

**ACCESS TO AFFORDABLE LIFE-SAVING
MEDICINES: THE SOUTH AFRICAN
RESPONSE**

BY

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DECLARATION OF CANDIDATE

I, Coral Jade Joseph, hereby declare that the contents of this dissertation represent my own unaided work and the dissertation has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the University of Kwa-Zulu Natal, Howard College Campus.

ABSTRACT

Patent protection grants the patent holder with a market monopoly, free from market competition allowing the patentee to charge any price; therefore medicines are sold at prices much higher than the marginal cost of production and distribution. The connection between international trade and intellectual property has aggravated human rights and public health concerns surrounding the inaccessibility of essential medicines. The World Trade Organisation's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement is an international instrument which has greatly impacted intellectual property rights protection and access to medicine. It has globalized intellectual property law by obliging all Members to subscribe to the minimum international standards of protection for intellectual property. South Africa is an example of the issues faced whilst attempting to bring their domestic laws into compliance with the Agreement. The government had to attempt to strike a balance between creating an effective intellectual property infrastructure whilst realizing the therapeutic needs of those affected by HIV/AIDS.

The South African Patents Act 57 of 1978 did not comply with the Agreement and was subsequently amended in order to bring its patent legislation in full compliance with the Agreement. Currently, South Africa grants patents for new uses or formulations of existing medicines consequently lengthening the period of patent monopoly by allowing pharmaceutical companies to obtain new patents for slight modifications to existing medicines. It is submitted that South Africa's patent legislation is more extensive than is necessary under international law, examples of this being disclosure standards and the process for compulsory licensing. In addition, it has not made use of provisions in its existing law to take measures to improve access to essential medicines, nor has it implemented legislative amendments consequent to the flexibilities established in the Doha Declaration.

This dissertation seeks to review the steps South Africa has taken in its compliance with the TRIPS Agreement with respect to the relevant intellectual property legislation that has been enacted, including its implications for access to essential medicines. The intention behind this dissertation is to assess the efficacy of the intellectual property legislation in South Africa and its impact on access to medicines.

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CHAPTER I: INTRODUCTION

The HIV/AIDS pandemic has received a great deal of attention because of its high prevalence, mortality rates and catastrophic socio-economic effects. According to Statistics South Africa, in 2010 the HIV prevalence rate was estimated to be 10,5% - the total number of people living with HIV is estimated at approximately 5,24 million.¹ With regards to the age group 15–49, approximately 17% of South African citizens were infected with HIV.² Although there is no cure for HIV, there have been important advances in technology and medicine which have enhanced public health and prolonged life expectancy.³ Despite the existence of new combinations of antiretroviral therapy and other medicines, nearly half of those infected with HIV/AIDS who require treatment lack access to it.⁴ As a consequence of economic inequities and extensive poverty, most originator pharmaceutical companies do not deem it profitable to develop new medicines for sale in developing countries or to lower the price of existing drugs so that they become affordable.⁵

The lack of access to medicines is not only a public health crisis, but also represents a human rights challenge. The International Covenant on Economic, Social and Cultural Rights (ICESCR) affirms each person's right to the enjoyment of the highest attainable standard of physical and mental health.⁶ Furthermore, this right incorporates access to essential medicines as “a minimum core obligation of State Parties.”⁷ South Africa has not yet ratified this Covenant, but became a signatory in 1994.

¹ Statistics South Africa: Statistical Release ‘Mid-Year Population Estimates 2010’ (2010) 1, 3 available at www.statssa.gov.za/publications/P0302/P03022010.pdf, accessed on 6 October 2012.

² Ibid.

³ AJ Anderson “Global Pharmaceutical Patent Law in Developing Countries- Amending TRIPS to Promote Access for All” (2006), 1.

⁴ L Forman “‘Rights’ and wrongs: What utility for the right to health in reforming trade rules on medicines?” (2008) 10 *Health and Human Rights* 2, 45 available at <http://www.hhrjournal.org/index.php/hhr/article/view/80/165>, accessed on 25 June 2012.

⁵ A Grover *et al* ‘Pharmaceutical companies and global lack of access to medicines: strengthening accountability under the right to health’ (2012) *Journal of Law, Medicine & Ethics* available at <http://business.highbeam.com/6391/article-1G1-298171392/pharmaceutical-companies-and-global-lack-access-medicines>, accessed on 28 September 2012.

