual benefit to both those Members which have called for higher intellectual property protection, on the one hand, and those Members which may be labelled as the consumers of intellectual property, on the other.

²³⁴ The Appellate Body however has disagreed with the Panel’s decision on legitimate expectations, ruling that a party’s legitimate expectations of a treaty are reflected in the language itself. See also Watal *Intellectual Property Rights in the WTO and Developing Countries* (2000) at p76.

²³⁵ At para 7.22

²³⁶ Watal *Intellectual Property Rights in the WTO and Developing Countries* (2000) at p76.

CHAPTER 4: CRITICISM OF TRIPS

This chapter critically analyses the relationship between the strengthening of intellectual property rights and its impact on health. Consideration will be given to various arguments raised by legal writers, both defenders of strengthened intellectual property rights, and those who raise concerns stemming from the strengthening of these rights. An analysis is undertaken on what measures Members have taken to provide solutions for the problems posed, and the success that these mechanisms have achieved. Conclusions are drawn, and recommendations made as to how poorer countries may utilize the “flexibilities”²³⁷ under the TRIPS Agreement in order to gain stronger bargaining power in other spheres of TRIPS.

4.1 The Issue of Patents and its Relation to Health: A Critical Perspective

In South Africa the HIV/AIDS prevalence rate in 2002 was 25.4%. AIDS and HIV related cases were estimated in 2000 to be at a figure of 203 000 and this figure has more than doubled to 620 000 in 2005.²³⁸ In 2000 the infection rate for those between the ages of 20 and 24 was 29.1%; between 25 and 29 years, 30.6%; between 30 and 34 years, 23.3%; between 35 and 39 years, 15.8%; between 40 and 44 years, 10.2%; and lastly, between the ages of 45 and 49, the rate was 13.1%.²³⁹ A report commissioned by LoveLife for an update on the HIV/AIDS epidemic shows that the main causes of death for people between the ages of 20 and 49 are AIDS related.²⁴⁰ The Medical Research Council (MRC) in 2001 published a report which confirms the escalating impact of HIV/AIDS on the South African community and indicates a significant increase in

²³⁷ “Flexibilities” entails the leeway that Members have to avoid conferring TRIPS protection on certain products or services in certain circumstances.

²³⁸ Joni “The Global Aids Crisis: Access to Treatment for HIV/AIDS: A Human Rights Issue in the Developing World” (2002) 17 *Conn. J. Int'l L.* 273 at p273.

²³⁹ *Ibid.*

²⁴⁰ *Ibid.*

mortality rates especially with regard to the adult population.²⁴¹ These results indicate that the HIV/AIDS epidemic has reached unparalleled proportions in South Africa.²⁴²

Global increases in statistics and extrapolations in developing and least developed countries relate not only to HIV/AIDS, but also to other life threatening diseases such as respiratory infections, malaria and tuberculosis.

It has been shown that these increases stem from a recent lack of essential drugs in developing and least developed countries. However, it has been professed by a minority of authors that these dramatic increases and the lack of access to essential medicines are the results of poverty and bear no relation to the TRIPS Agreement and its strengthening of patent rights in WTO Member countries.²⁴³ As a result, a great debate has ensued as to the role that TRIPS and patented pharmaceuticals have played in the access to essential pharmaceuticals in developing and least developed countries.²⁴⁴

Lehman²⁴⁵ contends that access to affordable medicines involves numerous issues which includes health care infrastructure, international pricing mechanisms, financing and tariffs. The author concludes:

“Perhaps the most important conclusion of this report is that the TRIPS Agreement is not an impediment to the distribution of HIV/AIDS pharmaceuticals. It does not yet apply to the majority of sub-Saharan African countries, and where it does, it permits sufficient flexibility for countries to avoid the negative effects. Similarly, patents are not an issue in access to drugs in sub-Saharan African countries, since most drug companies have not obtained patents widely in Africa. The real issue...is that of adequate financing of the overall health system and the development of health care infrastructures.”²⁴⁶

²⁴¹ *Ibid.*

²⁴² *Ibid.*

²⁴³ *Ibid.*

²⁴⁴ Lehman *Patents and Health* Discussion Paper (2002) at p12.

²⁴⁵ *Ibid.*

²⁴⁶ *Ibid.*

Dr Attarran corroborates this by contending that a lack of medicines in poorer countries is not a result of strengthened patents, but poverty. He argues that the fundamental obstruction to finding a solution to the problem of AIDS treatment in lesser developed countries is an absence of finances to set up a treatment infrastructure and to purchase and distribute antiretroviral therapies.²⁴⁷

Many authors, however, beg to differ and I subscribe to their view. For instance, Sirothiya submits:

“Around the world, public concern is mounting at how the introduction of strict patent regimes in developing countries required by the WTO's TRIPS Agreement is causing the price of patented drugs to be set at high, often exorbitant levels. The effective monopolies granted by TRIPS allow pharmaceutical giants to suppress competition from alternative, low-cost producers and to charge prices far above what is reasonable. This is done at the expense of many ordinary consumers who are too poor to afford treatment. Before the establishment of the TRIPS Agreement in 1994, countries were allowed more options to exclude sectors from patent rules in their national laws. Approximately 50 countries (both developed and developing) excluded pharmaceutical products from patenting. However, with the implementation of the TRIPS Agreement, member countries are no longer allowed to do this. In developing countries, the TRIPS Agreement has exacerbated conflicts between private corporate interests, and the public interest including public health. The controversy over access to medicines has highlighted just one aspect of the imbalances within the TRIPS Agreement, which is too heavily tilted in favour of private right holders and against the public interest. There is growing evidence of social and economic problems caused by the introduction and enforcement of stricter intellectual property rights, which developing countries are obliged to implement as part of their obligations under TRIPS...”²⁴⁸

The author continues:

“The multinational drug companies in these [developed] countries own most of the pharmaceutical technologies and products through patents...Domestic manufacturing of pharmaceutical products in developing countries will come to a standstill.”²⁴⁹

²⁴⁷ *Ibid.*

²⁴⁸ Sirothiya *Intellectual Property Rights And the Challenges Faced by the Pharmaceutical Industry* www.indlaw.com.

²⁴⁹ *Ibid.*

Oxfam raises the concern that:

“At the moment, TRIPS is highly discriminatory. It allows rich countries to override medicine patents in the public interest and to commission generic equivalents from another manufacturer but effectively denies this right to poor countries, which are the ones that most need affordable medicines... Almost all developing countries are caught in a Catch-22 situation. They don't have the technology or size of market to manufacture affordable generic versions of new medicines for themselves but TRIPS restricts any other country from supplying them. The bottom line is that they have to either pay the high price of the patented product – which they can ill-afford – or go without.

Rich countries can bargain effectively over prices but a developing country is at the mercy of Goliath-sized companies often bigger than its national economy”²⁵⁰

Considering the arguments relevant to this matter holistically, it is submitted that the factors mentioned by Lehman and Attaran cannot be understated. Nevertheless, it cannot go unseen that a strong causal link *does* exist between TRIPS and strengthened intellectual property rights, and the shortage of *affordable* medicines in developing and least developed countries. The TRIPS Agreement requires that Members are to protect inventions and that patents are to be recognised for pharmaceuticals without discrimination between imported and locally produced products.²⁵¹ Protection for patents is to be for at least 20 years from the date of application, the scope of exemptions is now limited and the rights are to be enforced judicially.²⁵² All Members are thus bound to grant patents for pharmaceutical products.

The most significant provisions of the TRIPS Agreement in relation to patent protection are found in Articles 27 to 34.²⁵³ These Articles impose obligations upon Members to provide minimum standards of protection for inventions (for a period of twenty years from the patent application filing date).²⁵⁴ Importantly, the provisions require Members to afford patent protection for inventions in all fields of technology whether the

²⁵⁰ Oxfam *TRIPS* Background Paper (2002) at p1.

²⁵¹ Correa *Health and Intellectual Property Rights* Bulletin of the World Health Organisation (2001) Ref no 01-1286 at p1.

²⁵² *Ibid.*

²⁵³ Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* at p218.

²⁵⁴ *Ibid.*

invention is a product or process.²⁵⁵ Article 28 confers upon patent holders certain exclusive rights, including a right to prevent third parties from exploiting the invention without the authority of the patent holder. A third party is consequently prevented from using, making, offering for sale, selling or importing the invention in absence of authority to do so.²⁵⁶

4.2 A Different Question

It is thus submitted that Lehman's investigation is premised upon a different question. What was investigated by the author was the local factors within specific countries. As a result, the learned author correctly concludes that access to pharmaceuticals in poorer countries depends substantially on infrastructure and finances.²⁵⁷ This submission has indisputable substance. What was not noted, however, is that the issue (whether TRIPS affects access to essential medicines) should not be investigated solely from the perspective of a certain country's abilities independently. The learned author correctly mentions that due to a *specific* country lacking the facilities and infrastructure, medicines are inaccessible.²⁵⁸ However, what was not noted is that other countries, such as India and Brazil, are well equipped to manufacture pharmaceuticals. If poorer countries were able to import from countries with these abilities, they would be able to provide more medicines, more affordably, while simultaneously developing their long term infrastructure. The poorer countries' position would be stronger if Brazil and India were then to compete with each other (hypothetically speaking). However, due to TRIPS, countries that possess the ability to produce cheaper drugs are not permitted to do so, let alone export the medicines to those countries unable to manufacture them themselves. It is in this manner that strengthened patent rights affect accessibility to health drugs. It is therefore submitted that Lehman's investigation addresses the issue of pharmaceutical inaccessibility from a different perspective. The author's inquiry was not: "What are the impacts of *TRIPS and strengthened patents* on access to essential pharmaceuticals?" but rather: "What are the major causes of a least developed country's

²⁵⁵ Article 27 of the TRIPS Agreement.

²⁵⁶ Article 28 of the TRIPS Agreement.

²⁵⁷ Lehman *Patents and Health* Discussion Paper (2002) at p12.

²⁵⁸ *Ibid.*

inaccessibility to essential pharmaceuticals?”. In this case obviously, the TRIPS Agreement would be one of the least important factors to pay attention to.

Lehman further submits²⁵⁹ that patents are not an issue in access to essential medicines in sub-Saharan African countries, since most drug companies have not obtained patents widely in Africa. The fact that most companies have not obtained patents in African countries *might* be true, but this has no significant bearing on how TRIPS affects accessibility to pharmaceuticals. Even if no patent protection exists in Sub-Saharan countries, these countries are harmless as they lack the ability to reproduce those unprotected medicines, and therefore, nothing results from it (which might be the main reason why the medicines are not protected in the first place). However, it is in those very countries that *do* possess the abilities to reproduce cheaper pharmaceuticals, where those pharmaceuticals are patented. The result is, that, even though no patent protection for pharmaceuticals *might* exist in these poorer countries, they are still unable to reproduce them, nor can they import cheaper ones, because those Members with the abilities to reproduce cheaper medicines are not allowed to reproduce the protected medicines (let alone export them).

Lehman also aptly points out that TRIPS permits sufficient flexibility for countries to avoid the negative effects of patent protection. As will be discussed below however, the Agreement poses problems, and the flexibilities highlighted by Lehman are harder to employ than appears to be apparent at first blush. Furthermore, if the real issue was inadequate financing, then how are poorer countries to address it if patents exacerbate the issue of cost and finance affordability?

²⁵⁹ *Ibid.*

4.3 A Suggested Analysis of the “True Position”

The intensive use of the patent system by major pharmaceutical firms is intended to protect their competitive edge by keeping out their competitors.²⁶⁰ Due to the strengthening of patent rights, which effectively allows for the exclusion of all others from a given market, giant pharmaceutical manufacturers hold strong patents on essential medicines and, as a result, these firms are able to unreasonably exploit the market and charge unreasonable and unaffordable prices for their products.²⁶¹ The patent holder is allowed to unilaterally set the prices of the patented commodity.²⁶² Employment of the patent mechanism in this manner stifles innovation, restricts the flow of information to poorer countries and eliminates competition from generic manufacturers.²⁶³ This position would have been different if the demand for the commodity was elastic, as this would enable market forces to temper with the ability to set high prices.²⁶⁴ However, the demand for essential medicines is inelastic as patients would basically pay any amount for a life-saving drug with total disregard for its price.²⁶⁵ This means that market forces can only insignificantly impact on price settings, granting the patent holder full liberty to set a price, with full knowledge that desperate people are prepared to make severe sacrifices to purchase the much needed drug.²⁶⁶ However, in developing and least developed countries unfortunately, the sacrifices ready to be made by individuals still fall far short of effective access to essential medicines.²⁶⁷

²⁶⁰ Sirothiya *Intellectual Property Rights And The Challenges Faced By The Pharmaceutical Industry* www.indlaw.com.

²⁶¹ Berger “The Global AIDS Crisis: Tripping Over Patents: AIDS, Access to Treatment and Manufacturing of Scarcity” (2002) 17 *Conn.J.Int’lL.* 157 at p168.

²⁶² *Ibid.*

²⁶³ Sirothiya *Intellectual Property Rights And The Challenges Faced By The Pharmaceutical Industry* www.indlaw.com.

²⁶⁴ Berger “The Global AIDS Crisis: Tripping Over Patents: AIDS, Access to Treatment and Manufacturing of Scarcity” (2002) 17 *Conn.J.Int’lL.* 157 at p168.

²⁶⁵ *Ibid.*

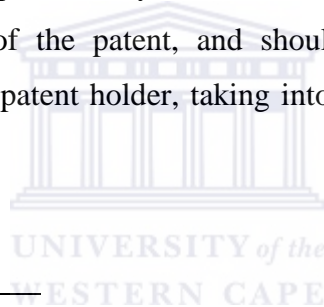
²⁶⁶ *Ibid.*

²⁶⁷ *Ibid.*

4.4 The “Limited” Exceptions

The TRIPS Agreement does however contain flexibilities and exceptions to its stringent patent protection in order to alleviate matters. These mechanisms may then be used as tools in order to limit the rights of the patent holder and thus offset the negative impact of the patent monopoly. Unfortunately, it has been shown that the remedies provided are ineffective.²⁶⁸ The most important exclusions from patent protection are the general exceptions provided by Article 30, the compulsory licence provisions of Article 31 and the parallel importing clauses contained in Articles 28 and Article 5.²⁶⁹

Article 30 permits Members to provide limited exceptions to the exclusive rights granted by patents, provided that these exceptions are compliant with the Article. Therefore, the exceptions provided by Members should not unreasonably conflict with the normal exploitation of the patent, and should not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.²⁷⁰



²⁶⁸ See for instance generally, Joni “The Global Aids Crisis: Access to Treatment for HIV/AIDS: A Human Rights Issue in the Developing World” (2002) 17 *Conn. J. Int’l L.* 273.

