MASTERS IN COMMERCIAL LAW

DISSERTATION TITLE:

PROMOTING PUBLIC HEALTH USING COMPETITION LAW: APPLYING THE ESSENTIAL FACILITIES DOCTRINE TO INCREASE ACCESS TO DRUGS IN SOUTH AFRICA.

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This research dissertation (21,741) words presented for the approval of Senate in fulfillment
of part of the requirements for a Master of Laws in approved courses and a minor dissertation. The other part of the requirements for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing submission of a Master of Laws dissertation, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

Signature: Signed by candidate Date 6th March 2009

DECLARATION

I Barbara Ntambirweki , do hereby declare that this minor dissertation submitted for the degree of Master of Laws at the University of Cape Town has not been previously submitted by me at this or any other University, that it is my own work and that all referenced material in it have been duly acknowledged.

Signed by candidate

Barbara Ntambirweki

DEDICATION

To my parents, Professor John Ntambirweki and Mrs. Pelucy Ntambirweki for their unfailing love and never ending support.

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1.0 INTRODUCTION TO THE STUDY

1.1 HIV/AIDS CRISIS IN SOUTH AFRICA

The impact and nature of HIV/AIDS pandemic epitomizes the greatest threat to public health and the most important challenge facing South Africa today.[1] In 2007, it was estimated that more than five million people are living with HIV/AIDS in South Africa which represents the highest number of sufferers in any country in the world.[2] It is likely that close to 400,000 South Africans die of the disease each year.[3] Despite this reality, the government for sometime was reluctant to deal with urgency and commitment required by the epidemic.[4] After many years of controversy with civil society, the government finally adopted a new National HIV/AIDS & STI Strategic Plan for South Africa 2007-11 (NSP). The primary aims of the NSP is to reduce the rate HIV infections by 50% by 2011 and reduce the impact of AIDS by expanding access to appropriate treatment care and support to 80% of those in need by 2011. The four priority areas of NSP include prevention, treatment, care, support; research monitoring and surveillance.[5]

Inspite of the efforts by the South African government, a number of obstacles continue to hinder the realization of access to affordable health treatment. One of the major causes for the overwhelming low rate of access is drug prices[6]. The drug prices are set by pharmaceutical companies that have invested money into research and

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[1] *Minister of Health v Treatment Action Campaign* 2002 (5) SA at 721 paragraphs 93 and 1 respectively.
[2] UNAIDS 2008 '*Report on the Global AIDS Epidemic 2008*'. Available at www.unaids.org/en/countryresponses/countries/south_africa.asp
[Accessed on 3rd December 2008].
[3] 'Complaint submitted by Treatment Action Campaign concerning the conduct of Merck &Company'. Available *at* http://www.wcl.american.edu/pijip/documents/berger-affidavit.pdf?rd=1
[Accessed on 3rd December 2008].
[4] 'Complaint submitted by the Treatment Action Campaign concerning the conduct of Merck & Company' (note 3) at 7.
[5] 'Government of South Africa Department of Health Strategic Plan 2007-2011' Available at www.doh.gov.za.
[Accessed on 4th December 2008].
[6] Tina S Bhatt 'Amending TRIPS: A New Hope for Increased Access to Essential Medicines' (2008) *Brooklyn Law Journal of International Law 597* .

development that leads to medical discoveries.[7] In order to recover research and development expenditures, the pharmaceutical companies patent their ideas to exclude other manufacturers from cheaply producing and profiting from their inventions. Therefore international trade regimes seek to guarantee that certain minimum standards are adopted for protection of intellectual property rights. Thus pharmaceutical patents as a major impediment to accessing affordable medicine will be discussed below.

1.2 PHARMACEUTICAL PATENTS

The main agreement for implementing universal patent protection is the Agreement on Trade Related Aspects of Intellectual Property (TRIPS).[8] A patent is an exclusive right conferred on an inventor who has the right to exclude others from using the invention for a limited period of time.[9] The owner of a patent has the right to exclude others from making, using, offering for sale or selling his or her invention for a period of 20years from the filing of the patent application.[10]

There are different types of pharmaceutical patents namely: product patents (covering pharmacologically active chemical and formulation), process patents (covering manufacturing process), Use patents (cover the use of a drug for a medical indication) and exclusive market rights (interim status that refers only to least

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[7] See Tina Bhatt (note 6) at 597.

[8] *'The Agreement on Trade Related Aspects of Intellectual Property Rights'*. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization signed in Marrakesh Morocco on 15th April 1994 Available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm [Accessed 29th November 2008].

[9] See definition of a patent at South African Institute of Intellectual Property Law website Available at http://www.saiipl.org.za/introductio-patents.htm Also see S. 25 of the South African Patents Act. [Accessed 5th December 2008].

[10] Bruce Lehman 'The Pharmaceutical Industry and the Patent System' *President, International Intellectual Property Institute.* Available at http://www.earthinstitute.columbia.edu/cgsd/documents/lehman.pdf [Accessed on 29th November 2008]

See also Article 33 of TRIPS Agreement which stipulates that a patent owner has monopoly that could last for 20years beginning with the first date of filing.

developed countries).[11] All these confer an exclusive right to manufacture, import and sell antiretroviral medicines.[12]

Patents play a vital role in limiting access to essential HIV medicines for poor people in developing countries. It is necessary to understand what it is about a patent that justifies high prices and whether it is inevitable? What lies at the heart of the patent protection?

1.2.1 RATIONALE FOR PATENT PROTECTION

At the heart of patent protection is the need to promote research and development efforts by pharmaceutical companies. Pharmaceutical companies argue that the patent system stimulates research and development by offering temporary monopoly for valuable innovation.[13] This argument posits the idea that imposing price controls will frustrate development of new drugs that have the capability of treating diseases and relieving suffering.[14] However this becomes a problem where the patented invention is an essential drug like antiretroviral medicine.

Secondly, patent holders are at liberty to a reward for the inventive effort in developing the pharmaceutical products. It operates on the premise that other people should not reap from the rewards at little or no cost.[15] However it is important to note that the charge placed on antiretroviral medicines in developing countries exceeds that

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[11] Idowu Ohioze 'Clogs in the wheel: Antiretrovirals and Constraints to Equal Access' at 11 Available at *http://www.osgoode.yorku.ca/glsa/2007conference/documents/Idowu%20Ohioze%20-%20Clogs%20in%20the%20Wheel.pdf*
[Accessed on 15th December 2008].

[12] See Idowu Ohioze supra (note 11) at 11.

[13] Junaid Subhan 'Scrutinized: The TRIPS Agreement and Public Health' Mc Gill Journal of Medicine 2006 July 9(2): 152-159 Available at *www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2323529*
[Accessed on 5th December 2008].

[14] See Idowu Ohioze (note 11) at 13.

[15] Edwin Cameron and Jonathan Berger 'Patents and Public Health: Principle, Politics and Paradox' at 6 *Inaugural British Academy Law Lecture held at the University of Edinburgh Tuesday 19 October 2004* Available at *http://www.law.ed.ac.uk/ahrc/files/59_cameronpatentsandpublichealth04.pdf*
[Accessed on 10th January 2009].

charged in the developed world. Higher prices are charged in developing countries due to the prevalence of the AIDS epidemic. There should be a balanced cost distribution mechanism across all users in spite of huge expenses connected to pharmaceutical research and invention.[16]

In my view, neither of the two justifications offers a convincing case for grant of absolute patent protection of pharmaceuticals. The importance of the need for rewards and incentives for purposes of ensuring innovation cannot be denied. However, the high prices charged due to patents makes antiretroviral medicine very expensive for poor people in developing countries. In the face of HIV/AIDS pandemic that continues to be a threat to millions of lives there is need to ensure greater flexibility of intellectual property laws to make them more accessible to the people who need them most.

1.3 THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The TRIPS Agreement has played a fundamental role in the debate on providing access to essential medicine to developing countries. TRIPS Agreement was promulgated by the World Trade Organization in 1994 and has been ratified by a vast number of the world's nations like South Africa[17]and sets out minimum standards for protection of international intellectual property rights including copyrights, patents and trademarks.[18] The goal of the TRIPS Agreement was to harmonize intellectual property laws and balance the differing interests between developed nations and developing nations.[19] The TRIPS Agreement advocates for protection of pharmaceutical patents

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[16]See Idowu Ohioze (note 11) at 15.

[17]*The TRIPS Agreement provided a perfect opportunity for pharmaceutical and other Intellectual Property dependant industries to advance their cause of ensuring that Intellectual property rights are protected.*

[18]Slone Pearson 'Will August 20, 2003 Decision of the WTO provide Adequate Protection for Patent holders rights and is Diversion still a threat to the pharmaceutical industry?' 2005(5) Journal of High Technology Law 381 at 383.

[19] Slone Pearson (note 18) at 384.

which is a barrier to access to essential medicines as the cost of the drugs is beyond the reach of most sufferers in developing countries.[20] However the TRIPS Agreement sets out mechanisms that allow countries to deal with emergencies like public health crises.

The mechanisms that deal with public health crises are compulsory licensing and parallel importing.[21] Compulsory licensing allows generic drug companies to manufacture and sell patent drugs at a lower price than the original price. Conversely, parallel importing allows a developing nation to take advantage of the common pricing of drugs across different countries. However these mechanisms have largely been unsuccessful due to the fact that they are merely optional and not obligatory on member nations.[22]

1.4 THE DOHA DECLARATION

Due to international and political pressure from public health activists, the World Trade Organization recognized weakness in the TRIPS Agreement and issued a declaration known as Doha Declaration[23] which affirmed the right for member states to take appropriate measures to deal with public health crises that are devastating many parts of the developing world.[24]The emergence of competition from generic manufacturers and direct negotiation with pharmaceutical companies has contributed to the increased drop in price of certain drugs to treat HIV/AIDS in developing countries.

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[20] Shinzo Kobori 'TRIPS and the Primacy of Public Health' *Asia Pacific Review 2002 Vol 9, No 1*

[21] See *Articles 7 and 8 of the TRIPS Agreement sets out some of the broad objectives of the agreement, including promotion of technological innovation, transfer and dissemination of technology and measures to protect public health, nutrition and public interest. These flexibilities are measures to help developing countries protect public health.*

[22] In South Africa for example the government failed to use compulsory licensing mechanism to license generic manufacturers to produce affordable antiretroviral medicine.

[23] *Doha Declaration was signed on 14th November 2001 at the Fourth Ministerial Conference in Doha, Qatar. The World Trade Organisation members decided to uphold the primacy of public health concerns over pharmaceutical patent rights in the TRIPS Agreement.* Available at http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm [Accessed on 29th November 2008]

[24] Peter Rott 'The Doha Declaration- Good news for Public Health' 2003 *Intellectual Property Quarterly 284-311.*

In 1997, the South African government revised the South African Medicines and Related Substances Control Act to allow compulsory licensing and parallel imports of generic versions of antiretroviral drugs from India.[25] The proposed revision was contested by 39 pharmaceutical companies and four multinational companies backed by the United States government on the grounds that it breached the Patents Act and Constitution of South Africa.[26] However the suit was withdrawn due to political pressure from activists around the world. This reflects the growing concern that rigid implementation of pharmaceutical patents is detrimental to the public health policies of developing countries.

Although the Doha Declaration was hailed as a victory for developing countries, very few countries have taken steps to make use of existing legislation to increase access to essential medicines. South Africa for instance has failed to take any steps towards issuing compulsory licenses for the importation or production of affordable antiretroviral medicines.[27] Therefore South Africa needs to impose measures like competition law to improve access to affordable medicines to the millions of HIV sufferers in the country.

It is against this background that questions have arisen as to the role and benefits of competition law in advancing public health concerns in South Africa which is a party to Intellectual Property Rights agreements. This paper attempts to answer this question, Can competition law contribute to the challenge of creating affordable essential medicine to people suffering from the AIDS epidemic? In addressing this issue this paper will discuss the benefits of using the essential facilities doctrine to increase access to antiretroviral medicines.

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[25] Shinzo Kobori (note 20) at 17

[26] Junaid Subhan (note 13) at 155

[27] *S.4 of the Patents Act, 57 of 1978 gives the Minister of State permission to use an invention for public purposes however the government has been adamant in invoking this power which if utilized could go a long way in providing access to medicine in South Africa.*

1.5 STATEMENT OF THE RESEARCH PROBLEM

The protection of public health is very critical to the needs of any developing country. South Africa has been hardest hit by the AIDS pandemic and has the largest number of people living with HIV than any country in the world. Therefore, the need to address the issue of access to medicines has become a matter of global priority. Pharmaceutical industries patent their drugs to charge excessive prices to recover research and development costs and make profit. Using their exclusive rights they deny appropriate licenses to other manufactures at the same time maintain high prices.

The negative implications of patents to access to medicines have far reaching implications and there is need for solutions to this global outcry. This paper advocates for the use of the essential facilities doctrine as a mechanism to deal with dominant pharmaceutical firms that refuse to license other generic producers to manufacture cheaper antiretroviral medicines to the poor people dying of AIDS in South Africa.