⁶ International Covenant on Economic, Social and Cultural Rights, 16 December 1966, 999 UNTS 3, 3 January 1976, Article 12.

⁷ DM Chirwa ‘The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicine’ (2003) 19 *SAJHR* 541, 542.

There are various factors which influence lack of access to medicines. However in most instances the exorbitant prices of medicines is a significant hurdle to essential treatment.⁸ The profit-seeking behaviour of pharmaceutical companies and strong intellectual property protection has exacerbated this problem.⁹ Therefore, in many developing countries it is considered more lucrative to sell medicines to the wealthy at higher prices than it would be to sell cheaper medicines to a larger number of people.¹⁰

The connection between global trade and intellectual property has aggravated human rights and public health concerns surrounding the inaccessibility of essential medicines. The World Trade Organisation's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement¹¹ is a comprehensive international instrument which has greatly impacted intellectual property rights protection and access to medicines in the developing world. This Agreement has effectively globalized intellectual property law by obliging all WTO countries to subscribe to the minimum international standards of protection for intellectual property.¹² Member States had to establish these intellectual property standards within their domestic legal systems, either by creating intellectual property protections in their domestic law or reformulating existing intellectual property laws so that they are in conformity with TRIPS.¹³

Intellectual property rights grant the rights holder exclusive control over a product for a limited period of time. TRIPS requires Member States to implement compulsory patent protection for inventions in all fields of technology for a minimum term of 20 years. A patent is a time-bound monopoly right which is given exclusively by the State to the inventor for the commercial exploitation of a scientific or technological invention; it also prevents use of the patented product by third parties without the patentee's permission.¹⁴ Within the pharmaceutical industry, patents allow for an extensive period of exclusive profit so that pharmaceutical companies can recoup research and development costs.¹⁵ In essence it costs

⁸ EFM t'Hoen 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, DOHA and Beyond' (2003), 41.

⁹ Ibid.

¹⁰ Grover (note 5 above).

¹¹ Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf, accessed on 24 May 2012.

¹² E t'Hoen *et al* 'Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines to All' (2011) 14 *Journal of International AIDS Society* 1, 2 available at <http://www.jiasociety.org/content/14/1/15>, accessed on 18 August 2012.

¹³ Grover (note 5 above).

¹⁴ C Van Gulik 'Impact of TRIPS on Access to Medicines and the Right to Health of Children' (2004), 8.

¹⁵ t'Hoen (note 8 above) 8.

pharmaceutical companies significant amounts of money to discover, develop and acquire regulatory approval for a new drug.¹⁶ Therefore, in the absence of patent protection, imitators are able to free ride on the innovator's regulatory approval and reproduce the product at a smaller cost than that of the originator.¹⁷ Fundamentally, reproduction costs are much lower when compared to the costs sustained by innovators for discovering and developing a new medicine.¹⁸ Patent protection grants the patent holder with a market monopoly, free from market competition which allows the patent holder to charge any price; therefore medicines are sold at prices much higher than the marginal cost of production and distribution.¹⁹

In 2001, the Doha Declaration on TRIPS and Public Health was adopted.²⁰ The Doha Declaration confirmed governments' right to implement measures to safeguard public health and granted least developed countries (LDCs) the flexibility not to grant or enforce pharmaceuticals patents until 2016.²¹ The Doha Declaration also reaffirmed some the TRIPS flexibilities that could aid access to medicines.

South Africa and India are primary examples of the issues faced by WTO Member States whilst attempting to bring their domestic patent laws into compliance with the TRIPS Agreement. In both countries, governments had to attempt to strike a balance between creating an effective intellectual property infrastructure whilst effectively realizing the therapeutic needs of the population affected by HIV/AIDS.

The South African intellectual property legislation, which includes its patent law, is national law which has been in existence for more than a century.²² In 1806, the British conquered the Dutch settlers and took over the Cape Region as part of the British Empire.²³ Within the rule, British patents could, in certain instances, be extended to British colonies; patent protection

¹⁶ H Grabowski 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries' (2002) 1, 4 available at <http://www.dklevine.com/archive/grabow-patents.pdf>, accessed on 14 October 2012.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ C Oh et al 'TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform'. Third World Network Briefing Paper (2001) available at <http://www.twinside.org.sg/title/drugs2.htm>, accessed on 15 August 2012.