²⁶⁹ Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* 211 at p219.

²⁷⁰ Article 30 of the TRIPS Agreement. In the *Canada- Pharmaceutical Patents* case the Panel held that the Article establishes three requirements: (1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; and (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. The Panel held that the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Therefore, failure to comply with any one of the three conditions results in failure to meet the requirements of the Article (see www.wto.org.) For instance, an exception that does not 'unreasonably conflict with the normal exploitation' of the invention could still 'unreasonably prejudice the legitimate interests' of the patent holder and thus fall foul of the ambit of the Article. Furthermore, Mercurio (in Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* 211 at fn 34) explains that Article 30 “authorises limited exceptions to patent rights for such things as research, prior user rights, and pre-expiration testing. Often called the “research exception”, the provision is commonly used by countries to advance science and technology by allowing researchers to use a patented invention to gain a better understanding of the technology. In addition, the provision is also used by countries to allow manufacturers of generic drugs to apply for marketing and safety approval without the patent owner’s permission and before the patent protection expires. The generic producers can then market the drug. This practice, often called the “regulatory exception” or “Bolar” provision, has been upheld as conforming with the TRIPs Agreement”.

4.5 Compulsory Licensing and its Ineffectiveness

The TRIPS Agreement also allows compulsory licensing. Compulsory licensing may be defined as “authorizations permitting a third party to make, use, or sell a patented invention” without authorisation from the patent holder.²⁷¹ In other words, it permits a third party to use a patented invention without the prior consent of the owner of the patent.²⁷² Compulsory licenses are generally authorised where the holder of the patent behaves undesirably (such as anti-competitive, non-working or blocking behaviour), in the event of public need (such as government infringement or national emergency) or in the context of food and drugs.²⁷³ They serve as an important tool to promote competition and increase the affordability of drugs, simultaneously providing reasonable compensation to the patent holder.²⁷⁴ The mechanism could be used to lower current medicines prices and increase access to patented medicines in poorer countries.²⁷⁵

The principle provision permitting compulsory licensing under the TRIPS Agreement is Article 31 thereto. Subject to certain restrictions being respected, the Article allows a WTO Member to authorise a compulsory license for use by its government or a third party who is authorised by that government. Where the Article is employed, non-permitted use of the patented invention is only possible subsequent to a prescribed procedure being followed and authorization is considered on individual merits.²⁷⁶ The proposed user (compulsory licensee) of the patented invention must first take reasonable measures to obtain consent to use from the holder of the patent on reasonable commercial terms.²⁷⁷ These steps must then have brought about an

²⁷¹ Chien “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” (2003) 18 *Berkeley Tech. L.J.* 853 at p854.

²⁷² Kongolo “WTO Doha Ministerial Declaration and Intellectual Property: African Perspectives” (2001) 9 *African Yearbook of International Law* 185 at p192.

²⁷³ Chien “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” (2003) 18 *Berkeley Tech. L.J.* 853 at p856.

²⁷⁴ Sirothiya *Intellectual Property Rights and the Challenges Faced by the Pharmaceutical Industry* www.indlaw.com.

²⁷⁵ *Ibid.*

²⁷⁶ Article 31 (a) of the TRIPS Agreement.

²⁷⁷ Article 31 (b) of the TRIPS Agreement.

unsuccessful result (which has to be pursued for a reasonable amount of time).²⁷⁸ However, a Member may waive this requirement where a “national emergency”, or a matter of “extreme urgency” exists or in cases where the patented invention is exploited for “public non-commercial use”.²⁷⁹ Use of the patented commodity must be non-exclusive and non-assignable.²⁸⁰ Importantly, Article 31 demands that use of the subject matter of the patent (the invention) must be predominantly for the supply of the domestic market of the Member authorizing such use.²⁸¹

The scope and duration of use is limited only to the purpose authorised, and use of the invention is to be terminated where the circumstances which lead to such use cease to exist and are “unlikely to recur”.²⁸² Of significant importance, is that the patent holder in all circumstances is to be adequately remunerated taking the economic value of the authorisation into account.²⁸³

Article 31 has given rise to several issues between developed and developing countries.²⁸⁴ Developing countries desire a more flexible regime in approaching compulsory licensing whereas developed countries attempt to restrain its use only to particular circumstances.²⁸⁵ Interestingly, it has been contended by defenders of strong patent rights that the use of compulsory licensing harms innovation.²⁸⁶ Defenders of strengthened patent rights contend that compulsory licensing acts as a disincentive to the development and marketing of new drugs (Research and Development).²⁸⁷ Chien²⁸⁸ however, questions this contention. In her article, she explores (in six different cases)

²⁷⁸ *Ibid.*

²⁷⁹ *Ibid.*

²⁸⁰ Article 31 (d) and (e) of the TRIPS Agreement.

²⁸¹ Article 31 (f) of the TRIPS Agreement. This is the requirement unless the patent holder has engaged in anti-competitive behaviour.

²⁸² Article 31 (g) of the TRIPS Agreement.

²⁸³ Article 31 (h) of the TRIPS Agreement.

²⁸⁴ Kongolo “WTO Doha Ministerial Declaration and Intellectual Property: African Perspectives” (2001) 9 *African Yearbook of International Law* 185 at p192.

²⁸⁵ *Ibid.*

²⁸⁶ Chien “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” (2003) 18 *Berkeley Tech. L.J.* 853 at p855.

²⁸⁷ *Ibid.*

²⁸⁸ *Ibid.*

whether the use of compulsory licensing over pharmaceuticals in the past, has led to a reduction in innovation. The author rejects the notion and submits:

“In five of the six cases I studied, I observed no measurable decline in innovation. This finding is consistent with earlier work. By available measures, the companies affected by licenses continued to perform research and development ("R&D") in the therapeutic areas targeted by the license. Even in the case of forward-looking compulsory licenses that spanned several years, the decline in R&D that advocates for strong patent rights might predict was not observed. While limited and anecdotal, this and past work suggest that concerns about compulsory licensing are overstated and that the blanket assertion that licensing categorically harms innovation is probably wrong.”²⁸⁹

Berger²⁹⁰ would appear to concur with Chien and expresses a similar line of thought. The author analyses the ‘innovation’ justification for strong pharmaceutical patents. He arrives at a finding that little justification exists for strong patent protection in developing countries and that an insignificant relationship exists between compulsory licensing and incentives for innovation. He sensibly comments: “If people do not have access to life-saving drugs, it makes little sense to provide incentives for their innovation.”²⁹¹

Even if it is argued that stronger patent rights provide incentives, can we not scrutinise the matter from a different perspective? Could it not be argued that where countries are allowed flexible exceptions to patents, the same or similar end would still be achieved? Could competition and a wider competitive market not be a stronger incentive to the development of health, than an unreasonable monopoly?

History and common sense have shown that the presence of competition and rivalry leads to adversaries trying to remain at the forefront of innovation and producing better results. The production of newer medicines and Research and Development would thus

²⁸⁹ Chien “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” (2003) 18 *Berkeley Tech. L.J.* 853 at p855.

²⁹⁰ Berger “The Global AIDS Crisis: Tripping Over Patents: AIDS, Access to Treatment and Manufacturing of Scarcity” (2002) 17 *Conn.J.Int’lL.* 157.

²⁹¹ *Ibid* at p168.

not alter substantially; as although the incentive would change, the result would remain the same. The present incentives are questionable as well. As Correa²⁹² submits, major pharmaceutical firms are driven more by profit than the reduction of diseases and illnesses in poor countries, and therefore mostly manufacture those medicines that are marketable as opposed to those which are much needed. In any case, Abbott²⁹³ has found that while poorer countries are paying such high prices for pharmaceuticals in the name of ‘incentives for innovation’, only 15% of the expenditure of large pharmaceutical firms go to Research and Development (whereas a large portion of the expenditure of these firms goes to advertising and promotion). Correa further submits that this very low expenditure of 15% for Research and Development is then substantially channelled into expanding on the coverage or maintenance of previous patent protection and is not channelled into the development of new drugs.²⁹⁴ Abbott, as a result of his research, correctly concludes that it seems unlikely that providing a mechanism by which developing countries could secure alternative, lower priced sources of medicines would affect pharmaceutical research and development.²⁹⁵

4.6 The Problems created by Article 31

Putting the “compulsory licensing” versus the “hampering of innovation” debate aside, use of Article 31 still poses significant problems. Article 31 prescribes:

“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected...

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;”

²⁹² Correa *Health and Intellectual Property Rights* Bulletin of the World Health Organisation (2001) Ref no 01-1286 at p1.

²⁹³ Abbott “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *A.J.I.L.* 317 at p 323.

²⁹⁴ Correa *Health and Intellectual Property Rights* Bulletin of the World Health Organisation (2001) Ref no 01-1286 at p1.

²⁹⁵ Abbott “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *A.J.I.L.* 317 at p324.

Subsection (f) of Article 31 has played a significant role in the current controversy surrounding strengthened patent protection and accessibility to pharmaceuticals in poorer countries (least developed and developing countries).²⁹⁶ The subsection requires the issuing of a compulsory license to be ‘predominantly for the supply of the domestic market’ of the Member which granted it (thus restricting use of the invention predominantly to within a Member’s borders). Therefore, a country with the ability to manufacture a pharmaceutical product may only issue a license for the *local* manufacture of the product and to supply its internal needs.²⁹⁷ By this requirement the licensee’s ability to export medicines to a poor country that is unable to manufacture pharmaceuticals for its own domestic supply is substantially retarded, and thus the Article is of no use to countries that lack the ability to manufacture pharmaceuticals through their own resources.²⁹⁸ Therefore, in essence, the wording of the Article has the unfortunate result that unless a Member possesses the resources to manufacture the pharmaceuticals *itself*, it cannot obtain the benefits of the already ‘limited’ exceptions under Article 31.

As Abbott submits:

“The limitation imposed by Article 31(f) creates two inter-linked problems:

1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;
2. By requiring compulsory licensees to supply a predominant part of their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.”²⁹⁹

²⁹⁶ Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* 211 at p220.

²⁹⁷ Abbott “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *A.J.I.L.* 317 at p320.

²⁹⁸ *Ibid.*

²⁹⁹ Abbott *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries* Study Paper for the British Commission on Intellectual Property Rights (2002) at p22.

Mercurio³⁰⁰ follows a similar line of thought. He submits:

“Therefore, while Article 31 grants Members the right to issue a compulsory license, it severely limits the circumstances under which such a license can be issued and requires that adequate remuneration be paid for the license. While it is argued that such limitations and conditions ensure against abuse, the practical effect of the limitations and conditions is that countries with manufacturing capabilities could make only very limited use of the provision, and those countries with insufficient or no manufacturing capabilities could not make use of the provision [at all].”

Developing and Least Developed Members³⁰¹ had identified this problem as early as 1998 and had raised much concern, placing enormous pressure on developed Members. As a result Members attempted to arrive at an amicable solution (even though only in theory as we will discover).

4.7 The Doha Declaration of the TRIPS Agreement and Public Health

The concerns raised on the relationship between the TRIPS Agreement and public health care were included on the agenda of discussions leading to a further round of negotiations on the “liberalization of the international trade regime”.³⁰² As a result of a number of developing and least developed countries bringing significant pressure to bear upon developed countries, and in recognition of the public health related problems brought about by the TRIPS Agreement, WTO Members adopted the “Doha Declaration of the TRIPS Agreement and Public Health” (The Doha Declaration).³⁰³ The Doha Declaration was adopted in November 2001 at the Ministerial Conference of the WTO meeting in Doha, Qatar, and seeks to clarify how the TRIPS Agreement and its flexibilities are to be interpreted.³⁰⁴ The Declaration re-affirms that the TRIPS Agreement is to be interpreted and implemented in a manner that protects the right to

³⁰⁰ Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* 211 at p220.

³⁰¹ For a list of Developed Members, see Annexure A1. For Developing Members, see Annexure A2. For a list of Least Developed Members, see Annexure B.

³⁰² Lehman *Patents and Health* Discussion Paper (2002) at p15.

³⁰³ The Doha Declaration of the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) . See Annexure C.

³⁰⁴ Abbott “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *A.J.I.L.* 317 at p319.

public health and particularly promotes accessibility to medicines for all.³⁰⁵ The Declaration states:

“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.”³⁰⁶

The above paragraph essentially declares that the protection of public health and promoting access to medicines is a legitimate basis for Members to enact exceptions to patent protection in their domestic regimes.³⁰⁷ Mercurio³⁰⁸ reiterates that the paragraph reinforces the plain meaning interpretation of Article 8 of TRIPS, which permits members to “adopt measures necessary to protect public health”.³⁰⁹ The Declaration also provides Members with greater liberties in relation to the use of Article 31 of the TRIPS Agreement. Paragraph 5 provides:

“Each Member has the right to grant compulsory licenses and the freedom to determine the grounds on which such licenses are granted... [and] the right to determine what constitutes a national emergency...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.”

So as a result of the above, Members were given more leeway to ascertain how to use the compulsory license mechanism. The problems posed by Article 31 (f) were, however, still not solved. Members unable to manufacture pharmaceuticals by means of their domestic resources still had no relief. Paragraph 6 of the Declaration left the matter undecided. Members recognised the problems faced by those countries unable to manufacture pharmaceuticals and make effective use of compulsory licensing, but did

³⁰⁵ *Ibid.*

³⁰⁶ See paragraph 4.

³⁰⁷ Mercurio “TRIPS, Patents and Access to Life Saving Drugs” (2004) 8 *Marquette Intellectual Property Law Review* 211 at p220.