Given the paucity of jurisprudence on the use of competition law to increase access to patented medicine, this paper attempts to shed more light on the role of competition law in increasing sustainable supply of affordable medicines. It attempts to use the essential facilities doctrine to strike a balance between public and private interests and how they can be reconciled to protect public health.

1.6 SCOPE OF THE STUDY

The purpose of this study is to examine the role that the essential facilities doctrine can play in South Africa in advancing public health by increasing access to sustainable and affordable essential medicine. In particular the paper will focus on a few key areas: the relevance of developed countries experiences in dealing with the essential facilities doctrine; what lessons can South Africa learn and how can they be applied to promote access to affordable medicine; the paper will also look at the South African experience and how the essential facilities doctrine has been applied and

recommendations will be made on the effectiveness of the essential facilities doctrine in improving access to medicines.

1.7 SYNOPSIS OF THE STUDY

CHAPTER 1: INTRODUCTION TO THE STUDY

This chapter provides a general background and introduction to the problem of access to drugs in South Africa.

CHAPTER 2: COMPARATIVE ANALYSIS OF THE ESSENTIAL FACILITIES DOCTRINE IN THE EUROPEAN UNION AND UNITED STATES.

This chapter analyzes the application of the essential facilities doctrine in the United States and European Union. The chapter concludes by looking at the need to balance the essential facilities doctrine and the issue of innovation to patent holders. It argues for the need to strike a balance between public and private interests to promote public health.

CHAPTER 3: THE SOUTH AFRICAN EXPERIENCE

This chapter analyzes the general regulatory framework in place to make drugs more accessible in South Africa. This chapter also analyzes the various cases that advocate for the promotion of public health by using competition law to make drugs more affordable and accessible.

CHAPTER 4: CONCLUSIONS AND RECOMMENDATIONS

This chapter will generally give conclusions as to whether the essential facilities doctrine can be applied to pharmaceutical patents and will make recommendations on the effectiveness of the essential facilities doctrine.

CHAPTER 2: COMPARATIVE ANALYSIS OF THE ESSENTIAL FACILITIES DOCTRINE IN THE EUROPEAN UNION AND THE UNITED STATES.

2.0 INTRODUCTION

In the recent years, there has been a great deal of controversy regarding access to drugs to treat HIV/AIDS in developing countries where millions of people are dying of the deadly disease[28]. Central to this debate is the issue of how patents on antiretroviral medicine have blocked access to life saving drugs to help the less fortunate in poor countries. Patents by nature create monopolies over patented pharmaceuticals thereby permitting patent holder to charge higher prices far above the cost of making cheaper generic drugs. Pharmaceutical companies argue that the patent system promotes innovation and creates reward incentives for investing in risky research and development. On the other hand competition law seeks to safeguard consumer welfare by avoiding deceptive, unfair anticompetitive conduct by dominant firms.

Against this background, it can be said that the aims of intellectual property rights and those of competition law are said to be conflicting with one another. Intellectual property rights grant exclusive rights to the holder of the patent over their innovation.[29]Conversely, competition law battles monopolies and seeks to create a level playing field by placing restrictions on the abuse of a dominant position[30]. It is imperative to note that rather than conflicting there are some areas where intellectual property rights and competition law complement each other by excluding others from using their ideas, they in turn provide incentives for innovation. This creates

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[28] Amir Attaran & Lee Gillespie White 'Do Patents for antiretroviral drugs constrain access to AIDS treatment in Africa?' Available at *http://www.iipi.org/articles/antiretroviral_article.pdf*. [Accessed on 15th January 2009]

[29] Cornelius Dube 'Intellectual property rights and Competition Policy' available at *www.cuts-international.org/pdf/viewpointppaper-IPRs-compPolicy.pdf*. [Accessed on 15th December 2008]

[30] Cornelius Dube (note 34) at 1.

competition on the market and promotes dynamic efficiency characterized by increased quality of goods which is one of the major goals of competition law.[31]

Therefore there is a need to regulate pharmaceutical patents using competition law policy options to reduce the scope of intellectual property rights. This regulation is required especially where intellectual property rights prohibit competition in the supply of goods that are essential to the social or economic development of a country such as essential medicines[32]. Competition law can and should be used to promote access to antiretroviral medicine and control monopoly powers of intellectual property rights.

This chapter will provide a comparative analysis of the application of the essential facilities doctrine in the United States and the European Union. This chapter will specifically explore through the lens of the essential facility doctrine how competition law may impose broader duties on pharmaceutical companies to increase access to medicine in developing countries like South Africa.

2.1. WHAT IS THE ESSENTIAL FACILITY DOCTRINE?

The essential facilities doctrine is a competition law concept that requires the owner of an 'essential facility' to provide other undertakings with equal or non discriminatory use of, or access to, the facility on fair terms.[33] The essential facilities doctrine has been applied to tangible property for example railway facilities, telecommunication networks, raw materials. In recent years, the doctrine has also been extended to intellectual property rights[34] mainly because of the increase in the number

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[31] See Alison Jones and Brenda Sufrin '*Text, Cases and Materials EC Competition Law*' 3ed (2008) 777. *Intellectual Property Law and Competition law do not have conflicting objectives rather they have the same goal to pursue the promotion of consumer welfare.*

[32] Sean M Flynn 'Using Competition Law to Promote Access to Knowledge'at 3 Available at http://www.wcl.american.edu/pijip_static/documents/flynn08122008.pdf?rd=1. [Accessed on 17th December 2008].

[33] Scott Makar 'The Essential Facilities Doctrine and the Health Care Industry' 21 Florida State University Law Review 913 Available http://www.heinonline.org.ezproxy.uct.ac.za [Accessed on 10th January 2009] .

[34] Frank Fine 'NDS/IMS: A Logical Application of the Essential Facilities Doctrine' *European Competition Law Review* (2002) at 457

of situations in which the monopolist's dominance is dependent on intellectual property since products and services are an epithet of ideas that represent an increasing part of the world today.[35] Therefore, pharmaceutical patents are 'essential facilities' to the public health sector and are a major obstacle to access to affordable drugs. The basic argument of this chapter is that the essential facilities doctrine can be used to improve access to essential medicines by imposing duties on pharmaceutical companies to share access of their patented products with generic manufacturers. It is imperative to analyze how the doctrine has been applied in the developed world. This is will provide a background upon which the scope of the essential facilities doctrine can be analyzed.

2.2 DEVELOPMENT OF THE ESSENTIAL FACILITIES DOCTRINE IN THE EUROPEAN UNION AND UNITED STATES.

The existence and application of the essential facilities doctrine has been recognized in the United States and European Union. Nevertheless it is imperative to point out that the doctrine has been applied differently by the courts in both sides of the Atlantic. In order to understand how the doctrine has developed over the years it is important to analyze the divergent approaches taken by the respective courts.

The European Union competition law imposes upon dominant firms a general duty to share as well as a duty to supply therefore the existence of these obligations precludes the need to compel general duties upon dominant firms.[36] Conversely, the United States does not impose general duties on dominant firms and has used the essential facilities doctrine to create an exception to the general principle that firms do not have a duty to deal.[37]

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[35] Robert Pitofsky, Donna Patterson 'The Essential Facilities Doctrine under US Antitrust Law' (2002) 70 *Antitrust Law Journal* at 443.

[36] Sergio Baches Opi 'The Application of the Essential Facilities Doctrine to Intellectual Property Licensing in the European Union and the United States: Are Intellectual Property Rights still Sacrosanct?'(2001) 11 *Fordham Intellectual Property, Media and Entertainment Law Journal* 409.

[37] Baches Opi (note 36) at 412.

2.2.1 ESSENTIAL FACILITIES DOCTRINE UNDER US LAW

A. *"The Traditional Doctrine"*

In the United States, the essential facilities doctrine traces its origin to the Supreme Court's 1912 decision in *United States v Terminal Railroad Association*[38]The case concerned the possession of a group of railroads controlling all railway bridges and switching yards converging at St Louis and barred competing railroad services from offering transportation services to and throughout that destination.[39] The Supreme Court decided that the refusal of the owner of a critical network such as a railway terminal to avail access to non owners may restrain commerce among the States and may be tantamount to an attempt to monopolize commerce among the States.[40]

The essential facility doctrine has been endorsed as a broader category of antitrust claims based on "refusal to deal" cases which generally places restrictions on a monopolist's ability to eliminate actual or potential rivals from competing with it[41]. The doctrine is an exception to the general principle in the United States that a firm is under no obligation to deal with others.[42]S.2 of the Sherman Act prohibits monopolization and attempts to monopolize and has been used in the United States to support the development of the essential facilities doctrine.[43]

Another decision associated with the development of the essential facilities doctrine is the case of *Otter Tail Power Co v US*[44] the Supreme Court applied the essential facilities doctrine under S.2 of the Sherman Act concerning the refusal of an electric company to open its grid to municipalities access and precluded municipalities from

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[38] 224 US 383(1912) cited in Robert Pitofsky(note 35) at 444.
[39] Antonio Copobianco 'The Essential Facility Doctrine: Similarities and Differences between the American and the European Approach' (2001) 26 *European Law Review* at 548.
[40] Antonio Copobianco (note 44) at 549.
[41] Gregory V. S Mc Curdy 'Intellectual Property and Competition: Does the Essential Facilities Doctrine Shed any light?' 2003 (25) *European Intellectual Property Review* at 473.
[42] Frank Fine (note 34) at 457.
[43] Baches Opi (note 36) at 411.
[44] 410 US 366 (1973) cited in Antonio Copabianco (note 39) 549.

entering the business of electric power distribution which was considered by the Supreme Court as an attempt to monopolize as well as actual monopolization.[45] The Supreme Court stated;

> *"The Sherman Act requires both facilities cannot be practically duplicated by would be competitors, those in possession of them must allow them to be shared on fair terms"*

Otter Tail was found to be a natural monopoly and its refusal to wheel power for its competitors was motivated by Otter Tails intention to exclude its competitors from the market and preserve its monopoly. [46]The Supreme Court made it clear that the legal basis of the violation was "attempt to monopolize" as expressed in the Sherman Act in S.2 since Otter Tails action had the effect of "preventing municipal electric systems."

Apart from the Otter Tail Case, the Supreme Court applied the essential facilities doctrine in the *Aspen Skiing Co v Aspen Highlands Skiing Corp case.*[47] The Supreme Court applied the essential facilities doctrine to a ski resort decision to terminate its long standing participation with a computer ski resort. Aspen Ski consisted of four mountain areas, the defendant owned three of those areas and the plaintiff who owned the fourth had cooperated for many years in issuance of a joint multi day all area ski ticket.[48]After demanding for increased proceeds the defendant terminated the joint ticket. The court described the multi area ticket as an "essential facility" to which the defendant was denying access, with intent to monopolize by putting the competitor ski resort out of business and was sufficient evidence to impose antitrust liability for refusal to deal.[49]

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[45] Antonio Copabianco (note 39) at 549.
[46] Joseph Coker 'Saving Otter Tail: The Essential Facilities Doctrine and Electric Power Post-Trinko' *Florida State University Law Review* Vol 33 at 231
[47] Aspen Skiing Co v Aspen Highlands Skiing Corp 472 U.S 585 at 601(1985) cited in Alison Jones &Brenda Sufrin (note 31) at 576
[48] Alison Jones & Brenda Sufrin (note 31) at 576.
[49] Robert Pitofsky & Donna Patterson (note 35) at 445.

Although the *Aspen* decision was based on the essential facilities doctrine, the Supreme Court refused to consider the case on essential facilities terms and instead decided the case on the basis of the Sherman Act analysis.[50]

Since the *Aspen case*, there has been a gradual narrowing of the essential facilities doctrine however the lower courts have repeatedly used it mainly because it represents a fundamental understanding about the nature of the misuse of monopoly power.[51]It is imperative to point out that the essential facilities doctrine is supported by the welfare enhancing goals of the United States Antitrust Policy.[52] The major aim of the essential facilities doctrine is to prevent a firm with monopoly control over an essential facility from unlawfully eliminating actual or dynamic competition which leads to development of consumer welfare enhancing innovations.[53]

2.2.2 THE "*MODERN*" ESSENTIAL FACILITIES DOCTRINE AND ITS CRITICS.

B. *"Modern Doctrine"*

The modern version of the doctrine and its elements were discussed in *MCI Communication v The American AT&T Co*[54]The Supreme Court applied the essential facilities doctrine to require the monopolist telecommunications provider to allow access to its local service network to its competitors. The court formulated four conditions necessary to establish liability under the essential facilities doctrine namely; (i) control of an essential facility by the monopolist, (ii) competitors inability to

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[50] Joseph R Coker (note 46) at 241.