²⁰ EFM t'Hoen 'The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health' (2009), xvi.

²¹ Ibid xvi.

²² YA Vawda 'Tripped Up on TRIPS: The Story of Shrinking Access to Drugs in Developing Countries' (2002) 13 *Stellenbosch L. Rev.* 325, 353.

²³ JT Pechacek 'The Past, Present, and Future of South Africa's Patent System' (2012) 3 *Intellectual Property Law Review* 188, 190.

was therefore allowed in the Cape Colony until the enactment of its own patent laws and could only be obtained through a British patent that was duly extended thereto.²⁴ During this period, the Roman-Dutch common-law continued to be in force, however it was soon “overlaid with a heavy English law influence.”²⁵ Thereafter the Cape Colony and the Natal Colony enacted their own patent statutes after being granted representative government. These patent statutes were founded upon English patent law called the Statute of Monopolies of 1623.²⁶ This statute was the foundation of English patent legislation, and was introduced into early South African patent law.²⁷ In 1910, Britain unified the four territories of South Africa. In 1916 the Union enacted the Patents, Designs, Trade Marks and Copyright Act. This statute was abolished by the 1952 Patents Act, which was in turn replaced by the current Patents Act 57 of 1978.

In 1994, South Africa signed the TRIPS Agreement.²⁸ The South African Patents Act 57 of 1978 did not comply with the Agreement in a number of respects and was subsequently amended by the Intellectual Property Laws Amendment Act 38 of 1997 in an attempt to bring South Africa’s patent legislation in full compliance with the Agreement.²⁹ Currently, South Africa grants patents for new uses or formulations of existing medicines consequently lengthening the period of patent monopoly by allowing pharmaceutical companies to obtain new patents for slight modifications to existing medicines.³⁰ Vawda submits that South Africa’s patent legislation is more extensive than is necessary under international law, examples of this being disclosure standards and the process for compulsory licensing.³¹ In addition, it has not made use of provisions in its existing law to take steps to advance access to essential medicines, nor has it made the required legislative amendments consequent to the flexibilities established in the Doha Declaration.³²

²⁴ H Klopper *et al* ‘Law of Intellectual Property in South Africa’ ED (2011) 268.

²⁵ Pechacek (note 23 above) 190.

²⁶ Klopper (note 24 above) 268.

²⁷ *Ibid.*

²⁸ World Trade Organisation available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, accessed on 10 October 2012.

²⁹ DF Sheppard ‘Patent Law in South Africa with Particular Reference to the TRIPS Agreement’ *The Journal of World Intellectual Property*, 607

³⁰ L Daniels ‘Health Advocates Eye Proposed changes to Patent Law in South Africa’ available at <http://www.fixthepatentlaws.org/?p=383#more-383>, accessed on 30 August 2012.

³¹ YA Vawda ‘Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa’(2011), 8.

³² *Ibid* 8.

India is an important example of the creative manner in which the TRIPS Agreement has been applied to its patent laws. In 1995, India signed the TRIPS Agreement.³³ In 2005, in order to satisfy the requirements of TRIPS, the Indian government made several amendments to the 1970 Indian Patents Act. The first Indian patent laws were introduced in 1856 by the British.³⁴ The intention behind this legislation was to encourage new and useful inventions and to encourage inventors to divulge the secret behind their inventions.³⁵ The Indian Patent Act has been modified from time to time. For the past three decades, the 1970 Act excluded product patents for pharmaceuticals whilst making provision for process patents.³⁶ While patent law authorised process patents with regards to medicines, its scope was limited.³⁷ India has a patent system which was viewed as a model for other developing countries as it sought to strike a balance between the need for granting incentives to inventors whilst making sure “that India's developmental needs are not ignored.”³⁸ Further, its patent laws facilitated the entry of local pharmaceutical firms that, through reverse engineering, could develop generic variations of patented medicines whilst ensuring that patents were not violated in India.³⁹

The 2005 amendments to India's patent law extended patent protection to food, drugs and medicines.⁴⁰ It adopted patentability criteria by introducing Section 3(d) into its Patent Act, which lists broad categories of exceptions to patentability. The following exclusions from patentability are important: natural substances; new uses of known substances; new forms of existing substances unless the new form displays increased efficacy; and methods of treating humans and/or animals.⁴¹ These provisions will effectively reduce the number of derivative patents being granted for pharmaceutical products. The Amendment Act also included and broadened the scope for post-grant opposition procedures.⁴²

³³ World Trade Organization (note 28 above).