³⁰⁸ *Ibid.*

³⁰⁹ *Ibid.*

not arrive at an amicable solution. The Council for TRIPS was however instructed to find an expeditious solution by the end of 2002.

4.8 The Implementation of Paragraph 6 of the Doha Declaration

It took two years to find a solution to paragraph 6 of the Doha Declaration when (finally) the General Council of the WTO accepted a negotiated settlement in 2003.³¹⁰ The solution was known as: “The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” (Implementation Agreement).³¹¹ The solution agreed upon creates an exception to Article 31 (f) (that a Member is only allowed to manufacture pharmaceuticals for its ‘domestic supply’) and allows Members with inadequate manufacturing capabilities to override stringent patent protection and import generic versions of patented pharmaceuticals in order to combat a public health crisis.³¹²

The Implementation Agreement allows a Member possessing pharmaceutical manufacturing capabilities to produce generic medicines of patented pharmaceuticals for, and export them to, those Members lacking manufacturing capacities.³¹³ It caters for this by allowing an “eligible importing Member”³¹⁴ to obtain generic pharmaceuticals from an “exporting Member”³¹⁵ which has obtained a compulsory licence through a waiver of Article 31 (f) of TRIPS (as permitted by Article 2 of the Implementation Agreement).³¹⁶ Article 3 of the Implementation Agreement then allows the importing Member to waive its obligation under Article 31 (h) of TRIPS (to provide

³¹⁰ *Ibid.*

³¹¹ *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* WT/L/540 2003. See Annexure D.

³¹² *Ibid.*

³¹³ Article 2 (a) of the Implementation Agreement.

³¹⁴ An “eligible importing Member” refers to any least-developed country Member, and any other Member that has notified the Council for TRIPS of its intention to use the system as an importer.

³¹⁵ An “exporting Member” refers to a Member using the system set out in the Implementation Agreement to produce pharmaceutical products for, and export them to, an eligible importing Member.

³¹⁶ *Hjertman Report Based on Questionnaire no:4: Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health* Special Committee Q94: GATT/WTO at p2.

the patent holder with adequate remuneration) as it requires the ‘*exporting Member*’ to do so. This prevents the patent holder from receiving double compensation.

In my opinion the model introduced by the Implementation Agreement entails a safeguard mechanism that is designed to allow the justifiable use of an invention by a Member, but prevent use that might lead to the unreasonable exploitation of the patent (which essentially leads to the degradation of the legitimate interests of the patent holder). This is achieved by requiring Members to satisfy certain conditions and follow a prescribed procedure in order to activate the mechanism. For it to be used effectively, the ‘importing Member’ is required to inform the Council for TRIPS of its intentions and must specify the expected quantities of the products needed.³¹⁷ If the importing Member is a developing country, it must further establish to the Council its inability to manufacture the pharmaceuticals itself.³¹⁸ Furthermore, if the product to be imported is patented within the borders of the ‘importing Member’, that Member must confirm to the Council that it has granted (or intends to grant) a compulsory license in accordance with Article 31 of TRIPS and the provisions of the Implementation Agreement.³¹⁹

Article 2 (b) of the Agreement then requires that the ‘exporting Member’ reproduce generics only to the extent that it meets the needs of the importing country, and also requires export of the entire production. Furthermore, the appearance of the reproduced generic must clearly indicate (through labelling, marking, colouring, shaping, packaging, etc.) that it has been reproduced for the purposes of, and through the mechanisms provided by, the Implementation Agreement.³²⁰

In summary, the Implementation Agreement brings a much needed solution to the problems facing developing and least developed Members (as a result of TRIPS), and

³¹⁷ Article 2 (a) of the Implementation Agreement.

³¹⁸ This requirement does not apply to least developed country Members, since these Members are *deemed* to lack manufacturing capacities in the pharmaceuticals sector. See Annex to the Agreement.

³¹⁹ Article 2 (a) of the Implementation Agreement.

³²⁰ The licensee is also required to post information on a website pertaining to the quantities being supplied to each destination and what the distinguishing features of the products are. These requirements (including the above mentioned) would obviously be to distinguish the generic product from the original product produced by the pharmaceutical firm. This generic product would then be disallowed for use in those Members where the compulsory licence is not granted.

introduces a workable mechanism that allows a more flexible exploitation of patented products. However, the Agreement retains strict regulation thereof. This is seen through the conditions required to be satisfied. Furthermore, through distinguishing the generic product from the original, and requiring a member to “post” information of the generic on a website (most likely a government website), indicate that Members have attempted to set up mechanisms that prevent these generic medicines from entering developed countries, and the sale thereof on the ‘black market’. The purpose of the Agreement is thus to retain the market of the original patent holder (so that the holder may fully benefit from the labour of his mind), but simultaneously allow exceptions so that Members may combat a “health crisis” or a “public emergency”.³²¹ Through this, it is submitted, only now, has the TRIPS Agreement achieved an equitable balance that levels the playing field between developed countries and developing and least developed countries. It can further be seen that the Agreement is to be used strictly for the purposes stated. Exportation of the entire production and prevention of re-exportation shows that Members are attempting to prevent the circumvention of the system and indicate that some Members have sought to prevent the widespread commercial use of the safety mechanism. It is submitted that the Agreement is much needed and will play a fundamental role in relation to public health, but also opens a Pandora’s Box at the same time. This box was intended to remain shut through Article 5 of the Agreement which requires Members to introduce effective legal structures to prevent the sale and importation of these generics within their borders. However, it remains inevitable that conduct, which I will term “generic smuggling”, is bound to occur. Nevertheless, the Agreement is to be welcomed by poorer countries and, properly applied, has the capacity to save human life. However, it is also bound to bring new interpretation challenges to the fore. These challenges are however dramatically decreased by Article 10, which prevents Members from challenging any measures taken in conformity with the provisions of the waivers contained in the Agreement.

³²¹ As mentioned previously, no standard test exists for Members to ascertain whether an emergency exists. Members are free to determine individually whether an emergency exists in order to use the mechanisms provided by TRIPS.

Interestingly, however, a recent survey conducted in 2005 has shown that out of 35 responses, 19 countries have indicated that no steps have been taken to implement any feature of the Implementation Agreement (such as amendments or legislative changes in order to provide import licences).³²² Only 13 countries indicated that ‘some’ measures have been taken or are under consideration and 3 countries were unable to respond.³²³ Nevertheless, the new Agreement brings some solutions to the problems presently faced by many poorer countries (if only temporarily) and is bound to be of great influence in providing easier access to essential pharmaceuticals, and amending the TRIPS Agreement to be initiated by the TRIPS Council as required by Article 11.³²⁴

4.9 Conclusions

Irrespective of the contentions advanced that the TRIPS Agreement does not affect the provision of pharmaceuticals to poorer countries, the introduction of the Doha Declaration and the subsequent Implementation Declaration show clearly that the health concerns raised by poorer countries were not simply ‘just theory’. Poorer countries were at the mercy of giant pharmaceutical companies in developed countries; however, they now possess greater leverage and negotiating powers. This leverage has its source in the many flexibilities given to them by TRIPS, Doha and the Implementation Agreement. These flexibilities include compulsory licensing, parallel importation³²⁵

³²² Hjertman *Report Based on Questionnaire no:4: Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health* Special Committee Q94: GATT/WTO at p4.

³²³ Amongst the 13 countries is South Africa, where consultations have commenced to introduce legislative amendments to existing intellectual property laws. At the same time, an amendment of the Medicines and Related Substances Act of 1965 has introduced an importation licensing model which allows South Africa to parallel import pharmaceuticals circulating in markets outside their borders. See Hjertman *Report Based on Questionnaire no:4: Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health* Special Committee Q94: GATT/WTO at p6.

³²⁴ Article 11 provides that the Implementation Agreement, “including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).”

³²⁵ The subject of parallel importation will be discussed in greater detail in chapter five. Nevertheless, it suffices to say that it refers to a situation “...where a third party, without the authorization of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder, his

and the exception under Article 30. It is virtually guaranteed that the mere threat of employing these flexibilities may result in an amicable compromise (as may be seen from the instance where Brazil had threatened to use compulsory licensing against the United States and which led to a mutually beneficial settlement). It is thus of utmost importance that poorer countries employ and utilize these mechanisms, so as to gain stronger negotiating powers in other spheres of TRIPS. To achieve this, poorer countries should continuously seek advice from sources such as UNCTAD and the WHO, and should pay substantial attention to putting in place the legal infrastructure to achieve this goal.³²⁶

As Correa succinctly concludes:

“Developing countries have some flexibility under the agreement *which they can use* to design national laws that respond to health policy objectives. Other WTO members must respect this flexibility, and recognize that letting commercial interests override public health interests can have disastrous consequences. Patent protection may be necessary for future investments in R&D [Research and Development], but the lives and well-being of millions of people in the developing world depend on this protection being effectively integrated with public health concerns.” (emphasis added)³²⁷

licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licensee. The practice is based on the principle that the patent holder has been remunerated through the first sale of the product and his further control over the resale of the product would unreasonably restrain trade and stifle competition. In other words, having been remunerated the right holders are said to have exhausted their rights”. See Musungu *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks* South Centre (2004) at p26.

³²⁶ Abbott *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health* Occasional Paper 9 (2002) www.geneva.quino.info/pdf/OP9%20Abbott.pdf.

³²⁷ Correa *Health and Intellectual Property Rights* Bulletin of the World Health Organisation (2001) Ref no 01-1286 at p1.

CHAPTER 5: SOUTH AFRICA'S COMPLIANCE WITH THE PROVISION OF TRIPS, WITH SPECIFIC REFERENCE TO ITS OBLIGATIONS IN RELATION TO PATENTS

“Section 15C flies in the face of South Africa’s obligations under TRIPS”³²⁸

To determine the extent of South Africa’s compliance with the provisions of TRIPS it must first be established what TRIPS essentially demands in this regard. In this chapter an analysis of South Africa’s compliance with TRIPS will focus mostly upon the issue of South Africa’s obligatory relationship toward the inventor of a patented invention relative to the question of access to health. Section 5 of the TRIPS Agreement deals with the issue of patents and Article 27 commences with a description of what would qualify as patentable subject matter.

5.1 South African Patent Legislation and TRIPS

Article 27:1 of TRIPS provides that a Member must confer a patent upon *any* invention, whether that invention is a product or process, and regardless of the field of technology of the invention, provided that the invention is (1) ‘new’, (2) involves an ‘inventive step’ (non-obvious) and (3) is capable of ‘industrial application’ (useful).³²⁹ This obligation is honoured by South Africa by virtue of section 25 of the Patents Act (the Act).³³⁰ The section provides that a patent may be granted by the state for *any* new invention, provided that the invention involves an inventive step, and is capable of being used or applied in trade or industry or agriculture. Section 25 is then complemented by section 61(1)(c) which further provides that a patent may be revoked on the ground that the invention is not patentable. Although the wording and structure

³²⁸ Burrell, T. *Burrell’s South African Patent and Design Law* 3 ed. (1999) at p26.

³²⁹ The Article further prescribes that Members are also required to make patent rights available, and enjoyable without discrimination. This relates to the category or the source of the invention and regardless of whether the invention was imported or produced locally.

³³⁰ Act 57 of 1978, as amended.

of section 25 of the Act differ slightly to those of Article 27 of TRIPS, it is nevertheless apparent that section 25 meets all three requirements set out in Article 27.

Similarly, section 45 of the Act honours the international obligations of South Africa imposed by Article 28 of TRIPS. Article 28 requires Members to confer certain rights upon the holders of a patent. Essentially, the rights granted must allow the patent holder to prevent specific conduct by third parties in relation to the invention, where authority was not granted. A patent holder must be empowered with the right to prevent third parties from making, using, offering for sale, selling or importing the patented product or process in the absence of authorization. Section 45 is an exact re-statement of Article 28 and provides that a patent granted by the state shall allow the holder of that patent to exclude others from “making, using, exercising, disposing or offering to dispose of, or importing the invention...”. This is so that the patentee may have and enjoy the full profit and all benefits which arise from and out of the invention.

With regard to the period of protection afforded to patent holders, South African law once again satisfies the international obligations imposed upon its government. Article 33 of the TRIPS Agreement prescribes that the term of protection to be granted to patents shall be for a period of twenty years commencing from the date of filing the application. Section 46 of the Patents Act, although in different wording, produces the same result; it states that the duration of a patent shall be twenty years from the date of application, unless provided otherwise.

As discussed previously in chapter 4, the TRIPS Agreement also permits the issuing of compulsory licenses, subject, however, to certain conditions. The proposed user (compulsory licensee) of the patented invention must first take reasonable measures to obtain “the consent of use” from the holder of the patent on reasonable commercial terms.³³¹ These steps must have brought about an unsuccessful result (which has to be pursued for a reasonable amount of time).³³² The requirement of prior and unsuccessful

³³¹ Article 31 (b) of the TRIPS Agreement.

³³² *Ibid.*

consultation (as prescribed by the TRIPS Agreement) is set out as a precondition for the granting of a compulsory license under the Act. Section 55 provides that a third party (in this case the proprietor of a dependent patent)³³³, may apply to the Commissioner of Patents (the Commissioner) for a compulsory license where an agreement cannot be reached with the holder of the patent. The same requirements are identified under section 56 of the Act, which permits the issuing of a compulsory license where an abuse of patent rights occurs and the patent holder has refused to grant same upon reasonable terms. Sections 55 and 56 further provide that any license granted shall be non-exclusive and non-assignable or transferable except in certain circumstances. This coincides with Article 31(d) and (e) of the TRIPS Agreement.

Reference to the above sections of the Act illustrates that the South African government has taken steps to comply with Article 31 of TRIPS that amongst other requirements, requires prior consultation with the holder of the patent by the third party.