[51] See Brett Frischmann &Spencer Weber Essential Facilities, Infrastructure and Open Access at 9. Available at http://www.usdoj.gov/atr/public/hearings/single_firm/comments/219672_a.htm. [Accessed on 25th January 2009].
Some United States courts have opined that antitrust liability under the essential facilities doctrine is applicable where access is denied due to anticompetitive animus ordinarily established by change of existing practices with the intent of harming rivals. See also Sunshine Cellular v Vanguard Cellular Sys. Inc 810 F Supp 486, 496-98 *where the lower Courts applied the essential facilities doctrine irrespective of whether the essential facility constitutes a separate vertically related market.*

[52]See Robert Pitofsky 'The Essential Facilities Doctrine under United States Antitrust Law' Available at http://www.ftc.gov/os/comments/intelpropertycomments/pitofskyrobert.pdf.
[Accessed on 15th January 2009].

[53] Robert Pitofsky (note 57) at 2.

[54] 708 F.2d 1081, 1132-33 (7th Circuit Court of Appeals of 1983) cited in Robert Pitofsky (note 57) at 444.

practically or reasonably duplicate the essential facility, (iii) the denial of the use of an essential facility to a competitor and (iv) the feasibility of providing the facility.

Despite the articulation of the essential facility doctrine by the courts in *MCI Communication case*, the US courts have read the doctrine narrowly and over the years tried to find a reliable test for ascertaining when the facility may be deemed "essential" for competition.[55] The threshold inquiry that courts must satisfy before applying the elements of an essential facilities claim is whether or not the facility in question is "essential." A facility is termed essential where the owner has great cost advantages over those who seek access and the facility is a relevant market for some input that is crucial to the production of some secondary product[56].

The development of the essential facilities doctrine over the past years has been subject to a great deal of scholarly criticism. Leading antitrust scholars Professor Areeda and Professor Hovenkamp have described the doctrine as "one of the most troublesome incoherent and unmanageable basis for S.2 liability."[57] They argue that forcing a firm to share its inputs with its rival is an exceptional drastic antitrust remedy, having the consequences of preserving monopoly and often turning the defendant's facility into what amounts to a public utility[58].

The Supreme Court decision in *Verizon Communications Inc v Trinko*[59], represents the near extinction of the essential facilities doctrine and has been considered not dead but "struggling for life" in the United States.[60] The facts were that customers who received local telephone services from competing local exchange carriers brought an

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[55] Antonio Copabianco (note 39) at 551.
[56] See Joseph Corker (note 46) at 242 *The Court stated that where a state or federal agency effectively has the authority to compel sharing and to regulate its scope and terms, essential facilities claims should be denied.*
[57] H. Hovenkamp *Federal Antitrust Policy* cited in Alison Jones and Brenda Sufrin (note 31) at 575.
[58] Gregory Mc Curdy (note 41) at 474
[59] LLP 124 S.Ct 872 (2004) cited in Jones & Sufrin (note 31) at 575
[60] Alexandros Stratakis 'Comparative Analysis of the US and EU Approach and Enforcement of the Essential Facilities Doctrine' (2006) 27 *European Competition Law Review* at 436.

action against the incumbent local exchange carriers alleging that it had breached its duty to share and violated section 2 of the Sherman Act.

Judge Scalia firmly stated that even when refusal to deal concerns access to a tangible infrastructure facility, dominant firms have no duty to open such facility to their competitors because compelling a dominant firm to share the source of her own advantage" ....is in some tension with the underlying purpose of antitrust law since it may lessen the incentive for the monopolist, the rival to invest in those economically beneficial facilities." [61]

The essential facilities post *Trinko* is on a more shaky ground in that, where a monopolist who has control over an essential facility falls under the jurisdiction of a regulatory body that can compel access to the essential facility the plaintiff will not be able to use the essential facility doctrine to compel access under antitrust laws.[62]

On the basis of case law discussed above, the courts have generally rejected to apply the essential facilities doctrine mainly because of the possible chilling effect on innovation in the long run. However, it is crucial to point out that even the doctrine's most prominent critics accept that it is important to require a monopolist to deal in certain exceptional circumstances.[63]Phillip Areeda argues that the court in *MCI case* was correct in holding that a monopolist must, when feasible make its essential facility available to a competitor who is unable to duplicate it[64].

The major argument of this chapter is that dominant pharmaceutical firms should share access of their patent rights with generic competitors which will improve

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[61]See Alison Jones& Brenda Sufrin (note 31) at 578; See also Emanuela Arezzo 'Intellectual Property Rights at the crossroad between monopolization and abuse of dominant position: American and European approaches compared'(2007) John Marshall Journal of Computer &Information Law Vol.24

[62] See Joseph Corker (note 46) at 246

[63] See Phillip Areeda 'Essential Facilities: An Epithet in need of Limiting Principles'(1998) 58 *Antitrust Law Journal* at 853

[64] See Phillip Areeda (note 63) at 853

the access to drugs problem in South Africa. However due to the criticisms leveled against the doctrine in the United States, it is necessary to explore the approach adopted in the European Union.

2.3 THE ESSENTIAL FACILITIES DOCTRINE IN THE EUROPEAN UNION

This section discusses the development of essential facilities doctrine in the European Union. An attempt will be made to analyze landmark decisions to understand the circumstances courts have imposed broader mandatory access duties to share. This serves as a basis of our discussion that the essential facilities doctrine can, and has been used, to share access where dominant firms control a facility essential to competition. The essential facilities doctrine can be used to force pharmaceutical companies to share their patent rights over drugs so as to improve the access to drugs in South Africa. The first part of the discussion will discuss the development of the doctrine under refusal to supply abuse paradigm. The next part of the discussion will discuss how the essential facilities doctrine has applied to intellectual property and the circumstances where court has imposed mandatory access.

2.3.1 DEVELOPMENT OF THE ESSENTIAL FACILITIES DOCTRINE IN THE EUROPEAN COURTS.

As discussed above, the essential facility doctrine originates from the United States dates back to as early as 1912 and has proved to be highly contentious.[65]Under European law the essential facility doctrine was developed by the Commission primarily under Article 82 of the EC treaty.[66] It is imperative to note that European competition bodies have shown concern towards protection of consumer welfare by protecting the competitive structures of the market. The protection of competitive

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[65] See *US v Terminal Railroad Association* 224 U.S. 383 (1912), See also Jones & Sufrin (note 31) at 537 *Leading antitrust scholars like Professor Areeda and Hovenkamp have described the essential facilities doctrine as troublesome, incoherent and unmanageable they suggest that the doctrine should be abandoned.*

[66] See Consolidated Treaty Establishing the European Community Dec 24, 2002 O.J (C 325) 65 (2002) http://eur-lex.europa.eu/en/treaties/index.htm
[Accessed on 6th December 2008]

structures of markets is in line with the *"special responsibility principle"* that a dominant firm by virtue of their peculiar strength in a relevant market are prohibited from engaging in behaviour that is detrimental to smaller competitors.[67]

The Commission was the first European institution to introduce the term "essential facilities" into European Competition law only recently in a string of decisions during the 1990's involving transportation infrastructure[68]. The Commission used the term "essential facility" explicitly in case of *B&I Line plc v Sea link Harbours Ltd and Sea Containers v Stena Sealink Ltd*[69]

In *B&I Line Plc v Sea Link Harbours Ltd,* the facts were Sea link acted as a port authority of Holy head and instituted timetable changes to the detriment of B & I and in support of its own activities.[70]

The Commission stated;

> *"The owner of an essential facility which uses the power in one market in order to strengthen the position in another related market, in particular by granting its competitor access to that related market on less favourable terms than those of its own services infringes article 86 when a competitive disadvantage is imposed on its competitor without objective justification."*

The definition of essential facility doctrine presupposes that a finding that an undertaking is dominant over essential facilities may result in that undertaking being forced to share its facilities or assets with its competitors. [71]This represents a serious

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[67] *The concept of special responsibility of dominant firms was first introduced by the ECJ in Michelin v Commission where it held that an undertaking concerned has a special responsibility not to allow its conduct impair genuine undistorted competition on the common market.*

[68] Gregory Mc Curdy (note 41) at 479.

[69] See *B&I Line Plc v Sealink Harbours Ltd and Sealink Stena Ltd* [1992] 5 CMLR 255 also reported in Jones and Sufrin (note 31) at 542 *In Stena Link the Commission concluded that Sealink had abused its market position on the market of port services by refusing to give access to the port on reasonable and non discriminatory grounds to a potential competitor. The Commission added that the principal of essential facility applies when the competitor seeking access to the essential facility is a new entrant into the relevant market.*

[70] Antionio Capobianco (note 39) at 552.

[71] Alison Jones & Brenda Sufrin (note 31) at 542.

interference with an undertaking's right and can only be justified where there would be a serious effect on competition which cannot be cured by less intrusive measures.[72]

Under European law, the essential facilities doctrine finds its origin in the context of refusal to supply and imposes a general duty to supply on dominant undertakings in two market situations, meaning that a dominant undertaking has to provide services or sell products except where it has objective justification not to do so.[73]

The most prominent case dealing with refusal to supply is *Commercial Solvents Corporation v Commission*[74] Commercial Solvents was a dominant supplier of a raw material and refused to supply an existing customer. The customer could not obtain supplies from any other source. The European Court of Justice decided that Commercial Solvents was in breach of Article 82 and held that an undertaking which has a dominant position in the market for raw materials and refuses to supply its downstream competitor is abusing its dominant position if this refusal may eliminate all competition on the part of the customer.

In *United Brands Co v The Commission*[75], the ECJ found that United Brands which was a distributor of Chiquita bananas abused its dominant position by cutting off supplies to a Danish ripener-distributor because the latter had begun advertising bananas of a competing brand. The court took into consideration the effect of United Brands termination on the willingness of other customers to distribute rival brands as well as the need to maintain the independence of small and medium size firms in their commercial position with a dominant company.[76]

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[72] Alison Jones & Brenda Sufrin (note 31) at 542.

[73] Csognor Istvan Nagy 'Refusal to deal and the Doctrine of Essential facilities in US and EC Competition Law: A Comparative Perspective and a Proposal for a Workable Analytical Framework' (2007) 32 *European Law Review* at 671.

[74] *Commercial Solvents v The Commission* [1974] ECR 223. cited in Alison Jones & Brenda Sufrin (note 31) at 530.

[75] *United Brands Company v The Commission* [1978] E.C.R 207 cited in Alison Jones & Brenda Sufrin(note 31) at 533.

[76] Sergio Baches Opi (note 36) at 416.

These two cases reveal two distinct tests in determining abuse of a dominant position under Article 82 of the EC treaty, Commercial Solvents is a monopoly leveraging case and United Brands deals with discriminatory refusals to deal.[77] United Brands illustrates a situation whereby a refusal to supply may constitute an abuse of a dominant position by foreclosing access to delivery channels for the relevant market.[78]This means that where a dominant company tries to deny access to a facility as a way of exerting pressure on a competitor to compete less vigorously, it is likely to commit an abuse "even if the facility is not essential."[79]

The *Commercial Solvents case* demonstrated that in cases involving selective refusal of access as a way of discouraging aggressive competition, courts will take into account special characteristics of the victim so as to establish how likely the refusal will cause the firm to be discouraged from entering the market, to compete aggressively or to be pushed out of the market entirely.[80]

The court's reasoning in these two cases explains the origin of the essential facilities doctrine under EC competition law and generally stresses the fact that not all essential facilities cases may fit the Commercial Solvents market paradigm ,any more than all refusal to supply cases as shown by United Brands must involve market leveraging.[81] Market foreclosure rather than market leveraging may provide a basis for the application of the essential facilities doctrine.[82]

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[77] Sergio Baches Opi (note 36) at 416
[78] Frank Fine (note 34) at 459
[79] Temple Lang 'Defining Legitimate Competition: Companies Duties to Supply Competitors and Access to Essential Facilities' (1994) 18 *Fordham International Law Journal* at 507
[80] Sergio Baches Opi (note 36) at 417.
[81] Frank Fine (note 34) at 459.
[82] Frank Fine (note 34) at 459.

The first case to deal with the right to access an essential facility was recognized as part of the European order was the case of *Tierce Ladbroke SA v Commission.*[83] The CFI held that:

"The refusal to supply the applicant could not fall within the prohibition laid down by Article 86 unless it concerned a product or service which was either essential for the exercise of the activity in question, in that there was no real or potential substitute, or was a new product whose introduction may be prevented, despite specific, constant and regular potential demand on the part of the consumers".

Therefore the case suggested that a refusal to supply under Article 82 is considered abusive where the refusal concerns a product or service which is essential for the existence of competition unless there is no real or potential substitute or where the emergence of a new product is prevented.

This point was clarified in the case of *Oscar Bronner v Media Print.*[84]The Court of Justice assessed whether the competitors network was an essential facility or not. It explained that there were other alternatives to home delivery systems. Denial of access to media print systems could not affect the plaintiff's business abilities since other systems existed even though they were not as beneficial. Therefore the *Oscar Bronner case* advocates for careful application of the essential facilities doctrine and establishes that a dominant firm has a duty to deal with its competitors only if it is essential to promote competition.