³⁴ R Saha ‘Management of Intellectual Property Rights in India’ (2005) 1, 3 available at <http://www.pfc.org.in/workshop/workshop.pdf>, accessed on 25 September 2012.

³⁵ RS Adukia ‘Handbook on Intellectual Property Rights in India’ (2012) 11 available at www.caaa.in/Image/34_Hb_on_IPR.pdf, accessed on 24 October 2012.

³⁶ t’Hoen (note 20 above) 56.

³⁷ A Kapczynski ‘Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector’ (2009) 97 *California Law Review* 1571, 1577.

³⁸ A Ramanna ‘India’s Patent Policy and Negotiations in TRIPS: Future Options for India and other Developing Countries’ (2002) available at www.iprsonline.org/icts/docs/ResourcesTRIPSanita_ramanna.doc, accessed on 10 October 2012.

³⁹ t’Hoen (note 20 above) 56.

⁴⁰ AK Hason and JE Shimotake ‘Recent Developments in Patent Rights for Pharmaceuticals in China and India’ (2006) 18 *Pace Int’l L. Rev* 303, 309.

⁴¹ Section 3 of India Patent (Amendment Act) 2005.

⁴² Ibid Section 25.

Bearing in mind and acknowledging the extensive literature that exists on this topic, this dissertation seeks to review the steps South Africa's has taken in its compliance with the TRIPS Agreement with respect to the relevant intellectual property legislation that has been enacted, including its implications for access to essential medicines. The intention behind this dissertation is to assess the efficacy of the intellectual property legislation in South Africa and its impact on access to essential medicines.

This dissertation aims to discuss some of the issues pertinent to the debate surrounding the TRIPS Agreement, patents and access to affordable medicines. Subsequent to this introduction, this dissertation is ordered into seven main chapters.

Chapter II

It provides an examination of South Africa's international and national socio-economic obligations on the right to health, thus establishing the extent of its duties regarding the right of access to essential medicines.

Chapter III

It provides an analysis of the key provisions guaranteed under the TRIPS Agreement and the duties it imposes on Member States. This includes the flexibilities and procedures under the TRIPS agreement which allows governments to facilitate access to essential medicines. It examines the restrictions on exclusive property rights of patent holders contained in the TRIPS Agreement. Such restrictions include parallel imports and compulsory licensing, which can be utilized to restrain anti-competitive practices and exploitation of intellectual property rights.

Chapter IV

This chapter analyses the legislative Acts adopted by South Africa relating to intellectual property rights and access to essential medicine. In particular, this chapter will focus on the Patents Act 57 of 1978; Medicines and Related Substances Control Act 101 of 1965 (as amended) and the Competition Act 98 of 1998. It will also examine the legislative steps taken in terms of the TRIPS agreement in order to make these Acts TRIPS-compliant.

Chapter V

This chapter outlines the strict patentability criteria adopted by India Act in order to become TRIPS-compliant. The Patent Amendment Act introduced Section 3(d) into its Patent law, which has been effective in curbing derivative patents being granted. In addition, the Act has also extended the grounds on which a patent can be opposed in the pre and post grant period. It also contains compulsory licensing provisions for the export of patented pharmaceutical products under certain circumstances. An analysis of important Indian judicial cases will be conducted outlining its impact on patents and access to essential medicines.

Chapter VI

This Chapter focuses on the legislative response to the TRIPS Agreement by Thailand and Brazil. It looks at how these countries have used the TRIPS flexibilities to make medicines more accessible.

Chapter VII

This chapter provides recommendations and a conclusion by looking at the ways in which the South Africa and India have complied with their obligations under the TRIPS Agreement. It will also discuss the pertinent lessons that South Africa can learn from India and other jurisdictions in their application of the TRIPS Agreement to their domestic legal systems, in its quest to improve access to affordable essential medicines.