Upon comparing the South African Patent Act with the TRIPS Agreement, it seems clear that South Africa has complied with its TRIPS obligations (in respect of patent law) in so far as the letter of the law is concerned. The Patents Act reflects an attempt by the South African government to comply with its international obligations in relation to intellectual property (specifically patents). But if this is so, then why has the South African government recently (in 2001) been the recipient of strong attack by (initially 42 in number) international pharmaceutical companies, who claimed that South Africa

³³³ “A dependent patent is a patent which as a matter of law cannot be worked without falling within the scope of protection of another patent.” See www.aippi.org. A ‘dependent patent’ may be explained as follows. Say for instance, Mark creates an invention and has it patented. However, his invention contains a contraption that is crucial to the functioning of his invention, but that contraption is an invention on its own and is also patented. Thus, the use of Mark’s invention might constitute an infringement of the patent that protects the contraption (the prior invention) and therefore, in order for Mark to use his own invention, he requires the consent of the patent holder of the contraption. In such circumstances, the patent protecting Mark’s invention is known as the dependent patent. The other patent (the one that the use of Mark’s invention depends on) is commonly known as the principal patent.

has breached its intellectual property protection obligations under the TRIPS Agreement?³³⁴

5.2 The Court Battle

Nelson Mandela:

“The Pharmaceuticals are exploiting the situation that exists in countries like South Africa in the developing world, because they charge exorbitant prices beyond the capacity of the ordinary HIV/AIDS person. That is completely wrong and must be condemned. The government is perfectly entitled, in facing that situation, to resort to generic drugs and it’s a gross error for the companies or the pharmaceuticals to take government to court. Having said that, I want also to say that we must also take responsibility for not doing sufficient work to persuade these pharmaceuticals (to) change their approach.”³³⁵

Ralph Cunningham:

“...with the world’s most powerful country, and its allies in Europe and Japan, placing the protection of patent and trademarks on the top of the political agenda, South African ministers will eventually find they are in a fight they cannot win. The only question is when this realization will come. Before the damage is done, or too late, when the foreign investors have packed up and gone somewhere else.”³³⁶

In 1997, in order to promote and provide better health care for its people, the South African government amended the *Medicines and Related Substances Control Act*³³⁷ (Medicines Act) by the *Medicines and Related Substances Amendment Act*³³⁸ (the

³³⁴ Nagan “International Intellectual Property, Access to Health Care, and Human Rights: South Africa v United States” (2002) 14 *Fla J. Int’l L* 155 at p163. This issue and the complaints forwarded will be discussed in greater detail below.

³³⁵ *Ibid.*

³³⁶ Cunningham “Is South Africa Safe for IP?-Government Proposals to Regulate the Pharmaceutical and Tobacco Industries are Threatening South Africa’s International Credibility?” *Managing Intellectual Property November* (1998).

³³⁷ Act 101 of 1965.

³³⁸ Act 90 of 1997.

Medicines Amendment Act). Amongst several changes, the most controversial amendment was the insertion of a new section, namely section 15(C), into the Medicines Act by virtue of section 10 of the Amendment Act which had the purpose of ensuring the supply of more affordable medicines in order to protect South African public health.³³⁹ The relevant section provides:

Section 15C

“The minister [of Health] may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), 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 onto the market by the owner of the medicine, or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported:

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).”

The amendment was “received with alarm” by multinational pharmaceutical firms who then exerted pressure on the United States administration to vigorously and effectively respond to the implementation of Section 15(C).³⁴⁰ Subsequently, the South African Pharmaceuticals Manufacturers Association (PMA), joined by 42 pharmaceutical companies, filed a lawsuit in the High Court of South Africa (Transvaal Provincial

³³⁹ See Kuhl *TRIPS and AIDS in South Africa: New Actors in International Relations- Weighing Patents, Pills and Patients* (2002) at p25.

³⁴⁰ Nagan “International Intellectual Property, Access to Health Care, and Human Rights: South Africa v United States” (2002) 14 *Fla J. Int'l L* 155 at p163.

Division).³⁴¹ The PMA sought an interdict preventing the Minister of Health (the Minister) from implementing the section. Its grounds were that section 15(C) violates South African intellectual property law, the South African constitution, and most relevant to our discussion, the TRIPS Agreement.³⁴² It should be noted that while the PMA and its affiliates challenged various sections of the Medicines Amendment Act, only the challenges to section 15 (C) will be investigated, as this relates directly to our discussion. Furthermore, while this investigation specifically relates to compliance with TRIPS, it would be beneficial to also discuss the constitutional objections to the section as the two issues are intertwined.

It was alleged in the PMA's Notice of Motion³⁴³ that the Medicines Amendment Act which introduces section 15 (C) is unconstitutional on one or more or all of the following grounds:

(1) It enabled and authorised the Minister of Health (in conflict with sections 43 and 44 of the Constitution of the Republic of South Africa) to unilaterally determine the prescribed conditions for the supply of more affordable medicines, without setting out guidelines which limit the powers granted.

(2) Section 15 (C) enabled the Minister of Health (in conflict with sections 43 and 44 of the Constitution) to determine the extent to which patent rights will and will not extend to the holder of a patent, irrespective of the provisions of the South African Patents Act.

(3) The relevant section enabled and authorised the Minister of Health (in conflict with section 25 of the Constitution) "...to deprive owners of intellectual property in respect of pharmaceutical products of such property, alternatively to expropriate such property without any provision for compensation to be paid in respect thereof".

³⁴¹ *Pharmaceutical Manufacturers Association v President of South Africa* Case no: 4183/98 (Transvaal Provincial Division filed Feb 1998) unreported case.

³⁴² Nagan "International Intellectual Property, Access to Health Care, and Human Rights: South Africa v United States" (2002) 14 *Fla J. Int'l L* 155 at p163.

³⁴³ This was the PMA's claims in their notice of motion. See www.cptech.org/ip/sa/pharma-v-sa.html.

(4) Section 15 (C) was “...discriminatory in respect of the enjoyment of patent rights in the pharmaceutical field” and such discrimination conflicted with the provisions of Article 27 of TRIPS and is further “in conflict with section 44 (4) of the Constitution read with sections 231(2) and 231(3) of the Constitution”

The lawsuit was subsequently postponed while the parties sought a settlement which eventually failed. In the interim, the United States government, the executive branch of the United States Trade Department, the United States Patent and Trademark Office and the United States Congress applied strong pressure on the South African government to repeal the law.³⁴⁴ After a three year delay the case was heard again in 2001. The contentions submitted by the PMA will now be dealt with in greater detail.

5.2.1 The PMA Contentions and the Responses thereto

5.2.1.1 Vagueness and Arbitrariness

The PMA firstly contends that section 15(C) breaches section 1(c) of the South African Constitution in that the section is vague and arbitrary as it lacks a rational connection to a “legitimate governmental purpose”. Section 1(c) provides:

“The Republic of South Africa is one sovereign democratic state founded on the following values:

(c) Supremacy of the constitution and the rule of law.”

The PMA’s contention is based on the constitutional ‘rule of law’ which prescribes that a law must possess clarity, and must refrain from vagueness, in order to be valid.³⁴⁵ The rule of law requires that a provision be stated in a clear and accessible manner and

³⁴⁴ Nagan “International Intellectual Property, Access to Health Care, and Human Rights: South Africa v United States” (2002) 14 *Fla J. Int’l L* 155 at p163.

³⁴⁵ Dicey *An Introduction to the Study of the Law of the Constitution* 10 ed. (1959) at p203.

should be precise so to allow for predictability.³⁴⁶ With regard to arbitrariness, state action should not be inharmonious with a constitutional order and should be compliant with the rule of law.³⁴⁷ The rule of law then expresses a principle of legality which prescribes that a provision should be legitimate in order to be lawful.³⁴⁸ Where a provision is unlawful or contradicts the rule of law, the vague or arbitrary provision may be set aside upon that very basis.³⁴⁹

The PMA submits that section 15(C) be set aside on the grounds of vagueness and arbitrariness in that it conflicts with the rule of law which requires clarity and predictability. It contends that section 15(C) is vague as the scope and the limits of the powers conferred upon the Minister are not readily determinable from the concepts and the words used by the section.³⁵⁰ The PMA further contends that section 15(C) is arbitrary as it has an “overbreadth” and thus demonstrates a lack of a rational connection to a legitimate government purpose. The rational connection is lacking as the purpose of section 15(C) does not conform to the stated purpose as expressed by the government’s National Drug Policy, which declares that the legislation is to permit the importation of medicines. The PMA contends further that the provisions of section 15(C) are not limited to importation only, but also apply to the supply of medicines otherwise than by parallel importation and extend to the importation of medicines produced “in breach of the rights of the patentee in the country of the product”.³⁵¹ Furthermore, section 15(C) legalizes third party conduct which is only to apply to the holder of the patent in terms of the Patents Act. It is thus contended by the PMA that section 15(C) bears no rational connection to the governmental objective intended to be served by the section.³⁵²

³⁴⁶ *Dawood and Another v Minister of Home Affairs and Another* 2000 (3) SA 936 (CC) at para 47.

³⁴⁷ *Prinsloo v Van der Linde and Another* 1997 (3) SA 1012 (CC) at para 25.

³⁴⁸ *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC) at para 56.

³⁴⁹ *Pharmaceutical Manufacturer’s Association of South Africa and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC) at para 20.

³⁵⁰ Applicant’s Final Heads of Argument at p191 at para 20.1.1.

³⁵¹ Applicant’s Final Heads of Argument at p203 at para 20.1.3.1.1.

³⁵² Applicant’s Final Heads of Argument at p205 at para 20.1.3.1.3.

However, the Fourth Respondent replies to this by reliance on the submission that section 15(C) is solely aimed at providing easier access to medicines by virtue of parallel importation. Therefore the section does not aim at supplying medicines in a manner otherwise than by parallel importation and does not extend to the importation of medicines produced “in breach of the rights of the patentee...” as contended by the PMA. The section is therefore rationally connected to a “legitimate governmental purpose” and this purpose will be advanced by virtue of section 15(C). The Respondent submits further that “upon proper construction...it can be contended that [section 15(C)] was not intended to go any further than allowing for parallel importation”,³⁵³ and was not intended to infringe the rights of patent holders.³⁵⁴

Furthermore, in respect of the above ‘*lack of a rational connection to a legitimate government purpose*’ submission by the PMA, the *amicus curiae* (friend of the court), the Treatment Action Campaign (TAC), submitted that a finding of irrationality is only likely to be made by a court in rare circumstances.³⁵⁵ Furthermore, all that is required in order for rationality to exist is that the legislation bears a purpose that is not unconstitutional and that it is rational to believe that the questioned legislation will advance this purpose.³⁵⁶ The TAC mentions at paragraph 4.7 of its Heads of Argument:

“A law which is overbroad or which overshoots the mark may be disproportional and may therefore fail the balancing test of the limitations clause enquiry but provided that, within its excessive ambit, part of what it does is to promote a legitimate governmental purpose, the law is not open to challenge at the level of rationality review. This distinction creates a weakness that lies at the heart of much of the applicant’s case.”³⁵⁷

The TAC submits that the government’s National Drug Policy was to “ensure the availability and accessibility of essential drugs to all citizens”, “to lower the cost of drugs” and “to promote the cost effective and rational use of drugs”.³⁵⁸ Section 15(C)

³⁵³ Fourth Respondent’s Answering Affidavit at p1460 para 80 (c).

³⁵⁴ Fourth Respondent’s Answering Affidavit at p1460 para 81 (a).

³⁵⁵ Treatment Action Campaign: Heads of Argument at para 4.5.2.

³⁵⁶ Treatment Action Campaign: Heads of Argument at para 4.6.

³⁵⁷ Treatment Action Campaign: Heads of Argument at para 4.7.

³⁵⁸ Treatment Action Campaign: Heads of Argument at para 3.4.2.

gives explicit expression to these policy objectives.³⁵⁹ Thus the TAC submits in its Replying Affidavit that the section is rational, and is based upon clear government policy and public need.³⁶⁰ The amicus submits that section 15(C) is a measure introduced by the government to allow the Minister of Health to regulate patented pharmaceuticals.³⁶¹ The relevant legislation will therefore reduce prices of pharmaceuticals in South Africa, and will thus have a direct bearing on the right to dignity, life and access to health.³⁶² In light of this, the *amicus* submits that the section is not arbitrary and thus does not conflict with the rule of law. With regard to arbitrariness, the *amicus* further submits:

“The amicus does not concede that section 15C, properly interpreted, interferes with the intellectual property rights of the applicants in all the ways they contend. However, even assuming for the purposes of argument that the applicant's draconian interpretation of the section is correct, the applicant's case on the arbitrariness of the section must fail. Once it is clear that section 15C will, *inter alia*, provide for the parallel importation of brand name drugs and thereby contribute to reducing prices for these drugs, the section passes rationality review: it is rational to believe that, whatever else may or may not be unfortunate about the provision, it will contribute to the achievement of the important government purpose of reducing drug prices through parallel importation.”³⁶³

Furthermore, the *amicus* submits that section 1 of the Constitution expresses the purport and objects of the Constitution.³⁶⁴ The judiciary, in its interpretation of a law, must give effect to the fundamental values which this section sets out. Thus, when analyzing a law being challenged constitutionally, the judiciary is under a duty to examine the object and purport of the questioned legislation, and is to, as far as it possibly can, read the legislation in a manner that conforms to the Constitution.³⁶⁵ The TAC thus contends

³⁵⁹ Treatment Action Campaign: Heads of Argument at para 3.5.

³⁶⁰ Treatment Action Campaign: Replying Affidavit at p 7 para 6.

³⁶¹ Treatment Action Campaign: Replying Affidavit at p14 para 20.

³⁶² Treatment Action Campaign: Founding Affidavit at para 48.

³⁶³ Treatment Action Campaign: Heads of Argument at para 6.9.

³⁶⁴ Treatment Action Campaign: Heads of Argument at para 3.12.

³⁶⁵ Reliance is placed on the following case: *The Investigating Directorate: Serious Economic Offences and Others v Hyundai Motor Distributors (Pty) Ltd and Others* 2001 (1) SA 545 (CC)

that section 15(C) must be interpreted by the courts in the manner which promotes the spirit, purport and objects of the Bill of Rights.³⁶⁶

5.2.1.2 Violation of the Right to Property

The Applicant submits that section 25 of the Constitution provides everyone with a right to property, and that no one may be deprived of property except in terms of law of general application and no law may permit the arbitrary deprivation of property.³⁶⁷ The applicant also submits that section 25 extends to intellectual property and thus to patents.