2.3.2 ESSENTIAL FACILITIES DOCTRINE AND INTELLECTUAL PROPERTY RIGHTS IN THE EUROPEAN UNION.

Although the European Court of Justice developed the concept of an essential facilities doctrine to certain infrastructure cases, it was generally believed that intellectual property was immune from competition law scrutiny.[85] In recent years, the

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[83] *Tierce Ladbroke SA v Commission* [1997] E.C.R II-923 cited in Alison Jones &Brenda Sufrin (note 31) at 561.

[84] See *Oscar Bronner v Media Print* 1998 ECR 1-7991 cited in Alison Jones &Brenda Sufrin (note 31) at 547.

[85] See James Turney 'Defining the Limits of the EU Essential Facilities Doctrine on Intellectual Property Rights: The Primacy of Securing Optimal Innovation'(2005) *Northwestern Journal of Technology and Intellectual Property* at 186.

development of the essential facilities doctrine within the European Union has been primarily based upon the emergence of a technology based economy, where dominance based on an intellectual property right is becoming more significant[86]. The holder of an intellectual property right has monopoly over his innovation.

Therefore the essential facilities doctrine has been used by the courts to break up the dominance associated with this right and advocates for equal conditions for competitors. Although the ultimate goal of European competition law is to promote consumer welfare, the Commission has emphasized the need to promote fair market conditions especially with regard to foreclosure of markets to potential competitors where benefits to consumers are uncertain. [87]

The courts have developed the concept of essential facilities doctrine and in some circumstances have issued compulsory license of dominant firms under exceptional circumstances. The "exceptional circumstances test" has been discussed in a number of cases. It is important to briefly examine landmark decisions where the court ordered compulsory license of intellectual property rights.

2.3.3 THE MAGILL CASE AND THE EXCEPTIONAL CIRCUMSTANCES TEST.

The *Magill case*[88] is the first case where the court upheld an issuance of compulsory licensing of an intellectual property right. The case involved the refusal to license copyright on TV listings by three broadcasters (RTE, ITV and BBC) broadcasting in Ireland and Northern Ireland. Each of these TV companies marketed its own TV programme schedules. Magill attempted to publish a weekly guide providing details of all programmes available to viewers in Ireland and Northern Ireland. The broadcasters invoked their copyrights to seek an injunction. Magill complained to the Commission that by refusing to give out advance listings of their TV programs were violating Article 82. The Commission held that the companies were each dominant in the market for

[86] See James Turney (note 85) at 181.
[87] James Turney (note 85) at 182.
[88] *RTE IPT v Commission case* C-241/91, [1995] ECR 1141 cited in Jones & Sufrin (note 31) at 557

their weekly listings and their policies in restricting the availability of the information was driven by the desire to protect their own weekly guides in the downstream market.

The court established the circumstances where an owner of intellectual property right abuses its dominant position and has been termed as the Magill test. The elements of the Magill test are;

a) Where the owner of an intellectual property right is an exclusive owner of a raw material essential to run a certain business on the market and is not duplicable.
b) Prevention of a new product into the market for which there is potential consumer demand
c) The refusal to license has no legitimate business justification
d) The owner knowingly reserves to himself a downstream market by foreclosing competition to other potential competitors.[89]

Although the *Magill case* established the circumstances under which compulsory licensing may be ordered by courts, considerable doubts remained as to whether the hindrance of a new product is a necessary or a sufficient ground for holding the refusal to supply to be abusive. The requirement for a new product is an integral component of the Magill exceptional circumstances thereby identifying such a product is a difficult task. In order to satisfy the test the competitor must develop a product that will compete in a separate market with the right holder. [90]

It is worth noting that the courts did not refer to this case as an "essential facility" or refer to the "essential facility doctrine" however the court borrowed the essentiality element by holding that the three broadcasting corporations were dominant over scarce resource (TV listings) which was essential to compete on the downstream market.[91]

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[89] RTE, IPT v Commission case C-241/91. [1995] ECR 1141 para 54 cited in Jones and Sufrin(note 31) 559
[90] James Turney (note 85) at 189
[91]See Emanela Arezzo 'Intellectual Property Rights at the Crossroad between Monopolization and abuse of Dominant position: American and European approaches compared'(2007) *John Marshall Journal of Computer &Information Law* Vol.24 at 28, *See also definition of the essential facility doctrine in the case of Sea Containers v Stena Sealink where it was held that an undertaking that occupies a dominant position in the provision of essential facility and prevents other companies from using that facility without objective justification*

The *Magill case* shed more light on the complex relation between intellectual property rights and competition law. This case established that competition law can take precedence over intellectual property rights. Where an intellectual property right is pursued contrary to the aims of Article 82 then the intellectual property right is exercised in a manner contradictory to its essential function. Therefore in such circumstances competition law will prevail over any intellectual property right.

2.3.4 THE IMS CASE.

The exceptional circumstances test established by Magill was later explored in the *IMS case.*[92]The case concerned a brick structure used by IMS is to represent regional pharmaceuticals sales data over which IMS claimed copyright. The brick structures were developed in connection with the recipients of the data and over time became the defacto industry standard. NDC attempted to enter the market and consumers were reluctant to use anything that did not look like the brick structure. When NDC began using a similar structure IMS sought an injunction claiming that the structure was based on copyright. Proceedings began in Germany and an injunction was granted against NDC. An interim decision was given in favour of NDC on the basis of there being exceptional circumstances.

The test employed by the Commission in deciding the case was whether there were exceptional circumstances under article 82 which granted IMS refusal to license constituted an abuse of a dominant position. The issue was whether the 1860 brick structure constituted an essential facility and whether by denying access to this facility would eliminate all competition on the German market.

The Commission decided that there were a number of factors that suggest the conclusion that the 1860 brick structure constituted an essential facility. The most

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and grants access to the facility on its own terms other than those it gives its own services violates article 82 if the other conditions of Article 82 are met.

[92] *NDC Health v IMS Health [2002] 4 CMLR 111* (Commission Decision 2002/165/EC of 3 July 2002) cited in Jones and Sufrin (note 31) at 563.

important being the 1860 brick structure was formed and approved by German Pharmaceutical industry as *de facto* standard for provision of sale reports.[93] The brick structure was a barrier to entry considering that the German pharmaceutical firms would not accept any other supplier. [94]Also the fact that the pharmaceutical firms had been involved in the structure which represented the product perfectly tailored to satisfy their needs.[95]

The IMS case differed from the Magill case because refusal to license was not directed at preventing a new product from entering the market instead NDC Health wanted to compete in the provision of market reports offered by IMS. The question of the new product requirement was discussed in the Microsoft case.

2.3.5 THE 2007 MICROSOFT CASE;

The judgment of the Court of First instance on Microsoft is the latest judicial pronouncement on the essential facility doctrine. The judgment confirms that the prevention established in Article 82 continue to determine the line between the "normal exercise" and "abusive exercise" of Intellectual Property Law.[96] This means that a holder of an intellectual property right is not immune from the realm of competition law. It found that Microsoft had abused its dominant position by refusing to grant interoperability information to competing companies and secondly by bundling the windows media player with windows personal computer operating system. The CFI upheld remedies designed to ensure interoperability of operating systems and the unbundling of the Windows Media Player.

The European Court of Justice held that the refusal to grant a license by a dominant undertaking cannot constitute an abuse of a dominant position however; the

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[93] Frank Fine (note 34) at 464

[94] See James Turney (note 85) at 192

[95] See Emmanuela Arezzo (note 91) at 30; The Commission found that without the participation of industry the development of postal code bricks was physically impossible because only German pharmaceutical manufacturers had detailed knowledge of the relationships between physicians and pharmacies which is critical for sales within one brick.

[96] Steve Anderman 'Microsoft v The Commission and the Interoperability Issue' (2008) *European Intellectual property Law Review* at 395.

exercise of an exclusive right may in "exceptional circumstances" involve abusive conduct[97].

The Microsoft case extended the scope of the new product requirement in Magill and IMS by finding that the requirement should be interpreted in accordance with Article 82(b) where a dominant firm's refusal limited outputs markets or technical development which could be direct or indirect showing limitation of consumer choice.[98] Therefore it was enough for complainants to show that their products would have had new or innovative features benefitting consumers and not necessarily new in the sense of being in a different market from licensor's products. The CFI discussed the new product market requirement under the auspices of Article 82(b). The court interpreted this condition to mean that the refusal to license may be harmful not only if it limits the appearance of a completely new product but also if it limits innovation and technological development in the downstream market.[99]

By the court relying on Article 82(b) they need not show that their products will be entirely new in the sense of being different from the licensors products but adds substantial elements arising from the competitors own research efforts.[100] The Court affirmed that Article 82(b) is an abuse to limit technical development to the prejudice of consumers and added that the refusal to provide indispensable interface information amounted to a blockage of interoperability in the information technology sector and a blow to innovation in the secondary market.[101]

The Microsoft case reformulated "new product" requirement to mean "new features" and established wider parameters than the "new product" rule in *Magill*. This

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[97] The European Court of Justice decided in Magill (C-241 & 242 /91P [1995] ECR I-743 and later in IMS Health that in some exceptional circumstances refusal to license may be an abuse pursuant to Article 82 EC.

[98] Ian Eagles &Louise Longdin 'Microsoft's Refusal to Disclose Software Interoperability Information and the Court of First Instance' 30(5) *European Intellectual Property Review*, 205-208.

[99] Renato Nazzini 'The Microsoft Case and the Future of Article 82' at 62. *Antitrust Spring* 2008.

[100] See Anderman (note 96) at 399.

[101] *Microsoft decision at para 305.*

test has been expanded to include a situation where a competitor in the secondary market already has advanced features in their own products and requires access to interface information to develop such advanced features a refusal in such circumstances will limit the technical development of the market.[102]

Therefore the court used essential facilities doctrine and ordered Microsoft to disclose interface information (but not the source code) of the Windows work group server to other competitors. The Microsoft case emphasizes the overall objective of Article 82 which is to avoid conduct which causes harm to effective competition on the market. An owner of an intellectual property right where dominant, may have certain special responsibilities towards competitors in the downstream market.

2.4 EUROPEAN UNION AND UNITED STATES APPROACHES COMPARED:

In both systems Essential facilities doctrine controls the market power inherent in the existence of a physical property or intellectual facility which is vital for proper functioning of a sustainable competitive environment.[103] Both systems prescribe that there is a duty to share in certain exceptional circumstances. However there seems to be a divergence in approach between the two systems due to the different interpretations of the essential facilities doctrine.

In the United States, the Sherman Act[104] punishes a person who monopolizes or attempts to monopolize a certain market. The issue of contention is whether the existence of monopoly power necessitates a monopolist to deal with its competitors or not. The US courts have held that there is no duty imposed to provide access to its competitors.[105] In some other cases a refusal to share is sufficient to sustain antitrust liability. It has been held that where facilities cannot practically be duplicated by would

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[102] Steve Anderman (note 96) at 401.
[103] Antonio Capobianco (note 39) at 553
[104] See Section 2 of Sherman Act 15 U.S.C.A Available at http://www.stolaf.edu/people/becker/antitrust/statutes/sherman.html.[Accessed on 5th December 2008]
[105] Verizon v Trinko LLP 540 U.S Judge Scalia commented that even where access to deal concerns a tangible infrastructural facility dominant firms have no duty to whatsoever to open such facility to its competitors because compelling a dominant firm to share is in some tension with the underlying purpose of antitrust law.

be competitors those in possession of them must allow them to be shared on fair terms.[106]

The European competition imposes a broad duty on dominant firms to cooperate with their competitors.[107] A firm that is dominant on the market has a special responsibility to the market itself and towards its competitors as well.[108]

The Rodby case shows how broadly the commission interprets duties of the of an essential facility;[109]

> "An undertaking that owns or manages and uses itself an essential facility or infrastructure without which its competitors are unable to offer their services to customers and refuses to grant them access to such a facility is abusing its dominant position"

Therefore it can be stated that the European approach to the application of the essential facilities doctrine imposes broader duties on dominant firms to share where access to a facility is essential for competition on the market.