CHAPTER II: SOUTH AFRICA'S SOCIO-ECONOMIC OBLIGATION TO ENSURE ACCESS TO ESSENTIAL MEDICINES

2. International Obligations:

Access to health care including essential medicines is especially important where such access can mean the difference between life and death. Access to essential medicines is a significant link in realising the right to health. The right to health has been protected in many national constitutions. Even though access to healthcare is a prerequisite for the realisation of the right to health, only five countries have identified that such access is crucial for the achievement of the right to health.⁴³

Notwithstanding this omission, many countries have signed and ratified international human rights treaties incorporating the right to health. The main instrument in this regard is the ICESCR, which was adopted in 1966⁴⁴ and since then it has become essential in defining economic, social and cultural rights.⁴⁵

2.1 Socio-Economic Obligations Contained in the International Covenant on Economic, Social and Cultural Rights:

Socio-economic rights are accepted as human rights in various international human rights instruments such as the Convention on the Rights of the Child and the Convention on the Elimination of All Forms of Discrimination against Women. The ICESCR is the most extensively adopted convention relating to social, economic and cultural rights, providing a basis for the legal requirements in terms of the right to health. South Africa has not yet ratified this instrument; however remains signatory to it, thus confirming its obligation to improve access to healthcare.⁴⁶ The duties that the Covenant enforces upon State Parties are provided for in Article 2(1). It instructs State Parties to take measures to the maximum of its

⁴³ K Balasubramaniam 'Access to Essential Medicines as a Human Right' (2011) *Politics of Medicine* available at <http://www.politicsofmedicines.org/articles/access-to-essential-medicines-as-a-human-right>, accessed on 3 August 2012.

⁴⁴ Office of the United Nations High Commissioner for Human Rights available at <http://www2.ohchr.org/english/law/cescr.htm>, accessed on 14 September 2012.

⁴⁵ Balasubramaniam (note 43 above) 546.

⁴⁶ R Phillips 'South Africa's Right to Healthcare: International and Constitutional Duties in Relation to the HIV/AIDS Epidemic' (2004) 11 *Human Rights Brief* 1,9 available at <http://www.wcl.american.edu/hrbrief/11/2phillips.pdf>, accessed on 19 July 2012.

existing resources to progressively achieve the full realization of the rights recognised in this treaty.

2.1.1 Access to Essential Medicines and the Right to Health:

Access to essential medicine is contained in the ICESCR as a significant aspect of the right to health contained in article 12,⁴⁷ which recognizes that everyone has the right to the enjoyment of the highest attainable standard of physical and mental health and instructs that these rights must be progressively realised. This provision suggests that there is an obligation on State Parties to supply essential medicines.⁴⁸ The implementation of the ICESCR is overseen by the Committee on Economic, Social and Cultural Rights (CESCR) which frequently issues interpretative and authoritative general comments which are non-binding in nature.⁴⁹ In 2000, the CESCR further defined the right to health in General Comment 14,⁵⁰ which interpreted the obligation under Article 12.2 (d) of the Covenant to include the provision of essential medicines.⁵¹

2.1.2 Duty to Provide Essential Medicines as a Core Obligation

Whereas the Covenant recognises progressive realization and acknowledges the availability of resources,⁵² the CESCR confirmed in General Comment No. 3⁵³ that States have a core obligation to guarantee the fulfilment “of minimum essential levels of the rights contained in the Covenant,”⁵⁴ which includes primary health care. Furthermore, State Parties are required to take expeditious steps in relation to the realisation of socio-economic rights.⁵⁵ While these

⁴⁷ HP Hestermeyer ‘Access to Medication as a Human Right’ (2004) *Max Plank UNYB* 102,125.

⁴⁸ Chirwa (note 7 above) 547.

⁴⁹ HV Hogerzeil et al ‘Access to Essential Medicines as part of the Fulfilment of the Right to Health: Is it Enforceable through the Courts?’ (2006), 305 available at http://www.who.int/medicines/news/Lancet_EssMedHumanRight.pdf, accessed on 25 July 2012.

⁵⁰ The Right to the Highest Attainable Standard of Health, General Comment No. 14, U.N. CESCR, 22nd Sess., Agenda item 3, E/C.12/2000/4 (2000) paragraph 12 available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument), accessed on 23 July 2012.

⁵¹ SP Marks ‘Access to Essential Medicines as a Component of the Right to Health’ (2009) *Health: A Human Rights Perspective* 80, 90.