The Applicant contends that where property is a patent, the holder thereof has the right to exclude others from certain conduct (making, using, exercising, disposing or offering to dispose of, importing etc.), so that the holder may fully enjoy the profit and advantages flowing from the invention. The PMA submits that section 15(C) purports to confer upon the Minister certain powers which deprive the patent holder of the rights conferred upon him. It purports to confer upon the Minister certain powers which permit a deprivation of property (within the meaning of section 25). The PMA submits however, that to escape the prohibition in section 25, deprivation must take place in terms of a law of “general application”, and they contend that this requirement is not met by section 15(C) as the section is excessively vague and arbitrary, and thus cannot be regarded as a law of general application.³⁶⁸

The PMA further contends that the lack of a rational connection between section 15(C) and its expressed government purpose demonstrates that the regulatory limitations on intellectual property rights have been overreached and thus amounts to expropriation. However, section 25 requires that the expropriation be for a public purpose and must be made subject to compensation. The PMA thus submits that section 15(C) does not

³⁶⁶ Treatment Action Campaign: Heads of Argument at para 3.13.

³⁶⁷ Section 25 provides: (1) No one may be deprived of property except in terms of law of general application and no law may permit arbitrary deprivation of property. (2) Property may be expropriated only in terms of law of general application - (a) for public purposes or in the public interest; and (b) subject to compensation, the amount, timing, and manner of payment, of which must be agreed, or decided or approved by a court.

³⁶⁸ Applicant’s Final Heads of Argument at p178 para 20.4.2.1. (c).

expropriate for a public purpose, is not made subject to compensation and is therefore unconstitutional.³⁶⁹

In response the Respondents maintain that the section is solely for the purposes of parallel importation, and thus does not infringe any rights of the patent holder. However, in response to these contentions, the *amicus* submits that section 15(C) does not expropriate property.³⁷⁰ The TAC submits that the section merely renders the rights of the holder ineffective and does not appropriate them for the state. Interference with the patentee's rights cannot lead to expropriation as the patentee retains his rights and neither the state nor a third party acquires those rights. Thus expropriation as governed by section 25 cannot occur and, at best, section 15(C) deprives the applicant of its property in terms of section 25(1). However, all that is required under section 25(1) in relation to deprivation of property is that the deprivation must be effected in terms of law of general application which is not arbitrary.³⁷¹ The *amicus* submits that section 15(C) is a law of general application and is not arbitrary as it passes the rationality test.³⁷² The object of the questioned legislation is to provide for the parallel importation of patented drugs. The *amicus* submits that section 15(C) is not overbroad as contended by the applicants, and if properly interpreted does not interfere with the intellectual property rights of the applicant.

5.2.1.3 Violation of sections 43 and 44 of the Constitution

The PMA contends that section 15(C) enables the Minister of Health (in conflict with sections 43 and 44 of the Constitution)³⁷³ to determine the extent to which patent rights will and will not extend to the holder of a patent, irrespective of the provisions of the South African Patents Act. Section 15(C) breaches sections 43 and 44 in the sense that

³⁶⁹ Applicant's Final Heads of Argument at p180 para 20.5.

³⁷⁰ Treatment Action Campaign: Heads of Argument at para 6.4.

³⁷¹ Treatment Action Campaign: Heads of Argument at para 6.6.

³⁷² Treatment Action Campaign: Heads of Argument at para 6.7.

³⁷³ Section 43 provides: "In the Republic, the legislative authority -

a. of the national sphere of government is vested in Parliament, as set out in section 44; ..."

Section 44 (1) provides: "The national legislative authority as vested in Parliament-

a. confers on the National Assembly the power -

(ii) to pass legislation with regard to any matter, including a matter within a functional area listed in Schedule 4..."

it purports to confer a power upon the Minister to prescribe or determine matters, and which has the result of amending or repealing provisions of the South African Patents Act. This legislative authority is vested in Parliament. The section is in further breach of sections 43 and 44 as it purports to permit the Minister to prescribe and determine certain matters, without setting out a framework to regulate the exercise of such powers.

The Respondents answer these allegations by reliance on the ‘principle of exhaustion’³⁷⁴ of patents, and submit that the section was only intended for the parallel importation of medicines. The Fourth Respondent, The Minister of Health, submits that “upon a proper construction... it can be contended that [section 15(C)] was not allowed to go any further than allowing for parallel importation”.³⁷⁵ The Respondents further submit that section 15(C) is not intended to authorize the Minister to deprive a patent holder of his rights to that patent, and thus in no way attempts to amend the Patents Act. The Fourth Respondent submits in its Replying Affidavit:

“I am advised, and I understand that, the said section 15C gives effect to the principle of exhaustion as I understand it, and that it is in no way intended to authorize nor does it have the effect of authorizing, the fourth respondent to take away rights which are granted to patentees.”³⁷⁶

5.2.1.4 Violation of the TRIPS Agreement

The PMA contends that section 15(C) conflicts with Articles 27, 28 and 31 of the TRIPS Agreement.

As discussed earlier, Article 28 imposes an obligation upon a signatory to ensure that a patent confers upon the holder thereof exclusive rights to commit the acts listed in Article 28(a) and (b) of TRIPS. The PMA contends that in so far as section 15(C)

³⁷⁴ The principle of exhaustion will be discussed in greater detail below.

³⁷⁵ Fourth Respondent’s Answering Affidavit at p1460 para 80 (c).

³⁷⁶ Fourth Respondent’s Answering Affidavit at p1460 para 81 (a).

confers powers upon the Minister to “prescribe” and “determine” that the use of a patented process by a third party is lawful, the section is in breach of Article 28(1)(b) of the TRIPS Agreement.³⁷⁷ Similarly, in so far as the section allows the Minister to “prescribe” and “determine” that reproducing a patented article is lawful, the section is in violation of Article 28(a) of the TRIPS Agreement.³⁷⁸ Additionally, the PMA contends that in so far as section 15(C) purports to confer upon the Minister the powers to “prescribe” and “determine” that the acts of “using, offering for sale, selling or importing” patented articles are lawful, “the provisions of section 15(C) are clearly in contravention of the provisions... of Article 28”.³⁷⁹ The Applicant further submits that in the same manner, section 15(C) is in breach of Article 31 of TRIPS as it purports to confer upon the Minister authority to prescribe or determine “conditions for the exercise of the rights of a compulsory licensee without the provisions of Article 31 of the TRIPS Agreement”, and allows for the issue of a compulsory license without following the conditions set out in Article 31.³⁸⁰

The Respondents once again reply to the above contention through reliance upon the principle of exhaustion. They contend that “section 15(C) deals with the exhaustion of patent rights which is not dealt with in the TRIPS Agreement”.³⁸¹ The principle of exhaustion is explained by Love³⁸² as follows:

“The principle of exhaustion is sometimes referred to as the first sale doctrine. When a good that benefits from patents, copyrights and/or trademarks is sold, the owner of the good has realized the benefits of the IP protection, and those rights are considered exhausted at the point of sale. Once the IP owner's rights are exhausted, the purchaser of the good is free to resell the good, even in cases where the reseller competes against the IP owners.”

³⁷⁷ Applicant’s Final Heads of Argument at p174 para 20.3.3 (f).

³⁷⁸ *Ibid.*

³⁷⁹ *Ibid.*

³⁸⁰ Applicant’s Final Heads of Argument at p176 para 20.3.4.

³⁸¹ Fourth Respondent’s Answering Affidavit at p1462 para 8.3.

³⁸² James Love *Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies* 1997. See www.cptech.org/pharm/sa/sa-10-97.html

Therefore, the doctrine of exhaustion entails that once a patented product is put onto a market and thus sold, the seller of the product forfeits all benefits flowing from the rights over that product. The purchaser of the product is then fully entitled to resell the product, even in competition with the first seller (and patent holder) of the product. This then allows for the importation of the resold product. The respondents rely on Articles 6, 8(1) and footnote 6 to Article 28 of TRIPS and submit that in light of these Articles parallel importation is allowed by TRIPS.³⁸³

The Applicants reject this submission of the Respondents and submit that reliance on these Articles is ill-founded. Firstly, the PMA contends that Article 6 is neutral on the subject of exhaustion. Article 6 of TRIPS provides:

“For the purposes of dispute settlement under this Agreement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

The PMA contends therefore that Article 6 does not deal with the issue of exhaustion or permit parallel importation, it is simply silent on the matter.³⁸⁴ The PMA thus contends that the principle of exhaustion does not justify the invasion of the Applicant’s patent rights.³⁸⁵ Secondly, the PMA contends that Article 6 only relates to international disputes, not disputes at a national level. Reliance is placed on the phrase “for the purposes of *dispute settlement under this Agreement*” (my emphasis) in Article 6. On this basis the PMA contends that Article 6 only applies to disputes at an international level via the WTO’s Dispute Settlement Understanding, and not in respect of those heard by the judicial bodies of a Member’s national regime.

³⁸³ Fourth Respondent’s Answering Affidavit at p1462 para 8.3.

³⁸⁴ Applicant’s Final Heads of Argument at p175 para 20.3.2.

³⁸⁵ *Ibid.*

However, the *amicus*' submissions seem to coincide with the submissions of the Respondents in this regard. The TAC submits that parallel importation *is* allowed by the TRIPS Agreement. The TAC further submits that Article 8 of TRIPS, read in conjunction with Articles 30 and 31, envisages situations where signatories may have to introduce provisions that may conflict with a strict application of TRIPS.³⁸⁶

5.2.2 The Outcome of the Case

Shortly after filing the documentation, the PMA (in April 2001) withdrew the case and therefore unfortunately, no decision was arrived at by the High Court. The PMA and the South African government had negotiated the matter and reached an amicable solution. The first paragraph of the “Joint Statement of Understanding between the Republic of South Africa and the Applicants” reads as follows:

“The Parties have reached an amicable settlement of the referenced litigation currently pending before the High Court of South Africa and in consequence, the referenced applicants agreed to withdraw from the present legal action. The Parties agreed that the challenges of accelerating access to care and treatment for the diseases that affect the health of the South Africa population require cooperation and partnership from all stakeholders. The pharmaceutical industry’, whose primary role in addressing these health challenges is to continue its investment in the search for new medicines and vaccines, wishes to work together with the government and citizens of the Republic of South Africa to help them achieve the greatest health benefits for the largest number of people — particularly with respect to the widespread and heavy burden that the emerging and re emerging communicable diseases are taking on South Africa’s families, communities and economy. The Parties share a commitment to work

³⁸⁶ Treatment Action Campaign: Founding Affidavit at para 74.

together to implement the Government's health care objectives and strategies, each contributing resources and expertise as appropriate."³⁸⁷



³⁸⁷ For the Joint Statement, see Annexure F.

5.3 Is Section 15(C) Unconstitutional?

To discuss whether the provisions of section 15(C) would have survived constitutional challenge falls beyond the ambit of this thesis. Nevertheless, it is worth discussing the possible success of the arguments forwarded by the relevant parties.

The PMA's fundamental contention is that section 15(C) contravenes the rule of law in that the section is vague and arbitrary and thus lacks a rational connection to a legitimate government purpose. This contention is inherent in most of its challenges submitted in relation to section 15(C). It was the very basis of the PMA's submissions that section 15(C) expropriates property in contravention of section 25 of the Constitution, and confers wide powers on the Minister in contravention of sections 43 and 44 of the Constitution.

It is submitted, however, that predictability and clarity in a law cancel vagueness; thus a law that is predictable and clear is not vague. "*It is an important principle of the rule of law that rules be stated in a clear and accessible manner.*"³⁸⁸ Furthermore, arbitrariness falls away when a rule in fact bears a rational connection to a legitimate government purpose.

"[The state] should not regulate in an arbitrary manner or manifest 'naked preferences' that serve no legitimate governmental purpose, for that would be inconsistent with the rule of law and the fundamental premises of the constitutional State."³⁸⁹

It is thus submitted that the view of the Respondents and the *amicus* that section 15(C) is predictable (by only allowing for parallel importation) and *does* in fact bear a rational connection to a legitimate government purpose (to "ensure the availability and

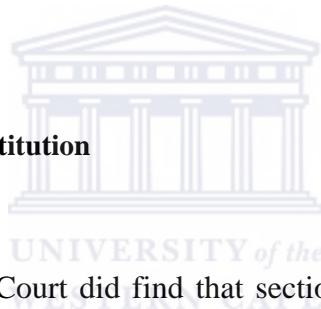
³⁸⁸ *Dawood and Another v Minister of Home Affairs and Another* 2000 (3) SA 936 (CC) at para 47 (emphasis added).

³⁸⁹ *Prinsloo v Van der Linde and Another* 1997 (3) SA 1012 (CC) at para 25.

accessibility of essential drugs to all citizens”, “to lower the cost of drugs” and “to promote the cost effective and rational use of drugs”), highlights a fundamental flaw in the contentions of the PMA.³⁹⁰ It negates the very basis of their contentions. In light of this, it is submitted that the Court would have leaned toward the submissions of the TAC, and thus the “vagueness and arbitrariness” issues raised, and which underpin the majority of the PMA’s contentions, would have failed.

The PMA also contends that section 15(C) contravenes sections 43 and 44 of the Constitution in so far as it allows the Minister to determine matters contrary to the Patents Act and thus has the effect of amending the Patents Act. However, it is submitted that this contention fails in light of the Respondent’s submission that section 15(C) only allows for parallel importation. This interpretation of section 15(C) has the result of leaving the patent holder’s rights in tact, and therefore in no way affects the Patents Act.

5.3.1 Section 36 of the Constitution



Nevertheless, even if the Court did find that section 15(C) infringes the rights of the Applicants, the issue of justifiability of such infringement under section 36 of the Constitution still has to be dealt with. Section 36 allows the state to limit the rights in the ‘Bill of Rights’ (in terms of a law of general application) if the limitation is justifiable and reasonable in an open and democratic society based on human dignity, equality and freedom (also taking into account all relevant factors). This would entail, as expressed by the Constitutional Court³⁹¹ and as submitted by the TAC,³⁹² “the weighing up of competing values, and ultimately an assessment based on proportionality ... which calls for the balancing of different interests”.