2.5 THE ESSENTIAL FACILITIES DOCTRINE AND BALANCING INNOVATION CONSIDERATIONS.

As discussed above, the essential facilities doctrine imposes on an intellectual property right holder a duty to share access to an essential facility. It has been argued that by imposing a broad mandatory access eliminates incentive for the owner of the facility to innovate. On the other hand imposing narrower access to share creates risks inhibits competition and in turn hurts consumers.[110] Therefore there is a need to balance the principle of a duty to deal of the owner of the essential facility and to promote innovation of new investments by both the owner of the facility and its competitors.[111]

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[106] Verizon v Trinko LLP 540 U.S].
[107] Antonio Capobianco (note 39) at 555.
[108] Emanela Arezzo(note 91) at 41.
[109] [1994] O.J L055/52

[110] Antonio Capobianco (note 39) at 554
[111] See Antonio Capobianco (note 39) at 554

The essential facilities doctrine is not free from criticism it has been regarded as superfluous. Professor Areeda advocates that the doctrine should be treated with the greatest caution, in particular because it is a dangerous disincentive to innovation.[112]

Thus according to Areeda , the essential facilities doctrine is "less a doctrine than an epithet....." He offers six limiting principles to guide any essential facilities inquiry: (1) compulsory access should be exceptional (2) a facility is essential only when it is vital to a plaintiff's vitality in the market and duplication of that facility is not practical (3) courts should not order sharing unless it is likely to improve market conditions (4)a legitimate business purpose defense should always be available (5) a defendant's intent should not be relevant (6) courts should not order compulsory access when the remedy is difficult to supervise.[113]

Other critics like Professor Hovenkamp have argued that forced sharing requires court to set the terms of access, and in essence act as a regulatory agency.[114] Unlike agencies courts are ill suited for a regulatory role and the use of the essential facilities doctrine may not improve consumer welfare. [115]Compulsory sharing reduces incentive to innovate as once a plaintiff has access to a defendant's facility he has no incentive to create his own facility. [116]

Despite the criticisms against the essential facilities doctrine the courts have continued to use it as a fundamental tool to require dominant firms to share access to essential facilities. Essentially this means that competition law encroaches on the exclusivity guaranteed by intellectual property.[117] Therefore compulsory licensing should be applied in such a way as not to create a disincentive to innovation.

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[112] P Areeda (note 63) 841.
[113] P. Areeda (note 63) at 852-853
[114] Herbert Hovenkamp Federal Antitrust Policy: The Law of Competition and its Practice 2 ed 1999 at 306.
[115]See Joseph Coker (note 46) 19
[116] Joseph Coker (note 46) at 224
[117] James Turney (note 90) at 196

The most important incentive to innovate is the prospect of future profits especially with regard to pharmaceutical patents where a lot of research and development has to be carried out to develop the particular drugs. Innovation is an important dynamic in both primary and downstream markets and the benefits should always be considered.[118] By allowing access to essential facilities competition will be improved in subsidiary markets to that of the intellectual property right, bringing the associated benefits of increased choice, lower prices and high quality.[119] Where an intellectual property right is indispensable, it is likely to create a monopoly position on the primary market thus becomes vital to share such a facility[120].

For these reasons, it is important to note that the essential facility doctrine does not introduce a generalized mandatory access regime[121]. It introduces the need for access to be granted to competitors wishing to enter complementary markets. The objective of the essential facilities doctrine is to grant access to competitors in the complementary markets that are more efficient than the incumbent and not necessarily to reduce profits originating from the use of the essential facility itself.[122]

2.6 CONCLUSION

This chapter has attempted to analyze the application of the essential facilities doctrine in the United States and European Community. Although it has been heavily criticized in the United States, it has been growing significantly in the European Union and the courts have generally embraced the doctrine. It is imperative to point out that even though the application of the essential facilities doctrine can have adverse effects on

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[118] James Turney (note 90) at 197

[119] James Turney (note 90) at 197

[120] James Turney note at 197

[121] Alberto Heimler Intellectual property right-based monopolies and ex-post competition: Some reflections on the essential facility doctrine Available *at* http://www.econ-pol.unisi.it/pubdocenti/almic.doc [Accessed on 16th January 2009]

[122] See Alberto Heimler note (121)

incentives to innovate it is necessary to force dominant firms to share access in certain circumstances. The Microsoft case is a landmark judgment and a good example of the use of the essential facilities doctrine to share access to software information. Therefore the same standards used in Microsoft can also be applied to open access to pharmaceutical patents in South Africa and in turn license generic producers to supply affordable essential medicine to the people dying of AIDS.

CHAPTER 3: THE SOUTH AFRICAN EXPERIENCE

3.0 INTRODUCTION:

The previous chapter provided an overview of the application of the essential facilities doctrine in the United States and the European Union. In the United States, the courts have been reluctant to apply the doctrine. Conversely, the European Union has embraced the doctrine and courts have used it to force dominant firms to share access to their patent rights. It is important to note that the courts in both jurisdictions agree that in certain circumstances it is appropriate to compel holders of intellectual property rights to share their rights with others where there is a risk to consumer harm. Therefore the essential facilities doctrine can be used as mechanism to force dominant pharmaceutical firms to license other generic manufacturers to produce cheaper medicines needed to promote basic health and welfare of South Africans who are dying of HIV/AIDS. The main objective of this chapter is to analyze the various regulatory mechanisms in place in South Africa to make drugs accessible to the people in need. It will assess whether the government has taken the initiative to make use of the various mechanisms to promote access to drugs or whether they merely exist on paper.

This chapter begins by exploring the extent and nature of HIV/AIDS pandemic in South Africa and the need for affordable treatment. The second part will discuss the international regulatory policy framework in place to make medicines more affordable. The third part of this chapter will discuss the national legal framework in South Africa by looking at the relevant laws and the relevant cases that have been decided by the Competition Commission in compelling dominant pharmaceutical firms to license generic manufacturers to produce cheaper antiretroviral drugs.

3.1 THE NATURE OF THE HIV/AIDS PANDEMIC IN SOUTH AFRICA.

The AIDS epidemic in South Africa is one of the most severe in the world. In 2007, it was estimated that more than five million people are living with HIV/AIDS in

South Africa which represents the highest number of sufferers in any country in the world.[123] It is likely that close to 400,000 South Africans die of the disease each year.[124] With such a public health crisis at hand, a strong and urgent response from the government is vital to ensure there is access to affordable treatment. However, the government's response to the AIDS crisis has been criticized both domestically and internationally.[125] Much of the criticism is due to the lack of access to antiretroviral medicine across the country and the attitudes towards AIDS of some of the government officials.

Former President, Thabo Mbeki has openly questioned the scientific basis of whether HIV causes AIDS [126] and former Health Minister Manto Tshabalala Msimang advocated for promotion of nutrition instead of antiretroviral medicine as a way of treating AIDS.[127] While it is true that nutrition is an important part of treatment, it is by no means a replacement for antiretroviral medicine. The Minister's position angered many including South African cleric Desmond Tutu:

> *"We are playing with the lives of people, with the lives of mothers who would not have died if they had drugs. If people want garlic and potatoes let them have them, but let us not play games..."*[128]

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[123] UNAIDS 2008, *Report on the Global AIDS Epidemic 2008*. Available at http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/ [Accessed on 3rd December 2008]

[124] 'Complaint submitted by Treatment Action Campaign concerning the Conduct of Merck & Company' (note 3)

[125] 'AIDS in South Africa: Treatment, Transmission and the Government'. Available at http://www.avert.org/aids-south-africa.htm. [Accessed on 10th December 2008]

[126] Edwin Cameron &Jonathan Berger (note 15) *at 19*.

[127] See 'AIDS in South Africa: Treatment, Transmission and the Government' at 2. (*Thabo Mbeki and Tshabala were replaced in 2008 which was seen as a beacon of hope for many activists on the transformation of the AIDS response*). See www.avert.org/aids-south-africa.htm[Accessed on 10th December 2008]

[128] Sunday Herald 18th June 2006 'Aparthied might be over, but the struggle goes on' cited in AIDS in South Africa: Treatment, Transmission and the Government (note 129).

According to the dogma of AIDS denialism, antiretroviral drugs are poisons that cause and do not treat the symptoms of AIDS.[129] This stance from the government has biased the role of antiretroviral medicine in the national response to AIDS.

However, in 2007, the South African government introduced a national HIV/AIDS and STI Strategic plan for South Africa 2007-2011(the NSP). The primary aims of the NSP are to reduce the rate of new HIV infections by 50% by 2011; and to reduce the impact of AIDS by expanding access to appropriate treatment, care and support to 80% to those in need by 2011. The introduction of the (NSP) has been a welcome relief from the government's long standing vacillation to the AIDS disease.

For a long time infection of HIV was seen as an "automatic death sentence" but today, for those with access to antiretroviral medicines, HIV has become a chronic but manageable medical condition.[130] Therefore access to antiretroviral medicines can improve the quality and quantity of life for people living with AIDS.[131] The fact that AIDS can be treated has changed the social nature of the disease in the sense that stigma and fear have diminished.[132] Nevertheless, while the decision to start antiretroviral drugs has been laudable, many South Africans are still not receiving treatment. According to the latest World Health Organization statistics at the end of 2007, 460,000 South Africans are receiving antiretroviral medicine which is about 28% of those in need of the treatment.[133]

This presents a major challenge and calls for strategies on how to improve access to medicines in South Africa. It is worth noting that the major reason for lack of access is the high prices charged by pharmaceutical companies and their rejection of generic

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[129] See Edwin Cameron(note 15) at 19

[130] Adila Hassim, Mark Heywood& Jonathan Berger *Health &Democracy A guide to Human Rights, Health Law and Policy in post-apartheid South Africa* 1ed (2007) 438.

[131] See Adila Hassim (note 130) at 438.

[132] See Edwin Cameron &Jonathan Berger (note 15) at 2

[133] WHO (2008) *Towards Universal Access: Scaling up priority HIV/AIDS interventions in the Health Sector.* Available http://www.who.int/hiv/mediacentre/2008progressreport/en/index.html [Accessed on 25th January 2009]

companies from producing cheaper drugs. For most South Africans HIV/AIDS remains a life threatening condition that leads to premature deaths.[134] Their deaths are unnecessary, modern medical advances make them unnecessary and yet modern medications are not accessible to them.[135] Therefore the high prices caused due to patent rights have directly and indirectly hindered access to lifesaving drugs in a way that lacks moral justification.[136]

Therefore South Africa needs to take steps to ensure a sustainable supply of access to medicines to millions of people who cannot access affordable antiretroviral treatment. In this way, South Africa will be honouring its international human rights obligations in a manner to ensure that access to medicines is a reality for all. It is necessary to analyze the international and regulatory policy framework for making medicines affordable in South Africa.

3.2 INTERNATIONAL AND REGULATORY POLICY FRAMEWORK FOR MAKING MEDICINES AFFORDABLE IN SOUTH AFRICA.

This thesis advocates that the essential facilities doctrine is a viable competition law mechanism that can be used to force dominant pharmaceutical firms to share their patent rights with generic manufacturers to make the drugs accessible and affordable for the millions of South Africans dying of AIDS. In assessing the use of the essential facilities doctrine it is imperative to analyze the legal framework in place that facilitates increased access to medicine. This section surveys the national and international commitments that are necessary to ensure that essential medicines are accessible.

3.2.1 SOUTH AFRICA'S INTERNATIONAL LAW OBLIGATIONS

South Africa has various international law obligations that are relevant to making drugs accessible and available. South Africa is bound by various International

[134] See Adila Hassim (note 130) at 440.
[135] See Edwin Cameron & Jonathan Berger (note 15) at 3
[136] See Adila Hassim(note 130) at 441

law instruments. The most important agreement relating to the issue of accessibility of drugs is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which obliges World Trade Organization members to respect certain minimum levels of intellectual protection.[137] TRIPS sets out standards to which each nation must adhere concerning the enforcement of domestic intellectual property rights.[138]These authorizations are enunciated in Article 8 of the TRIPS agreement which states that member states *"may adopt measures necessary to protect health" including special measures to prevent the abuse of intellectual property rights by right holders or resort to practices which unreasonably restrain trade."*[139] Although the main objective of the TRIPS agreement is to harmonize world intellectual property, it has greatly contributed to limitation of access to medicines needed during public health crises in many developing countries.[140]Multinational pharmaceutical companies use the TRIPS provisions to have monopoly over patented pharmaceuticals thus permit the patent holder to charge higher prices on the patented drugs which poor people in developing countries cannot afford.[141]

The World Trade Organization has addressed these concerns by including flexibilities like compulsory licensing into the TRIPS Agreement. Article 31 of the Agreement allows governments to issue compulsory licenses to companies to make patented products or use patented processes under license without the consent of the patent owner, but only under certain conditions aimed at protecting the legitimate interests of the patent owner.[142] The TRIPS Agreement allows compulsory licensing as a safeguard to strike a balance between promoting access to existing drugs and innovation.

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[137]TRIPS Agreement came into force on 1st January 1995 and is binding on all member states of the World Trade Organization

[138]Slone Pearson 'Will the August 20,2003 Decision of the WTO provide adequate protection for patent holders rights and is Diversion still a threat to the pharmaceutical Industry?' (2005) *Journal of High Technology Law at 384*

[139]See Article 8 of the Trade and Related Aspects of Intellectual Property Agreement.

[140]See Slone Pearson (note 138) at 384

[141] See Idowu Ohioze (note 11)

[142]Shinzo Kobori (note 20) at 15.