⁵² ICESCR (note 6 above) article 2(1).

⁵³ CESCR General Comment No 3 The Nature of States Parties' Obligations (art 2(1) of the ICESCR) (5th session, 14 December 1990) available at <http://www.unhcr.org/refworld/pdfid/4538838e10.pdf>, accessed on 3 August 2012.

⁵⁴ Hogerzeil (note 49 above) 305.

⁵⁵ Chirwa (note 7 above) 548.

essential levels are resource-dependent, they should be given priority by State Parties in their efforts to realize these rights.⁵⁶

The CESCR confirmed the non-derogable core obligations that States must ensure in terms of the right to health. These obligations include the right of access to health facilities, services and goods without discrimination, particularly for vulnerable or marginalized groups; the provision of essential medicines which has been explained in the World Health Organisation (WHO) Action Programme on Essential Drugs as well as the “equitable distribution of all health facilities, goods and services.”⁵⁷

In terms of the WHO, “essential medicines” are medicines which meet the health care needs of citizens, which are available within health systems at all times in sufficient amounts, suitable dosage forms, with quality, and at a price which everyone can afford.”⁵⁸ Access to essential medicines has four components: medicines must be available to everyone in sufficient quantity; treatment must be acceptable in terms of the culture and ethics of individuals and medicines must be of an appropriate quality.⁵⁹ Accessibility in this regard includes: (1) “physical accessibility (health facilities, goods and services must be within safe physical reach for everyone); (2) economic accessibility (health facilities, goods and services must be affordable to everyone); and (3) information accessibility (accessibility includes the right to seek, receive and impart information and ideas regarding health issues).”⁶⁰

In light of the above, the CESCR believes that every State Party is required to meet its minimum core obligations to guarantee the realisation of the minimum levels of each right. The South African Constitutional Court, in its interpretation of the socio-economic rights contained in the 1996 Constitution⁶¹ adopted the meaning of 'progressive realisation' and 'available resources' that was defined by the CESCR.⁶² However, the Court rejected the notion of minimum core obligations because of the difficulty of determining its scope and its

⁵⁶ World Health Organization Fact Sheet No. 31 ‘The Right to Health’ 25, available at www.ohchr.org/Documents/Publications/Factsheet31.pdf, accessed on 15 August 2011.

⁵⁷ General Comment No. 14 (note 50 above) paras 43(a)-(e).

⁵⁸ Marks (note 51 above) 81.

⁵⁹ General Comment No. 14 (note 50 above) para 12.

⁶⁰ *Ibid.*

⁶¹ Constitution of the Republic of South Africa, 1996 (1996 Constitution).

⁶² *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC); *Minister of Health v Treatment Action Campaign No 2* 2002 (5) SA 721 (CC).

inappropriateness “in the South African context.”⁶³ The Court did note, however, that the minimum core concept may be useful when determining whether “measures taken by the State in the realisation of socio-economic rights are reasonable.”⁶⁴

2.1.3 Duties Imposed upon State Parties

The right to health imposes obligations on States Parties, these include: the obligation to respect, protect and fulfil.⁶⁵ These levels give rise to both ‘negative’ (“abstention-bound and resource barren”) and ‘positive’ (“fulfilment-bound and resource-dependent”) obligations.⁶⁶

(a) The Duty to Respect

Under the ICESCR, the obligation to respect requires State Parties "to refrain from interfering directly or indirectly with the enjoyment of the right to health."⁶⁷ Within the ambit of access to medicines, this suggests that States must refrain from preventing or limiting access to essential medicines. Yamin submits that laws which limit access to medicines by proliferating drug prices would presumably violate State Party’s obligations under the Covenant.⁶⁸

It is submitted that in terms of global trade agreements and intellectual property protection mechanisms; TRIPS authorizes WTO Members "to adopt measures necessary to protect the public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."⁶⁹ In addition, the Doha Declaration declared “that the TRIPS Agreement does not prevent Member States from taking measures to protect public health and it should be interpreted and implemented in a manner supportive

⁶³ Ibid.

⁶⁴ Chirwa (note 7 above) 550.

⁶⁵ General Comment No. 14 (note 50 above) para 33.