³⁹⁰ Treatment Action Campaign: Heads of Argument at para 3.4.2.

³⁹¹ *S v Makwanyane* 1995 (3) SA 391 (CC) at para. 104.

³⁹² Treatment Action Campaign: Heads of Argument at para 9.9.

It is submitted that taking into account the HIV/AIDS epidemic, which is exacerbated by costly pharmaceuticals, and that section 15(C) is aimed at alleviating this by giving effect to government policy, would contribute significantly to a possible justification. It is further submitted that such an approach *would* be reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom and therefore, even if section 15(C) was found to be unconstitutional, that constitutional violation would still have been found to be justifiable. Nevertheless, the court would have been best suited to answer this question.

What is further to be noted, is that even if section 15(C) is found to fall short of being justified under section 36, the Court would still attempt to save the legislation by “severance” or “reading in”.³⁹³ As the TAC submits,³⁹⁴ and as expressed *De Lange v Smuts NO and Others*³⁹⁵ (which was required by section 35(2) of the Interim Constitution), a court is to (as best as is reasonably possible), construe a law as having a meaning which is consistent with the Constitution, as opposed to one which is not.

5.3.2 Conclusion

It is submitted that only the court would have been best placed to decide upon the constitutionality of section 15(C) and it thus unfortunate that the case had no outcome. Nevertheless, it is also submitted that although the contentions of the PMA were founded, the responses of the Respondents and the submissions by the TAC highlighted fatal flaws in their arguments. The Respondents also foresaw a possible success of the case by maintaining that the section only allows for parallel importation, and thus does not infringe the rights of the Applicant. Most importantly, we should note that the Court, before employing any drastic measures, would firstly have attempted to interpret the law in line with the Constitution as best as reasonably possible (whether by

³⁹³ “Severance” entails *deleting* certain parts of the challenged legislation in order to bring that legislation into conformity with the Constitution. “Reading in” entails *inserting* words into the challenged legislation so to bring it into conformity with the Constitution.

³⁹⁴ Treatment Action Campaign: Heads of Argument at para 9.3.

³⁹⁵ 1998 (3) SA 785 (CC) para 85.

severance or reading in), and therefore if the aim of the PMA was to prevent legitimate action taken by the state due to monetary agendas, they would not have been successful in doing so. It is for the above reasons submitted, (more specifically the establishment of a legitimate government purpose by the TAC and the Respondents and that section 15(C) is solely for the use of parallel importation as submitted by the Respondents), that the Court would most likely have found that section 15(C) does not violate constitutional requirements. It is however unfortunate that a decision was not arrived at.

5.4 Does Section 15 (C) Violate TRIPS by Providing for Parallel Importation?

Parallel importation entails the importation of a product through a medium other than that set up between the manufacturer of the product and its distributors.³⁹⁶ In other words, it entails an importer finding a national market where a certain product is sold at the lowest price, and then importing it into another national market where the product is sold at a higher price.³⁹⁷

As submitted by the PMA, there is no express provision in TRIPS allowing the parallel importation of medicines or any other product and Article 6 is somewhat neutral on the topic.³⁹⁸ However, certain Articles of TRIPS, read together, give clear authorisation to use this mechanism. As discussed earlier, Article 28 confers certain rights upon the holder of a patent, but makes this subject to the provisions of Article 6 of TRIPS. Article 6 provides that no obligation under TRIPS shall be used to address the issue of 'exhaustion' of intellectual property rights. Therefore, by virtue of these Articles, because the patent holder under the doctrine of exhaustion forfeits his rights to the product once sold, a third party may import the product in its original form from one country into another country where that product is sold at a higher price. Chung explains how section 15(C) caters for parallel importation. The author mentions:

³⁹⁶ Sako *Unreasonable Restrictions on Parallel Imports* (1996).

See www.faege.com/areas/area_ib9.html

³⁹⁷ James Love *Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies* 1997. See www.cptech.org/pharm/sa/sa-10-97.html.

³⁹⁸ *Ibid.*

“Under this section, “a medicine which is available abroad” and which is “identical to one registered by the same manufacturer in South Africa” need not be the subject of a separate registration and may therefore be imported and sold in competition with the medicine which is the subject of the local registration. This provision is aimed at increasing local price competition and lowering prices by allowing parallel importation, or the importation of drugs from other countries where they are cheaper. This section also allows the Minister of Health to threaten to begin parallel importation of a manufacturer’s drugs from other countries if the local prices do not conform with rates abroad.”³⁹⁹

Other countries have also implemented legislation in their national regimes which has the effect of parallel importation. It is in this regard that Love submits, for the same reasons as above, that the PMA’s contention that parallel importation violates intellectual property rights is wrong on several counts.⁴⁰⁰ Furthermore, as the TAC submits, countries, including the Philippines, the United Kingdom, Canada and Brazil have all enacted legislation which caters for the use of parallel importation.⁴⁰¹

My submission therefore corresponds with that of the Respondents’ in the sense that the TRIPS Agreement does in fact allow parallel importation of medicines by not expressly prohibiting it, and therefore section 15(C), by allowing parallel importation, is not in conflict with TRIPS. The European Courts⁴⁰² have similarly ruled in favour of parallel importation in a number of cases without any complaints from fellow Members. As a European Newsletter mentions:

“As the result of the principle of exhaustion of rights, the pharmaceutical company is unlikely, except in limited circumstances, to be able to rely on his national patent rights in the second

³⁹⁹Chung *Shocking the Conscience of the World: International Norms and the Access to AIDS Treatment in South Africa* (2002) at p23.

⁴⁰⁰ James Love *Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies* 1997. See www.cptech.org/pharm/sa/sa-10-97.html.

⁴⁰¹ Treatment Action Campaign’s Replying Affidavit at pp25-29 para 45-55.

⁴⁰² See for instance, *Mark v Primecrown and Beecham v Europharm* case no: c-267/95. Available at www.okuyama.com/c3volok.html.

Member State to prevent the importation of parallel import the company's rights having been exhausted by his placing of the goods on the market in the first Member State.”⁴⁰³

This finding is supported by the Doha Declaration which recognizes the gravity of the public health problems afflicting developing and least developed countries, and which affirms the right of all countries to protect public health through parallel importation.

5.5 Is South Africa’s Legal Framework Sufficiently Structured in Order to Meet its Needs: What About Compulsory Licensing?

South Africa has been effectively employing the use of voluntary licenses,⁴⁰⁴ which substantially increased competition and therefore resulted in a reduction of pharmaceutical prices. For instance, as Avafia mentions, an increasing number of generic manufacturing companies have been awarded voluntary licenses by patent holders in order to manufacture pharmaceuticals in South Africa.⁴⁰⁵ These generic manufacturers have subsequently been able to produce pharmaceuticals to provide the South African, market and furthermore possess great potential to export pharmaceuticals throughout sub-Saharan Africa.⁴⁰⁶ However, the development of new discoveries in the pharmaceutical sector has led to a decrease in the granting of compulsory licenses by pharmaceutical firms. Furthermore, even though prices are being reduced through the granting of voluntary licenses, the prices of pharmaceuticals remain too high for South Africa to adequately provide its people with better health care. Therefore, as correctly submitted by Avafia,⁴⁰⁷ South Africa’s regulatory framework is inadequate for its needs, and compulsory licensing serves as a more

⁴⁰³ For the reasons of Love’s submission in this regard, see James Love *Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies* (1997) at p5. See www.cptech.org/pharm/sa/sa-10-97.html.

⁴⁰⁴ A ‘voluntary license’ entails a license granted voluntarily by the holder of the patent to another so that the other may be entitled to perform those acts granted exclusively to the holder in relation to the patent. The license is usually subject to a royalty.

⁴⁰⁵ Avafia *The Ability of Select sub-Saharan African Countries to Use TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* Tralac Working Paper No 12/2006 at p4.

⁴⁰⁶ *Ibid.*

⁴⁰⁷ *Ibid* at p18.

“viable and more relevant remedy” for South Africa in relation to providing more affordable pharmaceuticals.

The South African Patents Act does however cater for the possibility of granting a compulsory license. Under the Patents Act a compulsory license may be issued in the event of the abuse of a patent,⁴⁰⁸ or in respect of dependent patents.⁴⁰⁹ Section 56(1) of the Patents Act allows a party who can establish abuse to apply to the Registrar of Patents for the issuance of a compulsory license. Section 56(2) deems there to be abuse of a patent where the patented invention is not being worked adequately or on a commercial scale, and no justifiable reason exists for not working the patent.⁴¹⁰ Abuse is also deemed to exist where adequate working of the patent or the working thereof on a commercial scale is deterred by the importation of the patented article,⁴¹¹ or where the demand for the article is not being met to an adequate extent and on reasonable terms.⁴¹² Abuse is further deemed to be present when the holder of the patent refuses to grant a voluntary license on reasonable terms, which in effect prejudices either the trade or industry or agriculture of South Africa, or the trade of any persons in the Republic, or the establishment of any new trade or industry in the Republic, and it is in the public interest to grant a compulsory license.⁴¹³ The final ground for abuse under the Patents Act is where the demand for the patented article is being satisfied by the importation of the article, and the price charged therefor by the holder or his affiliates is excessive in comparison to the price charged in other countries (where the article is manufactured or sold).⁴¹⁴

Interestingly, South Africa has never issued a compulsory license under section 56.⁴¹⁵ Of greater concern, though, is that South African patent law does not contain provisions

⁴⁰⁸ Section 56 of the South African Patents Act.

⁴⁰⁹ Section 55 of the South African Patents Act.

⁴¹⁰ Section 56(2)(a).

⁴¹¹ Section 56(2)(b).

⁴¹² Section 56(2)(c).

⁴¹³ Section 56(2)(d).

⁴¹⁴ Section 56(2)(e).

⁴¹⁵ Avafia *The Ability of Select sub-Saharan African Countries to Use TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* Tralac Working Paper No 12/2006 at p10.

that provide for compulsory licensing addressed *specifically* at remedying its health concerns or to cater for national emergencies, and thus fails to give full effect to the Doha Declaration, which provides Members with the leeway to alleviate its health burdens. Paragraph 5(b) of the Doha Declaration expressly grants Members the freedom to determine the grounds upon which a compulsory license may be granted and paragraph 5(c) thereof allows Members to freely determine the grounds for declaring a national emergency in order to cater to its public health needs. It is submitted that no provision exists in South Africa's intellectual property regime that specifically gives effect to the Doha Declaration (as opposed to the Brazilian patent act which does).⁴¹⁶ It is therefore submitted that the South African legislature should initiate the necessary steps to implement legislation providing for this, and which is in compliance with existing constitutional principles.

5.6 Can Section 15(C) Achieve this Recommended Purpose?

Certain commentators, such as Love,⁴¹⁷ are of the view that section 15(C) provides only for parallel importing. This coincides with the submissions of the South African government and the Minister of Health in their Answering Affidavit in the PMA v The President of SA case, that the section was aimed mainly at the parallel importation of medicines (which was ultimately what made the PMA's case weaker).⁴¹⁸

However, it is the view of the present writer that it was predominantly the 'discretionary authorization' that purported to give the Minister of Health the power to issue compulsory licenses that seems to have contributed substantially to the controversy and the 'TRIPS legitimacy' concerns. As Chung also mentions, some authors have interpreted section 15(C) to allow for compulsory licensing.⁴¹⁹

⁴¹⁶ See Article 71 of Law No. 9.279 of May 14, 1996.

⁴¹⁷ Love [*Pharm-policy*] *South Africa Proposes New Parallel Import Regs, but No New Compulsory Licensing Procedures* www.cptech.org/ip/health/sa/pharma-v-sa.html.

⁴¹⁸ See Chung *Shocking the Conscience of the World: International Norms and the Access to AIDS Treatment in South Africa* (2002) at p23.

⁴¹⁹ *Ibid.*

Chung states further that “...on a balance, [section] 15(C)(a) *does* seem to empower the government of South Africa to issue compulsory licenses, although it is not clear why the drafters of the legislation did not use more precise language”⁴²⁰.

My submissions in this regard are in line with those of Chung and, therefore, even if section 15(C)(a) was not drafted with the intention to allow the South African Government to issue compulsory licenses (as submitted by the South African government), the section nevertheless still allows the government do so.

Section 15(C)(a) provides:

“The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

(a) ... 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 onto the market by the owner of the medicine, or with his or her consent;”

It is submitted that the section essentially provides that: in order to protect public health, the Minister of Health may prescribe the conditions for the supply of affordable medicines only in *certain circumstances*. The Minister may particularly declare (with regard to certain conduct) that the protection of a patent need not (or shall not) extend to the patent holder of a pharmaceutical product which is already on the market. Therefore, the section essentially means that the Minister may put the patent holder in a position where his patent rights no longer exist, thus opening the way for the legitimate reproduction of the medicine by the government, without infringing any rights. As mentioned, a compulsory license allows a third party to reproduce a patented product without the consent of the patent holder. In comparing the purport of section 15(C)(a) (and the above submitted interpretation of the section), to the function of a compulsory license, it is submitted that an interpretation of section 15(C)(a) boils down to exactly what a compulsory license allows. In essence, it is submitted that even if the section

⁴²⁰ *Ibid.*

does not allow for compulsory licensing, it provides for a mechanism which achieves the same result as compulsory licensing.

5.7 Section 15(C): Compulsory Licensing and TRIPS Legitimacy

As discussed previously, compulsory licensing refers to authorizations that permit a third party to make, use, or sell a patented invention without authority from the patent holder.⁴²¹ The difference between parallel importation and compulsory licensing is that the former only allows the importation of the *original* product, whereas the latter allows the manufacturing or purchase of a generic version of the product.⁴²² Compulsory licensing thus allows a state to obtain pharmaceuticals at a lower price than what it would have paid through parallel importation, as it permits the purchase of generics.