In addition, the World Trade Organization's Declaration on the TRIPS Agreement and Public Health (The Doha Declaration) addressed these divergent concerns by recognizing that the agreement "does not and should not prevent WTO members from taking measures to protect public health."[143]In essence this gives members the right to use flexibilities guaranteed in the TRIPS Agreement to combat fatal pandemics like AIDS in South Africa in such a way as to protect public health and ensure access for all.

Despite the flexibilities guaranteed by the Doha Declaration, South Africa has failed to take appropriate steps to issue compulsory licenses for the importation of affordable generic antiretroviral medicines.[144] The issuing of a grant of compulsory license to produce or import generic medicines may require the state to issue a compulsory license or an interested person to institute a legal action for a license to produce or import.[145] Thus all the powers to make decisions are in the hands of a single minister who may not necessarily act quickly. While other concerned organizations like non-profit organizations (NPO) may wish to challenge the abuse of patent rights but find that they are powerless to act.[146] Under competition law, a complaint to the authorities is sufficient to issue licenses to other parties like generic manufacturers to produce cheap drugs. Therefore the essential facilities doctrine can be a viable tool in forcing mandatory access on dominant pharmaceutical companies to share their patent rights with generic manufacturers to ensure access to affordable drugs in South Africa.

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[143] Peter Rott 'The Doha Declaration- Good News for Public Health' (2003) Intellectual Property Quarterly at 285.

[144] Edwin Cameron &Jonathan Berger (note 15) at 18.

[145] See S.56 of South African Patents Act which allows for such persons to apply to the Commissioner of Patents for a compulsory license under the patent.

[146] See Jonathan Berger Advancing Public Health by Other Means: Using Competition Policy to Increase access to essential medicines at 16. Available at http://www.iprsonline.org/unctadictsd/bellagio/docs/Berger_Bellagio3.pdf [Accessed on 6th December 2008]

3.3 INTERNATIONAL HUMAN RIGHTS LAW OBLIGATIONS.

South Africa has obligations under International Human Rights law to interpret and implement its laws in such a manner as to ensure access to affordable medicine to those suffering from the deadly disease such as AIDS[147]. There are two important international law human rights instruments that are relevant to the issue of making drugs more affordable and accessible namely: International Covenant on Economic, Social and Cultural Rights (ICESCR) and the Universal Declaration of Human Rights (UDHR). These documents comprise the International Bill of Human Rights that make up the modern day human rights movement.[148]

The Universal Declaration on Human Rights states that everyone has a right to a standard of living adequate for the health and well being of himself and his family, including food, clothing, housing and medical care and necessary social services.[149] This concept is further reiterated in Articles 2 and 12 of the ICESCR which states that *"state parties to the present Covenant should recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."*[150] Also Article 2 of the ICESR requires that *"each state party undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources with a view to achieving progressively the full realization of the rights recognized in the present Covenant."*[151]

These international instruments demonstrate that the right to health is paramount which clearly implies that there should be access to affordable medicine for all. The right to access of pharmaceuticals has been implied in the Universal Declaration of Human Rights which states that everyone has a right to "share in

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[147] See Tina S Bhatt (note 6) at 599.
[148] See Tina S Bhatt (note 6) at 599
[149] Article 25(1) of the Universal Declaration of Human Rights. Available at http://www.un.org/Overview/rights.html
[Accessed on 26th January 2009]
[150] See Article 12 of the International Covenant on Economic Social and Cultural Rights. Available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm
[Accessed on 26th January 2009]
[151] See Article 2 of the International Covenant on Economic Social and Cultural Rights.

scientific advancement and its benefits"[152]The ICESCR also states that *"everyone has a right to enjoy the benefits of scientific progress and its applications.*[153]"

Lastly the right to life is regarded as "closely related" to the right to health and they are said to be wholly dependent on each other.[154] Therefore the right to life is the basis for the right to health thus, access to drugs is a human right that should be protected and should not be deprived. A violation of the obligation to fulfill the right to health occurs when the state fails to take necessary steps to ensure realization of the right to health including a failure to take measures to reduce the inequitable distribution of health facilities goods and services.[155] In South Africa it has been established that those with the means can access the best health care for treatment of AIDS and also can afford antiretroviral medicine however, the majority of South Africans who are poor cannot afford quality health care[156]. This is a major violation of the right to health; access to medicine should be available to all regardless of status.

3.4 SOUTH AFRICA NATIONAL LEGAL FRAMEWORK:

3.4.1 THE CONSTITUTION

According to the Constitution of the Republic of South Africa, the state has a duty to take reasonable steps to put in place a legal framework that facilitates access to health care services[157]. According to the case of Minister of Health v Treatment Action Campaign[158] The Constitutional Court affirmed that under South African law, as under

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[152] See Article 27(1) of the Universal Declaration of Human Rights.
[153] See Article 15 (1) of the International Covenant on Economic, Social and Cultural Rights.
[154] See Tina S Bhatt (note 6) at 600
[155] General Comment; Para 52 of the UN Committee on Economic, Social and Cultural Rights.
[156] This was discussed in Statement of Information by Consumer project on Technology concerning the alleged prohibited practice in terms of section 49B (2)(a) of the Competition Act 89 of 1998. Available at http://www.cptech.org/ip/health/cl/cl-cases/rsa-tac/cptech-statement.doc
[Accessed on 15th January 2009]
[157] See Adila Hassim (note 130) at 445
[158] *Minister of Health v The Treatment Action Campaign (No 2) 2002 (5) SA 721* cited in Adila Hassim note at 445. Also see judgment of Chaskalson CJ in *Minister of Health v The New Clicks South Africa (Pty) Ltd (2006)*

international human rights law, access to medicine is a component of the right to health services that the state must protect, promote and fulfill and adopt programmes within its available resources to progressively realize.

Therefore the Constitution imposes an obligation on the government to take reasonable steps to put in place a legal frame work that assists improved access to essential medicines. In essence this implies that the government should do more than provide goods and services it also has a constitutional duty to take reasonable steps towards reducing the prices of drugs and ensures that there is a sustainable supply to affordable medicine.[159]

The state has a duty to honour social and economic rights and implement programmes that address the basic needs of those that cannot provide for themselves in situations of crisis[160]. This was opined in the case of *Grootboom v Republic of South Africa*[161] it was stated that:

> *"Towards this end, we are aware that the government is currently considering the extent to which it will fund the provision of ARVs to those who need them and cannot afford them. The states duties under the right to access health services do not, however, begin with and end with such programmes..... the state must create conditions for access for people at all economic levels of our society, including unblocking the system where market barriers inhibit the enjoyment of rights"*

Therefore this case suggests that the government must take measures necessary to create suitable conditions for access to medicines by unblocking market barriers to enable the poor people who cannot afford to provide for themselves.

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(2) SA 311 at paragraph 314. It was stated that the state has an obligation to take reasonable steps to ensure access to health care.

[159] See Adila Hassim (note 130) at 445 *this point was further elucidated in the case of Minister of Health v New Clicks South Africa(See note above) where it confirmed that when the state regulates it must do so in a reasonable way ensuring that measures are taken to make medicines affordable and should not by design make them unavailable.*

[160] See Statement of Information by Consumer Project on Technology concerning an alleged prohibited practice in terms of Section 49B (2)(a) of the Competition Act 89 of 1998 (note 156)

[161] See *Case of Grootboom v The Republic of South Africa 2000 (11) BCLR 1169* para 41- 44

3.4.2 THE PATENTS ACT

The Patent Act[162] offers a number of mechanisms to increase access to essential medicines. These are; (1) State use of patented products for public purposes (2) Compulsory Licensing to deal with the abuse of a patent and (3) the *"Bolar amendment"*. These will be discussed briefly to show that the patents Act can play a vital role in ensuring access to medicine for people dying of AIDS.

According to Section 4 of the Patents Act[163], a Minister may use an intervention for public purposes on such conditions as agreed upon with the patentee. This means that the Minister of Health has the power to issue compulsory licenses to state entities or to private companies. The term "public purposes" suggests that appropriate steps must be taken to ensure an increase access to essential medicine, even where medicines are not excessively priced, a compulsory license may be used to ensure sustainability of efficient supply of medicine[164].

However it is worthy to note that the South African government has repeatedly refused to invoke this power to order compulsory licensing for importation of cheaper generic antiretroviral medicine[165]. This has been a huge obstacle in improving access to medicines to people who are suffering from AIDS and other diseases.

The Bolar amendment[166] is another mechanism in the Patents Act that can be used to improve access to medicine. The Bolar Amendment derives its name from the US court of Appeals for the Federal Circuit Case of *Roche Products, Inc v Bolar*

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[162] See Patent Act No 58 of 1978 as amended by Patents Amendment Act of 2002 Available at *http://www.gpa.co.za/pdf/legislation/Patents%20Act.pdf*.
[Accessed on 28th January 2009].

[163] S.4 of the Patents Act *states that a patent shall have like effect against the state as it has against the person. Provided that the minister of State may use invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the Commissioner on application by or on behalf of such Minister and after hearing the patentee.*

[164] See Adila Hassim (note 130) at 459.

[165] See Edwin Cameron & Jonathan Berger (note 15) at 18 *To emphasize this point, civil society has a number of times approached the government to use section 4 of the Patents Act to issue compulsory licenses so that a sustainable supply of cheaper generic version of antiretroviral medicines are made available. The government has been reluctant to use this provision to improve access to medicine.*

[166] See Section 69A of the Patents Act

Pharmaceutical Company[167]; this case decided that drug regulatory authority approval could not take place before the patent had expired. The South African law was amended leading to Section 69A of the Patents Act stating that:

"It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates manufacture, production, distribution, use or sale of any product."

The Bolar amendment permits generic manufacturers to register medicines without infringing existing patents.[168] The generic company must take appropriate steps to register the drugs with the MCC and the local production of the drugs can only take place after the patent has expired.[169] The basis of registering the product is that generic companies can start selling their products as soon as the patent expires. The effect of this is to ensure knowledge remains not only protected but secret.[170]

It is imperative to point out that the government unwillingness to use its statutory powers to issue compulsory licensing under the Patents Act is incomprehensible and negligent of their duty to take care of the millions of people who are suffering due to lack of access to essential medicine.

3.4.3 THE COMPETITION ACT.

South Africa's Competition Act has been in force for eleven years the Act has been used to advance public health concerns. The Constitution specifically states that when interpreting any legislation such as the Competition Act, every court, tribunal or

[167] *Roche Products Inc v Bolar Pharmaceutical Company USR733 F2d 858 (Fed. Cir 1984) 469 US 856* (1984) cited in Adila Hassim (note 130) at 460.
[168] See Cameron & Jonathan Berger (note 15) at 19.
[169] See Adila Hassim (note 130) at 461.
[170] See Cameron &Jonathan Berger (note 15) at 19.

forum must promote the spirit, purport and objects of the Bill of Rights[171] this includes the right of everyone to have access to health care services.[172]

The Competition Act is mainly intended to regulate certain aspects of economic activity in South Africa. The Act was designed to "provide for all South Africans equal opportunity to participate fairly in the national economy." Also to provide markets in which consumers have access to, and can freely select, the quality and variety of goods and services they desire" and to regulate the transfer of economic ownership in keeping with the public interest."[173] Therefore when pharmaceutical companies abuse their patent rights by refusing to license generic manufacturers to produce cheaper drugs they limit access to affordable drugs which is against the social and economic objectives of the Act.

One of the most important aspects of competition law is its relationship with patent law. The objectives of intellectual property rights and competition law are said to be in conflict with one another. Intellectual property rights grant exclusive rights to the holder of the patent over their innovation.[174] While competition law battles monopolies and seeks to create a level playing field by placing restrictions on the abuse of a dominant position.[175] It is generally accepted that intellectual property law and competition law are not in conflict with one another, they both pursue the same goal to promote consumer welfare.[176]

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[171] Section 39(2) of the Constitution of South Africa 1996 Available at http://www.info.gov.za/documents/constitution/1996/a108-96.pdf
[Accessed on 17th January 2009]

[172] Section 27 of the Constitution of South Africa 1996.

[173] See *Purpose of the South African Competition Act which is to promote and maintain competition in the Republic in order to provide consumers with competitive prices and product choices.* Available at http://www.compcom.co.za/thelaw/ConsolidatedAct.doc.
[Accessed on 10th January 2009]

[174] Cornelius Dube 'Intellectual property rights and Competition Policy' Available at www.cuts-international.org/pdf/viewpointppaper-IPRs-compPolicy.pdf.
[Accessed on 15th December 2008]

[175] Cornelius Dube (note174) at 1.

[176] See Jones & Sufrin (note 31) at 777

Competition law can be used to challenge the abuse of patent rights and can play a vital role in increasing access to medicine in South Africa. Patents by nature are anticompetitive with a patent holder having the right to exclude competition. The Competition Act has various mechanisms to control the exercise of patent rights. The Act prohibits "abuse of dominance," prohibits "restrictive practices" and prohibits "denying access to an essential facility when it is feasible to do so." These mechanisms are enshrined in section 8 of the Competition Act. The aim of S.8 of the Competition Act is to advance consumer welfare by ensuring access to affordable medicine.