⁶⁶ L Chenwi ‘Monitoring the progressive realisation of socio-economic rights: Lessons from the United Nations Committee on Economic, Social and Cultural Rights and the South African Constitutional Court’ (2010) *Research paper written for Studies in Poverty and Inequality Institute*, 16.

⁶⁷ General Comment No. 14 (note 50 above) para 33.

⁶⁸ AE Yamin ‘Not Just a Tragedy: Access to Medications as a Right under International Law’ (2003) 21 *B.U. Int’l LJ* 325, 353.

⁶⁹ TRIPS Agreement (note 11 above) article 8.

of WTO Member's right to protect public health and to promote access to medicines for all.⁷⁰

(b) The Duty to Protect

The obligation to protect requires State Parties to prevent third parties from interfering with the right to health. It requires State Parties to adopt legislation or other measures to guarantee equal access to health care and to ensure that privatisation “does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.”⁷¹

The importance of the duty to protect is especially significant with regard to essential medicines as most pharmaceutical products are manufactured and marketed in the private sector. Since accessibility is a vital aspect of the right to health, State Parties are under an obligation to ensure that pharmaceutical manufacturers do not unduly limit access to essential medicines.

(c) The Duty to Fulfil

The obligation to fulfil requires State Parties to adopt appropriate administrative, budgetary, judicial, legislative, promotional and other measures to achieve the full realisation of the right to health.⁷²

2.2 Domestic Obligation

2.2.1 Socio-Economic Obligations under the 1996 Constitution

The 1996 South African Constitution created and protected progressive rights and in particular saw the entrenchment of a variety of justiciable socio-economic rights.⁷³ The Constitution guarantees these rights almost in the same manner as the ICESCR. However it goes further by incorporating other rights such as access to water and a healthy environment

⁷⁰ World Trade Organisation ‘Doha Declaration on the TRIPS Agreement and Public Health’ (2001) para 4 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm, accessed on 15 September 2012.

⁷¹ General Comment No. 14 (note 50 above) para 35.

⁷² Ibid para 33.

⁷³ Constitution (note 61 above) Chapter 2.

which are not expressly provided for in the Covenant. Furthermore, the Constitution explicitly requires the State to take action to realise these socio-economic rights. The right to primary healthcare is entrenched in section 27.⁷⁴

Section 27 is not only limited to instructing the State to refrain from unfairly interfering with a person's right to secure healthcare services. However, its importance lies in the fact that it imposes a positive duty upon the State to provide healthcare according to necessity rather than affordability.⁷⁵ This section obliges the State to progressively realise socio-economic rights within its available resources by taking reasonable legislative and other measures.

The Bill of Rights is 'clearly modelled' on the ICESCR.⁷⁶ The 1996 Constitution also recognises that socio-economic rights cannot be achieved overnight, therefore the rights must be realised progressively and its implementation is dependent on resources. While article 2(1) requires State Parties to use the 'maximum of its available resources', the Constitution uses the phrase 'within available resources', implying that the obligations placed on the government does not require more than what is available. The ICESCR takes a wider stance with regard to the use of resources.

However, the provision of healthcare in the Constitution is a narrower formulation than that contained in the Covenant i.e. the Constitution provides for 'a right of access' whereas the ICESCR provides for 'a right to', thus requiring the South African government to facilitate access to these rights.⁷⁷ The scope of this tapered right to access healthcare services is not clear from the wording of section 27, which provides little suggestion of what the entitlement to health care services encompasses, nor does it provide an explanation of the extent to which resource restrictions and the notion of progressive realisation could limit the State's obligation to ensure access.⁷⁸

⁷⁴ Section 27 states:

27(1): Everyone has the right to have access to health care services, including reproductive healthcare;

(2): The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3): No one may be refused emergency medical treatment.

⁷⁵ D Brand 'Introduction to Socio-economic Rights in the South African Constitution' *D Brand and C Heyns* (2005) 1,132.

⁷⁶ *Residents of Bon Vista Mansions v Southern Metropolitan Local Council* (2002) (6) BCLR 625 (W), para 15.

⁷⁷ L Chenwi and R Hardowar 'Promoting Socio-Economic Rights in South Africa through the Ratification and Implementation of the ICESCR and its Optional Protocol' (2010) 11 *ESR Review* 3-6, 2.