There is no express provision permitting compulsory licensing under the TRIPS Agreement. However, as mentioned by Avedissian⁴²³, the permissibility of compulsory licensing is implied when Article 31 of TRIPS is read in conjunction with Article 2 (1) of TRIPS and Article 5(A)(2) of the Paris Convention of 1967. To recap, Article 2 (1) of TRIPS provides that in respect of Part II of the TRIPS Agreement (which includes Article 31) Members are to comply with Articles 1 through to 12, and Article 19 of the Paris Convention (which includes Article 5). Article 5(A)(2) of the Paris Convention expressly allows the use of compulsory licensing by governmental authorities so to prevent the abuse of patents by their holders.⁴²⁴ This is reinforced by the Doha Declaration which provides Members with the liberty to issue compulsory licenses.

Therefore, if section 15(C)(a) of the Medicines Amendment Act provided for the issuing of compulsory licences, then South African law would nevertheless still be in

⁴²¹ Chien “Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?” 18 *Berkeley Tech. L.J.* 853 at p845.

⁴²² See TAC TAC *Statement on the Court Case: An Explanation of the Medicines Act and the Implications of the Court Victory* (2001). www.tac.org.za.

⁴²³ Avedissian “Global Implications of a Potential US Policy Shift Toward Compulsory Licensing of Medical Inventions in a new era of “Super Terrorism”” (2002) 18 *Am.U. Int’l L.Rev.* 237 at p243.

⁴²⁴ *Ibid.* Article 5 of the Paris Convention provides: “Each Country of the Union shall have the right to prevent the abuses which might result from the exercises of the exclusive rights conferred by the patent...”

compliance with TRIPS. Furthermore, if this interpretation is followed, then South African law *does in fact* contain a provision which gives effect to the Doha Declaration, and allows the government to make use of its TRIPS flexibilities which enables it to improve public health.

However, it is noted by the present writer that this interpretation of section 15(C) will undoubtedly be susceptible to constitutional challenge and TRIPS legitimacy review as the section is broadly phrased, and this is the main reason why the South African government maintained that the section only provided for parallel importation. Nevertheless, it is strongly urged that the South African government employ its 'TRIPS legitimate' flexibilities as well as the mechanisms provided in the Doha documents on Public Health to provide for compulsory licensing. Section 15(C) brings the South African government closest to employing its rights under TRIPS and Doha and it is therefore submitted that section 15(C) be reviewed in order to bring it into conformity with the Constitution and TRIPS, so that the South African government may resort to measures that allow for access to more affordable pharmaceuticals. In this reviewing process, the contentions of the PMA in the above court battle may be of valuable contribution in constructing the legislation.

Therefore, in reconsidering the legislation the South African government should aim at decreasing the vagueness of the section and should draft the section in a manner that makes it more specific. Words that decrease ambiguity and incomprehensibility should be used. It is also desirable that a rational connection to a legitimate government purpose be clear from the wording of the section. Furthermore, the powers conferred upon the Minister should be more specific and should be subject to a legal framework set out by an Act of Parliament. In drafting this framework the South African government should turn its attention to Brazil and its compulsory licensing laws and should subsequently implement laws that are similar in nature.

5.8 A Beacon of Light

Brazil and its approach to TRIPS in relation to patents and pharmaceuticals should also be seen as a beacon of light for the South African government to follow. Brazil has been successful in providing access to *free* essential pharmaceuticals, in a TRIPS compliant manner. It is submitted that the South African Health Department should closely study the policies introduced in Brazil (without adopting its unsuccessful elements) so to improve access to pharmaceuticals and better employ mechanisms providing for compulsory licensing.

The Brazilian patent law provides:

Art. 71. In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee do not satisfy such need, a temporary non-exclusive compulsory license to exploit the patent may be granted *ex officio*, without prejudice to the rights of the owner of the patent.⁴²⁵

Article 73 then sets out certain requirements with regard to the grant of the licence. It is submitted that the South African government closely study these mechanisms which have proved successful in Brazil.

In light of the above submissions, the following amendments to section 15(C) are proposed in order to better negate possible objections to the section, and so that it may be used for compulsory licensing. Note that the submissions of the present writer provide merely a framework, which is subject to improvement by the South African government. It is subsequently therefore proposed that in order to provide for compulsory licensing to improve access to health, section 15(C)(a) should read:

⁴²⁵ Law No. 9.279 of May 14, 1996.

Section 15C

“The Minister [of Health] may in compliance with Article 31 of TRIPS and the Patents Act, prescribe conditions for the supply of more affordable medicines in certain circumstances and subject to a legal framework set out by an Act of Parliament, so as to protect the health of the public, and in particular may-

(a) 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 onto the market by the owner of the medicine, or with his or her consent;

This version negates or decreases constitutional objections and caters for TRIPS legitimacy.

5.9 South Africa Needs to Do Something

In light of the fact that section 15(C) is in compliance with the TRIPS Agreement, and provides for parallel importing and compulsory licensing (this being subject to a certain interpretation), South Africa has the full right and capacity to provide better access to health for its citizens and needs to do so expeditiously. As mentioned by Lewis:

“And while I’m on the issue of treatment, I am bound to raise South Africa. South Africa is the unkindest cut of all. It is the only country in Africa, amongst all the countries I have traversed in the last five years, whose government is still *obtuse, dilatory and negligent about rolling out treatment*. It is the only country in Africa whose government continues to propound theories more worthy of a lunatic fringe than of a concerned and compassionate state. Between six and eight hundred people a day die of AIDS in South Africa. The government has a lot to atone for. I’m of the opinion that they can *never* achieve redemption.”⁴²⁶ (emphasis added.)

⁴²⁶ Remarks by Stephen Lewis, UN Special Envoy for HIV/AIDS in Africa to the Closing Session of the XVI International AIDS Conference, Toronto August 2006

The most suitable time for the South African government to take ‘TRIPS legitimate’ action with regard to pharmaceuticals is now. This is especially so now that the United States has agreed to implement trade policies that does not interfere with the quest of developing and least-developed countries to provide medicines to their people.⁴²⁷

5.10 A Crucial Realisation

It is crucial to realise that the challenge brought by the PMA illustrates the power of the pharmaceutical industry, and its resources are such that it can delay the implementation of legitimate laws (almost indefinitely).⁴²⁸ It is thus imperative that with regard to any challenges brought to the fore in this sphere, the judicial system moves expeditiously, and that the government sets mechanisms in place in order to prevent abuse of the system in this regard (disguised as legitimate TRIPS concerns). Importantly, for a country to issue a compulsory license or to make use of parallel imports, in no way reflects that it blatantly disregards the TRIPS Agreement or the intellectual property rights of intellectual property right holders. It should be remembered that these mechanisms are *legitimate* exceptions under the TRIPS Agreement and thus a country’s intellectual property regime is not undermined, nor jeopardised by the use thereof. Thus, Member governments should not be pressured by the commercial interests of ‘private’ pharmaceutical firms, when a ‘public’ pharmaceutical crisis confronts them. As succinctly mentioned by the TAC of South Africa, “[t]he responsibility of government is to ensure the effective use and distribution of medicines they purchase. International treaties (such as the TRIPS

⁴²⁷See Chung *Shocking the Conscience of the World: International Norms and the Access to AIDS Treatment in South Africa* (2002) at p34. In 2000 Bill Clinton, the President of the United States at the time, signed Executive Order 13155 entitled, “Access to HIV/AIDS Pharmaceutical and Medical Technologies”. It provides that the United States shall not seek the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country that regulates HIV/AIDS pharmaceuticals or medical technologies. This essentially means that these countries are now (in the situations mentioned) protected from United States trade retaliations.

⁴²⁸ South Centre Bulletin *South African Court Case: Spotlight on TRIPS Switched Off* Bulletin-11 2001.

Agreement) and domestic legislation set the legal framework for this transaction- *not the pharmaceutical companies*”.⁴²⁹ (emphasis added)



⁴²⁹ Treatment Action Campaign: Replying Affidavit at para 61.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

“The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.”⁴³⁰

In light of previous discussions and weighing the relevant competing interests, it is noted that a strong intellectual property regime is of utmost importance to the distribution of knowledge and wealth. However, this does not mean that a tolerable and mutually beneficial international intellectual property regime is unattainable. In line with earlier submissions, it cannot be ignored that the present international intellectual property regime, namely, the TRIPS Agreement, poses major threats to the dissemination of knowledge, technology and evolution, and most importantly, access to essential pharmaceuticals in developing and least developed countries. This requires urgent expert attention (especially in the sphere of patents in relation to pharmaceuticals).

Importantly, it should be noted, that the granting of a monopoly and strengthened intellectual property rights to a *stronger minority* of society, should not be done at the expense of the health of a *weaker majority* of society. A right to stronger and adequate intellectual property protection under TRIPS should exist. However, if a society is entitled to strengthened intellectual property rights through TRIPS, then that same society has a parallel right to evolve, live a higher quality of life and digest knowledge by virtue of TRIPS.

This evolution towards a higher quality of life and health may be gradually achieved by poorer countries in time, by employing all possible mechanisms within their legal regimes in a manner that promotes health and access to public health care. It is thus submitted that countries take the following factors into consideration in endeavouring to achieve this aim.

⁴³⁰ Indira Gandhi, spoken at the World Health Assembly in May 1982

6.1 The TRIPS Agreement Should be Interpreted in the Spirit of the Expressed Balance

As mentioned, the Preamble to the TRIPS Agreement attempts to strike a balance between the protection of individual rights and the promotion of international trade. It states that Members should reduce “distortions and impediments” to international trade and should seek an enhancement of the protection of intellectual property rights. Article 7 then provides that the measures employed by TRIPS must contribute to the promotion of technological innovation, the transfer and circulation of technology, should benefit both producers of technological knowledge as well as to the consumers thereof, and should promote social and economic welfare. Article 8 then provides that TRIPS must protect public health and nutrition, and must promote public interest in such sectors that are of *vital* importance to socio-economic and technological development. Read together, these sections aim to achieve a balance in the entire Agreement.

This expressed balance should not merely constitute the letter of the Preamble and these Articles, but should constitute the very spirit of the Agreement. Therefore, it is submitted that these Articles should be the heart and threshold requirements of the Agreement, and that all Articles of TRIPS should be interpreted by the Dispute Settlement Body in this spirit. It is imperative that developing and least developed Members make every attempt to push for this interpretation in forthcoming TRIPS negotiations. The Agreement should thus be interpreted in a manner that is conducive to: (1) the achievement of the objectives resulting in the innovation and dissemination of technology; (2) a mutual benefit of technology by the creators and consumers thereof; and (3) a balance of the rights and obligations of Members. It is submitted that if use of any provision falls short of this suggested interpretation, then the implementation of that provision should fall short of TRIPS compliance.

6.2 Possible Reformation

Various approaches to the reformation of TRIPS are possible. For instance, Oxfam suggests a “twin-track” strategy which focuses on concrete changes achievable in the short-term, while simultaneously focusing on more fundamental changes in the long-term.⁴³¹ The consistent achievement of smaller short-term gains inevitably serves as a bridge to greater long-term gains. Changes should also aim at gradually alleviating the obligations imposed upon developing and least developed Members. Furthermore, those provisions designed at promoting the transfer and dissemination of technology and access to better health should be strengthened. Most importantly, developing and least developed Members should, during TRIPS negotiations, consistently focus on moulding the TRIPS Agreement to practically (and not just in theory) serve as a reciprocal mechanism to both sides (developed Members on one hand and developing and least developed Members on the other) in relation to investment, dissemination of knowledge and access to continuous better health.

6.3 Bilateral Agreements

The United States has been pursuing TRIPS-plus protection outside TRIPS through bilateral treaties. The obligations imposed by these treaties have the effect of nullifying the TRIPS flexibilities granted to Members and prevents Members from employing the leeway granted to them by TRIPS and the Doha Declaration.⁴³² An example of a treaty of this nature is the Free Trade Area of the Americas Agreement (FTAA). This Agreement limits the circumstances under which compulsory licenses for pharmaceuticals may be granted, increases the protection term for patents beyond twenty years, prohibits the exporting of pharmaceuticals produced under compulsory licenses, limits the use of parallel importation mechanisms, and grants exclusive rights to test data which have the

⁴³¹ www.oxfam.org.uk/what_we_do/issues/trade/trips_wsf2002.htm. (Accessed on 11 October 2006)

⁴³² Médecins Sans Frontières *Doha Derailed: A Progress Report on TRIPS and Access to Medicines* Briefing for the Fifth WTO Ministerial Conference, Cancun 2003 at p4.

effect of delaying the introduction of generic versions onto the market.⁴³³ It in essence negates the majority, if not all, of the flexibilities granted to weaker members by TRIPS and Doha.

Developing and least developed Members are strongly advised to steer clear of bilateral treaties of this nature. These higher levels of intellectual protection demanded could “adversely affect” the public interests of developing and least developed Members including health, education technology transfer and food security.⁴³⁴

6.4 Compulsory Licensing and Doha

The Doha Declaration recognises the gravity of health concerns affecting developing and least developed Members, and, while it acknowledges that intellectual property protection is important, it nevertheless identifies the great concern that intellectual property protection has a dramatic effect on the price of essential pharmaceuticals. Members are thus given leeway to cater for the health needs of their people.

Weaker countries should employ and utilize these presently ‘dormant’ flexibilities given to them by the TRIPS Agreement in order to further improve access to public health. One of these flexibilities is compulsory licensing which will serve as an important public policy tool and undoubtedly improve access to pharmaceuticals and inventions that promote public health.⁴³⁵ The Doha Declaration expressly provides that the TRIPS Agreement does not and should not prevent members from taking steps to protect public health. Therefore TRIPS should be implemented and supported in a manner that supports a Member’s right to protect public health, and its obligation to provide pharmaceuticals to its people.

⁴³³ *Ibid.*

⁴³⁴ Vivas *Regional and Bilateral agreements and a TRIPS-plus world: The Free Trade Area of the Americas (FTAA)* Trips Issues Paper 1. www.bilaterals.org/IMG/pdf/Vivas_BTs_study_jul03-2.pdf.