3.4.4 ABUSE OF DOMINANCE

Competition law recognizes the fact that firms for various reasons may dominate a market. In the pharmaceutical industry, market dominance is often associated with patent protection.[177] The existence of patent protection does not necessarily translate to market dominance however it is the abuse of the patent that confers dominance on a particular firm.[178] Before determination of whether the alleged conduct shows abuse of dominance a proper market must be defined.

The key factor in determining abuse of a dominant firm is enshrined in Section 8 of the Competition Act. The three types of abuse namely excessive pricing or charging prices that cannot be objectively justified, dominant firms engaging in exclusionary acts and denying access to a competitor to an essential facility when it is feasible to do so.

3.4.5 EXCESSIVE PRICING S. 8(a)

Section 8(a) makes it an illegal practice for a dominant firm to "charge an excessive price to the detriment of customers. An "excessive price" is defined as a price

[177] See Adila Hassim(note 130) at 463
[178] See Adila Hassim (note 130) at 464

that is higher than, and bears no reasonable relation to, the economic value of that good or service.[179]"

A number of complaints have been brought before the competition authorities in South Africa on the basis of this provision which mainly relate to the exercise of intellectual property rights. As part of the campaign to increase access to medicines for HIV/AIDS in South Africa decisive steps have been taken by the civil society to reduce the prices associated with antiretroviral medicine they lodged a complaint against GlaxoSmithkline and Boehringer Ingelheim with South Africa Competition Commission in 2002.

In the case of *Hazel Tau and others v Glaxo Smithkline South Africa (Pty) Ltd& Boehringer Ingelheim (Pty) Ltd*[180]

The basis of the complaint was that the two pharmaceutical companies Glaxo Smithkline and Boehringer Ingelheim were charging excessive prices for their patented antiretroviral medicine. The complainants alleged that the prices charged by the two companies were responsible for the premature, predictable and avoidable loss of life. [181]

In particular the complaint argued that the prices at which the antiretroviral medicines are sold could not be justified; even when the full costs of manufacturing, research and development are taken into account, more than fair profit is received by

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[179] See Section 1(ix) of the Competition Act which defines *"excessive price" means price for a good which bears no reasonable relation to the economic value of that good and service and is higher than the value referred to (a) above.*

[180] Hazel Tau and others v Glaxo Smithkline South Africa (Pty) Ltd& Boehringer Ingelheim (Pty) Ltd Available at www.alp.org.za
[Accessed on 16th January 2009]

[181] See Statement of Complaint submitted by Treatment Action Campaign concerning the conduct of Merck &Company' (note 3)

the companies.[182] By challenging the high prices of drugs the complainant sought to ensure that people living with AIDS can afford to buy medicines to save their lives.[183]

The complaints also alleged that as far as antiretroviral medicine is concerned, the respondents were dominant firms as contemplated by Section 7 of the Act.[184] The lack of competition in respect of antiretroviral medicine led the drug companies to have monopoly powers in the market and abused this power by charging excessive prices.[185] It is imperative to note that the Competition Act does not prohibit monopoly power rather the abuse of such power[186] Both Glaxo Smithkline and Boehringer Ingelheim exceeded the 45% market share as stipulated in S.7 of the Competition Act and were therefore dominant in the relevant antiretroviral markets.

The Competition Commission investigated this case and found hard evidence to support the complainant. It found three abuses of dominance under S.7 of the Competition Act (a)Excessive pricing, (b) refusing to give a competitor access to an essential facility, when its economically feasible to do so, and (c) engaging in exclusionary conduct if the anti competitive effect of the act outweighs its technological efficiency or other precompetitive gains.[187]

Menzi Simelane a Commissioner at the Competition, explained

> *"Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide competition between firms and their generic competitors. We will request the tribunal to make an order authorizing any person to exploit the patents to*

[182] See The price of life: Hazel Tau and Others v Glaxosmithkline and Boehringer Ingelheim available at http://alp.org.za.dedi20a.yourserver.co.za/modules.php?op=modload&name=News&file=article&sid=222 [Accessed on 20th January 2009].
[183] Jonathan Berger (note 146) at 17.
[184] See Statement of 'Complaint submitted by Treatment Action Campaign concerning the conduct of Merck &Company'(note 3).
[185] See The Price of Life Hazel Tau & Others (note 182).
[186] See Price of life Hazel Tau & Others(note 182).
[187] Media Release from the Competition Commission 16th October 2003 Available at www.compcom.co.za/resources/media2003.asp. [Accessed on 5th December 2008]

market generic versions of the respondents patented medicines or fixed dose combinations that require these patents in return for the payment of a reasonable loyalty".[188]

Following the Competition Commission statement, the two pharmaceutical companies decided to settle out of court with the complainants. They agreed to issue multiple licenses to South African and Indian generic producers who supply cheaper versions of the medications in South Africa[189].This case was of great significance as it led to lower prices of antiretroviral drugs in dispute. The civil society was able to take the lead in advancing public health concerns by taking appropriate measures to ensure the licensing of generic manufacturers to produce cheaper medicines. However, the State has failed to invoke its powers under patent law to issue compulsory licenses to generic manufacturers.

3.4.6 THE ISSUE OF DENYING A COMPETITOR ACCESS TO AN ESSENTIAL FACILITY. S.8 (b)

Section 8(b) of the Competition Act prohibits a dominant firm from refusing to give a competitor access to an essential facility when it is economically feasible to do so. In terms of the Act an essential facility means "infrastructure or resource which cannot be duplicated and without access to which competitors cannot reasonably necessary to allow them to provide goods or services to their customers."[190]

This provision allows competitors to force an intellectual property holder to license their rights where it is crucial to allow them access to provide goods and services to their own customers.[191] However it is important to note that the issue of

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[188] The Competition Commission's Media Release No.29 of 2003 Available at www.compcom.co.za [Accessed on 10th January 2009]

[189] See Adila Hassim note at 464

[190] See S.1 (viii) Competition *Act "essential facility" means an infrastructure or resource that cannot be reasonably duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.*

[191] Nkonzo Hlatshwayo 'The Challenges of Intellectual Property Protection and Competition Enforcement: An Analysis of the Microsofts Decisions and their Implications for South African Intellectual Property and Competition Law'.*(2008) University of Warwick Journal of Information law and Technology* Available at http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/2008_2/hlatshwayo. [Accessed on 20th January 2009]

denying a competitor access to an essential facility in South Africa is relatively underdeveloped and a few cases have been handled by the Competition authorities in this regard.

For example the *Hazel Tau Case*[192]concerned abuse of dominance by two dominant pharmaceutical firms for charging exorbitant prices for their antiretroviral medicine. At the time of the complaint GlaxoSmithKline enjoyed patent protection over three drugs central to the fight against AIDS while Boehringer Ingelheim enjoyed patent protection of the drug nevirapine. The two companies refused to license other generic manufacturers to produce cheaper versions of antiretroviral medicine.

The Commission announced that the two companies had abused the dominance provisions stipulated in the Act. The Competition Commission recommended that a voluntary license was an "essential facility" because competitors, who were in all other respects capable of making the medicines, could not do this without a license.

This case is not a very useful precedent in determining that refusal to license competitors constituted an essential facility. However this case portrays that in certain circumstances it is necessary to force dominant firms to license certain medicines to improve access to drugs in South Africa. It is evident that the essential facilities doctrine is a valid ground to force a dominant company to share access to an essential resource.

The only South African case where the essential facilities doctrine was considered *is Glaxo Welcome (Pty) Ltd and the National Association of Pharmaceutical Wholesalers*[193]

In this case the complainants were pharmaceutical wholesalers and distributors while the respondents are manufacturers of pharmaceutical products which were sold and

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[192] See case of *Hazel Tau v Glaxosmithkline &Boehringer Ingelheim.*

[193] Druggist Distributors (Pty) Ltd and the National Association of Pharmaceutical Wholesalers 15/ CAC/ Feb 02 Available at http://www.saflii.org/za/cases/ZACAC/2002/3.html [Accessed on 20th January 2009].

distributed by the complainants.[194] The issue of contention in this case was the modification of Druggist Distributors (8th Respondents) from a wholesaler into a distribution agent.[195] The complainants used to purchase products from the respondents at a standard discount of 17.5% after the conversion the 8th respondents (Druggist Distributors) to distribution agent stopped offering the complainants a discount of 17.5% as per the tradition.

The complainants objected to the respondent's decision to set up the distribution agent and sought relief against the respondents through the Act alleging contravention of Sections 4, 5, 8 and 9 of the Competition Act. Therefore the alleged conduct on the part of the respondents amounted to; (a) denial of access to an essential facility (b) the charging of excessive prices and (c)predatory pricing.

With regard to the issue of denying access to an essential facility in accordance with S.8 (b) of the Competition Act, the learned judge was of the view that the respondent's product constituted resources that could not be reasonably be duplicated in accordance with definition of the Act.[196] The learned judge pointed out that the definition of resource was not meant to be interpreted as products, goods and services and therefore the pharmaceutical products do not qualify as essential facilities. The court cautioned on the use of the essential facilities doctrine provision except in appropriate circumstances:

> *"The legislature intended from the architecture of the Act, that there should be limits to the essential facilities doctrine. To demand that a dominant firm should grant access to its facilities is a substantial intervention on the part of a competition authority. The widening of the application and scope of the essential facilities doctrine can have harmful economic effects such as*

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[194] Druggist Distributors (Pty) Ltd and the National Association of Pharmaceutical Wholesalers (note 193).
[195] Druggist Distributors (Pty) Ltd and the National Association of Pharmaceutical Wholesalers (note 193).
[196] Judge Husain JA did not agree with the complainants that the pharmaceutical products qualify as essential facilities. He was of the opinion that the essential facilities doctrine should be applied with caution. See (note 193) at http://www.saflii.org/za/cases/ZACAC/2002/3.html
[Accessed on 20th January 2009].

discouraging investment in infrastructure. An investor might be reluctant to invest for fear of a third party demanding a free ride on the fruits of such an investment".

It is important to state that this case did not involve the application of the essential facilities doctrine to intellectual property. The issue was whether scarce goods or products could be essential facilities. The court was of the opinion that the essential facilities doctrine should be applied in only appropriate circumstances.

Notwithstanding the difficulties of the application of the essential facilities doctrine, it can be a useful competition law weapon in dealing with monopoly rights of a patent holder. Especially with regard to the issue of access to drugs where the drugs are patented, the manufacturers charge exorbitant prices which the poor in developing countries cannot afford.

3.5 ENGAGING IN EXCLUSIONARY CONDUCT

In South Africa, AIDS activists have resorted to competition law to force dominant companies to share access to essential medicine patents. In November 2007, a complaint was filed by Treatment Action Campaign against multinational pharmaceutical company, Merck and Company and its South African branch MSD[197]alleging its refusal to grant licenses to generic manufacturers to import and sell AIDS medicine called Efavirenz. The complaint is still pending before the Commission.

The legal submission supporting the complaint states:

"In refusing to license on reasonable and non discriminatory terms, the respondents have without good cause threatened access to comprehensive treatment for HIV/AIDS in both public and private sectors and in so doing have engaged in exclusionary acts where the anticompetitive effects of those acts outweigh their technological, efficiency or other pro competitive gains as prohibited by section 8(c) of the Competition Act."[198]

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[197] See (note 3) Statement of Complaint by Treatment Action Campaign against conduct of Merck Companies.

[198] See Legal Submissions submitted by Treatment Action Campaign against conduct of Merck Companies Available at http://www.wcl.american.edu/pijip_static/documents/legalsubmissions.pdf?rd=1

According to S.8(c) of the Competition Act, a dominant firm is prohibited from engaging in exclusionary acts if the dominant if the anticompetitive effect of the act outweighs its technological, efficiency and other pro-competitive gain.[199]In determining whether Merck was engaging in exclusionary act, it is necessary to find out whether the act impedes the firm from entering into or expanding within a market.[200] In assessing the anticompetitive effect of an exclusionary act the following factors need to be taken into account namely; (1) "evidence of actual harm to consumer welfare" and (2) the degree to which the "exclusionary act is substantial or significant in terms of its effect on foreclosing markets to rivals".[201]

According to the complaint, Merck refusing to license other generic manufacturers is detrimental to consumer welfare and prevents new products from coming onto the market.[202] Therefore by limiting the number of generic suppliers on the market, consumer welfare is harmed due to the shortages of the Efavirenz drug in South Africa.[203]

This is the second competition complaint filed by AIDS activists in South Africa in an attempt to use competition law to open access to essential medicine patents. The complaint is based on section 8(c) of the Competition Act which prohibits dominant firms from engaging in exclusionary acts. I believe that the essential facilities doctrine can also be used to force dominant firms like Merck to share their patent rights with generic manufacturers.