⁴³⁵ www.twinside.org.sg/title/foster.htm. (Accessed on 11 October 2006)

Developing and least developed Members are thus urged to implement legislation within their regimes which gives effect to these rights and that empowers Members to employ them. It is submitted that just the mere threat of employing these flexibilities provides these weaker countries with stronger negotiating powers than before, and may possibly result in amicable compromises between developing and least developed Members, and developed Members.

6.5 Intellectual Property and Human Rights

In interpreting a law the judiciary must give effect to the fundamental values which the Constitution sets out, and should read legislation in a manner that conforms to the Constitution. Section 39(2) of the South African Constitution provides that the purport, spirit and objects of the Bill of Rights should be considered when interpreting any legislation in the Republic. Section 27(1) provides that everyone has the right to have access to health care services and therefore the state must take reasonable legislative measures to achieve this. On the other hand, section 25 provides that everyone has the right not to be deprived of his or her property.

Section 36 then allows the state to limit the rights in the 'Bill of Rights' (in terms of a law of general application) if the limitation is justifiable and reasonable in an open and democratic society based on human dignity, equality and freedom (also taking into account all relevant factors).

In this regard two competing rights exist, namely, the 'right to health' and the 'right to property'. Both rights require adequate protection. Nevertheless the Constitution also provides that when interpreting the Bill of Rights, a court must consider international law. With respect to patents under international law, TRIPS provides that a Member should confer exclusive rights upon the holder of a patent. However, TRIPS and Doha also then provide that these patent rights may be circumvented where a Member aims to alleviate its health crisis. In this light, international law allows the circumvention of a patent when health requires it. Therefore it could be argued that under international law a holder is

granted exclusive rights, subject to a Member alleviating its health issues. Thus, when balancing the rights to health and intellectual property, international law gives priority to health; and, therefore, in interpreting the law a court must consider this preference. It is submitted that judicial bodies within national regimes of developing and least developed countries should attempt to use their constitutional principles in a similar manner and argue similarly in order to improve access to more affordable pharmaceuticals.

In this regard the balance to be struck between these competing rights should be explored by constitutional lawyers in developing and least developed Members, and possible justifications must be investigated so that a government may rely thereon in cases of intellectual property violations when attempting to provide its citizens with better health care.

6.6 Competition Law

Easier access to public health may be further enhanced by effective use of a Member's competition laws.⁴³⁶ Patent practice may be declared to be anti-competitive; therefore decreasing behaviour of this nature, which in turn increases participation in the pharmaceutical field, and thus reduces pharmaceuticals' prices due to demand and supply.⁴³⁷ An understanding of the relationship between competition law and intellectual property rights has the potential to increase the legal tools possessed by a developing or least developed Member and may contribute substantially to easier access to pharmaceuticals.⁴³⁸ It may also be critical in effectively balancing intellectual property rights and human rights.⁴³⁹ As argued by Baker, proper implementation of a vibrant competition policy creates possibilities for lesser abuse or excessive pricing, more

⁴³⁶ Berger *Using Competition Law to Increase Access to Treatment for HIV/AIDS* (2002).

⁴³⁷ *Ibid.*

⁴³⁸ *Ibid.*

⁴³⁹ Nauche *Human Rights – Relevant Considerations in Respect of Intellectual Property and Competition Law* (2005). See www.law.edu.ac.uk/ahrb/script-edu/vol2-4/enyinna.asp#competition.

voluntary participation by pharmaceutical firms during negotiation processes, and greater access to essential technology.⁴⁴⁰

The TRIPS Agreement, by virtue of Articles 8, 30, 31 and 40, read in conjunction with the Doha Declaration and the Implementation Agreement, enables developed and least developed Members to design a competition law regime which is aimed at the achievement of more affordable access to medicines.⁴⁴¹ It is thus submitted that these Members make full use of their competition laws in order to achieve this purpose.

6.7 Final Remarks

In essence, a Member has various inherent tools within its national regime to employ in order to mould a body of laws and precedent that will pave the way to easier access to pharmaceuticals for its people. In this light, it is imperative that national laws should be interpreted in a flexible and purposive manner, which best suits the needs of the relevant country. Developing and least developed Members should note that focusing solely on TRIPS legislation is acting short-sightedly; and this is not where the matter ends. In order to gradually and consistently provide easier access and more affordable access to health, entails that a Member mould and nurture not only its patent laws; it includes the introduction of legislation for parallel importation, compulsory licensing, the nurturing of constitutional law, the nurturing of competition law, and related matters. When seen in conjunction with each other and as a single strategy, these steps will manifest sensitivity to health concerns, and provide governments with powerful tools to provide access to health for all. For in essence:

“While it may never be the case that we can create another world ... we can still try to make the world we live in a better one.”⁴⁴²

⁴⁴⁰ Baker *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilise TRIPS Flexibilities in Non-producing Countries* (2004). See www.healthsystems.org.

⁴⁴¹ Nauche *Human Rights – Relevant Considerations in Respect of Intellectual Property and Competition Law* (2005). See www.law.edu.ac.uk/ahrb/script-edu/vol2-4/enyinna.asp#competition.

⁴⁴² My emphasis. Halbert *Globalized Resistance to Intellectual Property* (2005). See www.globalization.icaap.org/content/v5.2/halbert.html.

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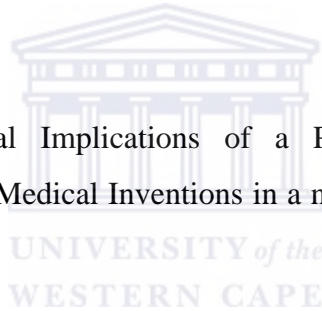
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(Excluding Bibliography, Annexures and Footnotes)



UNIVERSITY *of the*
WESTERN CAPE

ANNEXURES

Annexure: A 1

List of Developed Countries:

Andorra
Australia
Austria
Belgium
Bermuda (*UK*)
Canada
Denmark
Faroe Islands (*Den.*)
Finland
France
Germany
Gibraltar (*UK*)
Greenland (*Den.*)
Greece
Hong Kong (*PRC*)
Iceland
Ireland
Israel
Italy
Japan
Liechtenstein
Luxembourg
Macau (*PRC*)



Monaco
Netherlands
New Zealand
Norway
Portugal
San Marino
Singapore
Spain
South Korea
Sweden
Switzerland
Republic of China (Taiwan)
United Kingdom
United States
Vatican City (Holy See)



List of non-sovereign Developed Territories or Regions

WESTERN CAPE

Macau (People's Republic of China)
Hong Kong (People's Republic of China)
Greenland (Denmark)
Faroe Islands (Denmark)
Bermuda (United Kingdom)

Source: Wikipedia Website at:

http://en.wikipedia.org/wiki/Developed_country

(14 October 2006)

Annexure A2:

List of Developing Countries:

East Asia and Pacific (20)

Cambodia
China
Fiji
Indonesia
Kiribati
Lao PDR
Malaysia
Marshall Islands
Micronesia, Fed. Sts
Mongolia
Palau
Papua New Guinea
Philippines
Samoa
Solomon Islands
Thailand
Timor-Leste
Tonga
Vanuatu
Vietnam



Europe and Central Asia (27)

Armenia
Azerbaijan
Belarus

Bosnia and Herzegovina

Bulgaria

Croatia

Georgia

Hungary

Kazakhstan

Kosovo

Kyrgyz Republic

Latvia

Macedonia, FYR

Moldova

Poland

Romania

Russian Federation

Serbia and Montenegro

Slovak Republic

Tajikistan

Turkey

Turkmenistan

Ukraine

Uzbekistan



Latin America and the Caribbean (31)

Antigua and Barbuda

Argentina

Barbados

Belize

Bolivia

Brazil

Chile

Colombia
Costa Rica
Dominica
Dominican Republic
Ecuador
El Salvador
Grenada
Guatemala
Guyana
Haiti
Honduras
Jamaica
Mexico
Nicaragua
Panama
Paraguay
Peru
St. Kitts and Nevis
St. Lucia
St. Vincent and the Grenadines
Suriname
Trinidad and Tobago
Uruguay
Venezuela, RB



Middle East and North Africa (14)

Algeria
Djibouti
Egypt, Arab Rep.
Iran, Islamic Rep.

Iraq
Jordan
Lebanon
Libya
Morocco
Oman
Syrian Arab Republic
Tunisia
West Bank and Gaza
Yemen, Rep.

South Asia (8)

Afghanistan
Bangladesh
Bhutan
India
Maldives
Nepal
Pakistan
Sri Lanka



Sub-Saharan Africa (48)

Angola
Benin
Botswana
Burkina Faso
Burundi
Cameroon
Cape Verde
Central African Republic

Chad
Comoros
Congo, Dem. Rep.
Congo, Rep
Cote d'Ivoire
Equatorial Guinea
Eritrea Ethiopia
Gabon
Gambia, The
Ghana
Guinea
Guinea-Bissau
Kenya
Lesotho
Liberia
Madagascar
Malawi
Mali
Mauritania
Mauritius
Mayotte
Mozambique
Namibia
Niger
Nigeria
Rwanda
Sao Tome and Principe
Senegal
Seychelles
Sierra Leone
Somalia



South Africa

Sudan

Swaziland

Tanzania

Togo

Uganda

Zambia

Zimbabwe



Source: World Bank Website at:

<http://web.worldbank.org/WBSITE/EXTERNAL/OPPORTUNITIES/GRANTS/DEVMARKETPLACE/0,,contentMDK:20666605~pagePK:180691~piPK:174492~theSitePK:205098,00.html>

(14 October 2006)

Annexure B:

List of Least Developed Countries:

Afghanistan#

Angola

Bangladesh

Benin

Bhutan #

Burkina Faso #

Burundi #

Cambodia

Cape Verde *

Central African Republic #

Chad #

Comoros *

Democratic Republic of the Congo

Djibouti

Equatorial Guinea

Eritrea

Ethiopia #

Gambia

Guinea

Guinea-Bissau

*Haiti *

Kiribati *

Lao People's Democratic Republic #

Lesotho#

Liberia

Madagascar

Malawi #



Maldives *
Mali #
Mauritania
Mozambique
Myanmar
Nepal #
Niger #
Rwanda #
Samoa *
São Tomé and Príncipe *
Senegal
Sierra Leone
Solomon Islands *
Somalia
Sudan
Timor-Lesté *
Togo
Tuvalu *
Uganda #
United Republic of Tanzania
Vanuatu *
Yemen
Zambia #



***Also SIDS**

Also LLDCs

Source: UNO website at:

www.un.org/special-rep/ohrls/ldc/list.htm

(14 October 2006).

Annexure C:

World Trade

ORGANIZATION

WT/MIN(01)/DEC/2

20 November 2001

MINISTERIAL CONFERENCE

Fourth Session

Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH



Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

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

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

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

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

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

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free

to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

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

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

Source:WTO Website at:

www.wto.org (14 October 2006)

Annexure D

**WORLD TRADE
ORGANIZATION**

WT/L/540

2 September 2003

(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003*

UNIVERSITY of the
WESTERN CAPE

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

For the purposes of this Decision:

"pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included⁴⁴³;

"eligible importing Member" means any least-developed country Member, and any other Member that has made a notification⁴⁴⁴ to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases

⁴⁴³ This subparagraph is without prejudice to subparagraph 1(b).

⁴⁴⁴ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members⁴⁴⁵ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

"exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

the eligible importing Member(s)⁴⁴⁶ has made a notification² to the Council for TRIPS, that:

- (i) specifies the names and expected quantities of the product(s) needed⁴⁴⁷;
- (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

⁴⁴⁵ Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

⁴⁴⁶ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁴⁴⁷ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision⁴⁴⁸;

the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

before shipment begins, the licensee shall post on a website⁴⁴⁹ the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

the exporting Member shall notify⁴⁵⁰ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁴⁵¹ The information

⁴⁴⁸ This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

⁴⁴⁹ The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

⁴⁵⁰ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers

⁴⁵¹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to

the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

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

Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

ANNEXURE E:

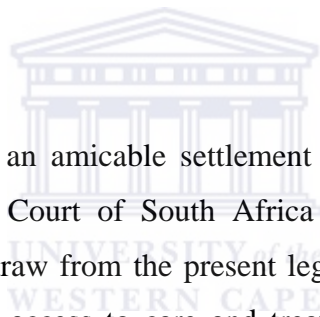
In the matter between:

The Pharmaceutical Manufacturers' Association of South Africa, et. al,

And

The President of the Republic of South Africa, et. al.

**JOINT STATEMENT OF UNDERSTANDING BETWEEN THE REPUBLIC OF
SOUTH AFRICA AND THE APPLICANTS**



The Parties have reached an amicable settlement of the referenced litigation currently pending before the High Court of South Africa and in consequence, the referenced applicants agreed to withdraw from the present legal action. The Parties agreed that the challenges of accelerating access to care and treatment for the diseases that affect the health of the South Africa population require cooperation and partnership from all stakeholders. The pharmaceutical industry', whose primary role in addressing these health challenges is to continue its investment in the search for new medicines and vaccines, wishes to work together with the government and citizens of the Republic of South Africa to help them achieve the greatest health benefits for the largest number of people — particularly with respect to the widespread and heavy burden that the emerging and re emerging communicable diseases are taking on South Africa's families, communities and economy. The Parties share a commitment to work together to implement the Government's health care objectives and strategies, each contributing resources and expertise as appropriate.

In furtherance of this commitment, the Ministry of Health shall invite a working party from the pharmaceutical industry, and also request members of the public, to consult with the government in relation to the regulations currently in development and other measures as may be necessary that will implement and give effect to the Medicines and Related Substances Control Amendment Act, Act 90 of 1997, including Section 15 C thereof. The Industry welcomes and looks forward to the opportunity to join with the government in this important work.

The government of the Republic of South Africa reiterates its commitment to honour its international obligations including the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS). In reliance of this commitment, the referenced applicants recognize and reaffirm that the Republic of South Africa may enact national laws or regulations, including regulations implementing Act 90 of 1997 or adopt measures necessary to protect public health, and broaden access to medicines in accordance with the South African Constitution and TRIPS.

The Parties recognize, with thanks, the efforts of the Secretary — General of the United Nations and the President of the Republic of South Africa in facilitating this agreement ~

APRIL 2001