[Accessed on 25th January 2009]

[199] Article 8(c) states that it is prohibited for a dominant firm to engage in exclusionary conduct other than an act listed in paragraph (d), if the anticompetitive effect of the act outweighs its technological efficiency or other precompetitive gain.

[200] See S.1(1)(i)(x) an exclusionary act is an act that impedes or prevents a firm from entering into, or expanding within a market.

[201]See Statement of the Complaint submitted by Treatment Action Campaign concerning the conduct of Merck Companies See (note 3).

[202] See Statement of Complaint submitted by Treatment Action campaign concerning the conduct of Merck Companies see (note 3)

[203] See Statement of Complaint submitted by Treatment Action Campaign concerning the conduct of Merck Companies see (note 3)

This paper strongly advocates for the use of the essential facilities doctrine to be used on companies like Merck who refuse to license other generic manufacturers to produce cheaper antiretroviral drugs. Although the essential facilities doctrine has been criticized as discouraging investments and having harmful effects on innovation, it can be used as a useful competition tool to curb monopoly rights of medicine patent holders.

The experience in South Africa has helped other countries use competition law as a viable weapon to force dominant firms to share their patent rights with others**. In Thailand for example, treatment activists filed a competition complaint against Abbot Laboratories for refusing to supply new drugs in Thailand to punish the government for issuing a compulsory license on the AIDS drug *Kaletra*.[204]The Thai government had issued a compulsory license to issue generic purchases of one of Abbots AIDS drugs[205]. Thailand's competition law prohibits dominant companies doing commerce in the country from withholding provision of products without adequate pro- competitive justification.[206] Therefore Abbott's refusal to license other generic manufacturers can be brought under the competition law realm by using the essential facilities doctrine to regulate Abbot's dominance on the market.

3.6 APPLYING THE ESSENTIAL FACILITIES DOCTRINE IN SOUTH AFRICA WHAT LESSONS CAN BE LEARNT?

From the discussion above, South African courts have generally been reluctant to use the essential facilities doctrine to force compulsory dominant firms to share access. This thesis advocates for the use of the essential facilities doctrine to be used to force dominant pharmaceutical companies to share access to their patent rights by licensing other generic producers so that antiretroviral medicine is affordable and cheap for the millions of South Africans dying of AIDS.

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[204] See Sean M Flynn note 32 at 21.

[205] See Sean M Flynn note 32 at 21.

[206] See Section 25(3) of Thailand Competition Act which prohibits a dominant firm from suspending reducing, or restricting services, production purchase, distribution, deliveries, or importation without justifiable reasons cited in Flynn (note 32).

The recent decision on Microsoft is the only case where the essential facilities doctrine has been implemented and therefore it is necessary to discuss the terms of access decided by the Commission in order to serve as a model in using the essential facilities doctrine to increase access to medicine in South Africa. In advocating for the essential facilities doctrine the Commission should ensure that there should be a practical solution on the shelves to put an end to anticompetitive conduct.[207]

As discussed above, Microsoft refused to supply interface information to its competitors Sun Microsystems and others. The Court of First Instance found Microsoft guilty of infringing Article 82 of the EC Treaty by refusing to supply other competitors interface information that is needed to offer compatible products.[208]Microsoft argued that the interface information was protected by patents and therefore are not necessarily obliged to disclose this information to Sun Microsystems. The Commission decided that the interface information was an essential facility and Microsoft's refusal to supply demonstrated leverage and foreclosure conduct. Microsoft was ordered to give access to specifications to its interface information.

The earlier discussion in the paper discussed the exceptional circumstances to force access to interface information as an essential facility. However, this section will deal with the appropriate terms of access required in forcing a dominant firm to share access. It should be noted that very little has been discussed on the terms of access in European cases. In the IMS case, the court stated that IMS should license the German brick structure on terms that are reasonable and non discriminatory. The court left it to the parties to reach an agreement on the terms on the prices and suggested that an

[207] Francois Leveque 'Innovation Leveraging and Essential Facilities: Interoperability licensing in the EU Micosoft case' (2005) Available at *http://www.cerna.ensmp.fr/Documents/FL-Ms-WorldCompetition.pdf* [Accessed 27th Janauary 2009]

[208] See Case T-201/04 Microsoft Corporation v The Commission (September 2007) Available at *http://merlin.obs.coe.int/iris/2007/9/article4.en.html* [Accessed on 20th November 2008]

independent expert be appointed to adjudicate the result in the event that a resolution was not reached by the parties.[209]

The Microsoft decision also ordered that licensing of the interoperability data should be done on terms that are reasonable and non discriminatory and added that Microsoft's remuneration from licensing should not reflect the strategic value stemming from Microsoft's power in the clients PC operating market or in the work group server operating systems market[210]. To implement this order the Commission designated a trustee to ensure that the information provided by Microsoft was accurate, complete and should be disclosed in a timely manner.[211]The Commission also authorized Microsoft to charge reasonable royalty for using its intellectual property on its interface information. However the standard of reasonableness was not elaborated by the Commission.

This case presents a unique learning opportunity for the South African competition Commission and establishes a number of lessons which should be implemented in using the essential facilities doctrine.

- Firstly, the terms of access should be elaborately defined in forcing pharmaceutical firms to share access.
- Secondly pharmaceutical firms can charge reasonable royalty for use of their patent rights. The terms of their reasonableness should be defined precisely by the institution mandated to determine access and the exact value to be paid should be clearly stipulated in defined terms.
- The Competition authorities should act as a relevant authority in mandating the terms of access. The competition authorities have a duty to make sure that there is promotion of consumer welfare and at the competitive structure.

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[209] Derek Ridyard 'Compulsory Access under EC Competition Law- A New Doctrine of "Convenient Facilities" and the Case for Price Regulation' 2004 ECLR 609

[210] Microsoft decision para 008 see (note 208).

[211] Francois Leveque (note 207)

3.7 CONCLUSION:

The South African experience has shown that competition law can be used and has been used to promote access to essential medicines. The civil society has taken an active role in promoting access to medicines. The government has failed to use the provisions in the Patent Act to issue compulsory licenses. The general regulatory framework requires a lot of work. South Africa lacks guidelines on the enforcement of competition law in respect to exercise of intellectual property. This is a major obstacle in dealing with the exercise of intellectual property rights. Also, the terms of access should be precisely defined and value of the royalty to be paid to the pharmaceutical firms should be stated in clear terms.

The South African government should make use of provisions in the law to ensure access to medicine. The South African Competition Commission has been reluctant to use the essential facilities doctrine. It is imperative to note that the essential facilities doctrine presents unique challenges nevertheless it can be used to promote access to medicines in South Africa.

CHAPTER 4 : CONCLUSIONS AND RECOMMENDATIONS

As explained in the paper, South Africa is still suffering from one of the worst epidemics in the world. AIDS has become a chronic but manageable medical condition; however in conditions of poverty its exaction of human suffering remains extreme. AIDS pandemic does not discriminate it affects the rich and poor alike. The low income earners need to afford antiretroviral medicines. Therefore access to antiretroviral medicines remains a challenge to the many who cannot afford these medicines; it is a matter of life and death for many people in developing countries like South Africa. Patent protection of essential medicine has been used to limit access to medicines by charging excessive prices which poor people cannot afford.

The TRIPS Agreement has a number of remedies that can help developing countries deal with public health crises. These are com

importing. These remedies can assist developing countries like South Africa deal with the AIDS pandemic. As discussed in the paper, the government has failed to use compulsory licensing mechanism to issue licenses to generic manufacturers to make medicines cheaper and affordable. In my opinion, competition law plays a significant role in creating cheap and affordable medicine for people dying of AIDS. The number of people dying of AIDS in South Africa is increasing day by day therefore affirmative action needs to be taken to create access to affordable medicine.

This paper began by posing this question: Can competition law contribute to the challenge of creating affordable essential medicine to people suffering from AIDS epidemic in South Africa?

In finding answers to this question, the focus of this paper was applying the essential facilities doctrine to force dominant pharmaceutical firms to share access their

patent rights by licensing other generic manufacturers to produce cheaper medicine for the millions of people dying of AIDS. The essential facility doctrine has been subject to increasing scholarly criticism in the United States especially Professor Areeda and Hovenkamp[212] describe the doctrine as harmful and unnecessary they contend that the doctrine should be abandoned altogether. Hovenkamp argues that forced sharing requires court to set the terms of access and in essence function as an administrative agency. In this particular situation where majority of the population depend on antiretroviral medicine for survival, competition law agencies must take up responsibility and act as a regulators in order to promote consumer welfare so that access to drugs is affordable.

Regardless of their criticism, in Europe the essential facilities doctrine has gained momentum and the courts have applied this doctrine to force dominant firms to share access to their patent rights. A case in point is the recent Microsoft case where Sun Microsystems initiated a complaint with the European Commission. Microsoft had refused to disclose some of its interfaces arguing that compelling it to share information with competitors would reduce its return in investment and yet they had invested large sums of money in developing the interfaces. The Court of First Instance compelled Microsoft to share interoperability information which will provide the competitors the necessary information in order to compete favourably in the market. The Microsoft case shows that the courts in the European Union have embraced the essential facilities doctrine and are willing to use it on dominant firms that refuse to share their intellectual property protected information with its competitors. The Microsoft case is a good illustration of the application of the essential facilities doctrine and can be applied in South Africa to force dominant pharmaceutical firms to license other generic producers to manufacture cheap drugs that people can afford.

This paper has demonstrated that the essential facilities doctrine can be applied to pharmaceutical patents. Where a pharmaceutical product is an essential facility, the

[212] Herbert Hovenkamp (note 114) at 306

owner of the patent must grant access to other generic producers to manufacture cheaper drugs so as to make access affordable. It has been argued that the essential facilities by imposing broad mandatory access on pharmaceutical firms, reduces incentives to innovate because huge sums of money go into research and developing the medicine. However, where public health interests are concerned and where millions of lives depend on antiretroviral medicine, enforcement of the essential facility doctrine is paramount because patent rights of pharmaceutical companies cause more harm than benefits to the consumer.

From the analysis of the essential facilities doctrine in the European Union, intellectual property rights like patents can constitute an essential facility therefore can be used by court to make such facility available to its competitors.

In South Africa the courts have been reluctant to enforce the use of the essential facilities doctrine on dominant firms to share access to their intellectual property rights. This paper advocates that the competition authorities should enforce a robust application of the essential facilities doctrine so as to improve access to drugs in South Africa. It is important to note that no strategy is without risks there are risks to using competition law strategies like the essential facilities doctrine to open up access. The risks that will follow from application of the essential facilities doctrine is nothing compared to the millions of lives that will be saved as a result of taking such measures[213]. Therefore the competition authorities should rise up and take this challenge and use the essential facilities doctrine to regulate dominant pharmaceutical firms.

It is important to point out that the South African experience has been used as an example to other developing nations that competition law can indeed be used as a strategy to increase access to medicine. A case in point is *GlaxoSmithkline &Boehringer*

[213] Sean M Flynn (note 32) at 32

Ingelheim case[214] where the pharmaceutical firms concluded agreements with the South African Competition Commission and agreed to issue patented licenses of anti retroviral drugs to generic manufacturers. However, in 2007 another complaint was filed by Treatment Action Campaign against a multinational pharmaceutical company Merck alleging its refusal to grant licenses to generic manufacturers. In my view, the essential facilities doctrine should be used in this case to open up access through licensing generic manufacturers and should serve as a precedent to other countries and promote access to needed medicines.

As stated above, it is important to reiterate that the experience in South Africa helps other developing countries use competition law not only as a remedy but as a way of communicating to the public about an issue. There is a need to reconcile the differences between intellectual property and competition law however with regard to the treatment of intellectual property and competition law, South Africa generally follows the European Union model. South Africa has not developed any guidelines as to the enforcement of competition law in respect to exercise of intellectual property. This is a major setback and makes it difficult to determine the factors that would be determined in dealing with the exercise of intellectual property rights. The government should draw up a comprehensive legal framework that deals with Intellectual property and the regulation of medicine in an organized manner.

Therefore the Competition Commission should develop a regulatory framework this is necessary in determining the Competition Commissions approach to exercise of intellectual property rights and will serve as guidance to holders of intellectual property rights as well as consumers. Without this framework dominant multinational pharmaceutical companies will continue taking advantage of the markets in developing countries like South Africa and refuse to license other generic manufacturers.

[214] See (note 192) *GlaxoSmithkline &Boehringer Ingelheim case*

The access to drugs problem is a public health crisis in South Africa, it is imperative to note that this problem cannot be solved by one entity such as the Competition Commission. It requires a concerted effort by the government, activists, international institutions and organizations. They all have a significant role to play in improving the situation by preventing a whole generation from dying of AIDS in South Africa.

It is important to keep in mind that competition law does not only exist for the benefit of large companies but most importantly for the benefit of the consumer. The major goal of competition law is to protect the competitive process and protect consumers from deceptive and unfair anticompetitive conduct and can be an effective mechanism in addressing the problem of access to drugs in South Africa.

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