⁷⁸ L Forman 'Ensuring Reasonable Health: Health Rights, the Judiciary, and South African HIV/AIDS Policy' (2005) *Journal of Law, Medicine & Ethics* 711, 713.

Sections 27 and 28 became the source of complaint regarding access to Nevirapine, which came before the South African Constitutional Court. The applicants, the Treatment Action Campaign (TAC), argued that the refusal of the South African government to make Nevirapine available in the public health sector in order to prevent mother-to-child transmission of HIV breached these constitutional rights. The Court held that section 27 of the Constitution obliges the government to devise and implement, within its available resources, a comprehensive and coordinated programme to progressively realise the rights of pregnant women and their newborn children to have access to healthcare services.⁷⁹ The Court also confirmed that the state has a duty to ensure that children are afforded the protection guaranteed in section 28(1)(c) of the Constitution.⁸⁰ The South African government was ordered to withdraw the restrictions that prohibited Nevirapine from being made accessible to HIV-infected mothers.

2.2.2 What are the State's Duties

Section 7(2) of the Constitution provides that the State must respect, protect, promote and fulfil the rights contained in the Bill of Rights. This section goes further than international law by providing an additional duty, namely the duty to promote.

The duty to "respect" is a negative obligation which requires the state to abstain from interfering with these rights, where such interference cannot be avoided; the State must take steps to mitigate its impact.⁸¹ The right not to be refused emergency medical treatment guaranteed in section 27(3) of the Constitution can be interpreted to give expression to the State's duty to respect socio-economic rights. In the *Soobramoney* case, the Constitutional Court found that this right requires the State not to arbitrarily refuse emergency medical treatment where it exists.⁸²

The duty to "protect" is a positive obligation; it requires the State to protect the existing enjoyment of rights, and the capacity of individuals to improve their enjoyment of rights or

⁷⁹ Treatment Action Campaign (note 62 above) para 122.

⁸⁰ *Ibid* para 79.

⁸¹ Brand (note 75 above) 30.

⁸² *Soobramoney v Minister of Health, KwaZulu Natal* (1998) 1 SA 765 (CC).

newly to have access to the enjoyment of rights against interferences from third parties.⁸³ The duty to "promote and fulfil" is also positive in that it requires the state to employ its power to advance these rights and assist individual right-holders to realise them.

⁸³ Brand (note 75 above) 37.

CHAPTER III: THE TRIPS AGREEMENT AND PATENTS ON ESSENTIAL MEDICINES

Since 1995, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights set international standards for intellectual property protection. Patents on pharmaceutical products grant pharmaceutical companies a monopoly over the production and marketing of medicines, therefore allowing them to charge higher drug prices in order to increase profits. Before the creation of the TRIPS Agreement, countries had the freedom to determine the length of patents; many countries did not authorise patent protection for pharmaceutical products whilst others excluded pharmaceutical processes from the ambit of patent protection.⁸⁴ For example, in 1959 Rajagopala Ayyangar drafted policy recommendations to change India's patent system.⁸⁵ The Ayyangar Report led to enactment of India's 1970 Patents Act, which eliminated product patent protection for pharmaceuticals and provided the legislative framework that permitted Indian pharmaceutical manufacturers to create generic variations of existing patented medicines which were sold at cheaper prices.⁸⁶

The Agreement does permit limitations upon the granting of patents to ensure that governments are able to meet public health needs, these limitations contain (but are not limited to) parallel importation and compulsory licensing. However, the use of these mechanisms by developing countries has been constrained by the constant fear that such use would invite pressure and trade sanctions from developed countries in which the patent holding pharmaceutical companies are established, looking to safeguard the interests of those companies.⁸⁷ In addition, there has been widespread public criticism regarding the legitimacy of patents on essential medicines. Consequently, there have been requests for amendments to

⁸⁴ United Nations Development Programme 'Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement' (2010), 5 available at <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf>, accessed on 3 August 2012.

⁸⁵ M Pillai *et al* 'Patent Procurement in India' *Chair of the Intellectual Property Owners Association ("IPO") Asian Practice Committee* 1,3 available at <http://www.ipo.org/AM/Template.cfm?Section=Patents&Template=/CM/ContentDisplay.cfm&ContentID=22900>, accessed on 15 October 2012.

⁸⁶ E Jackson 'Funding and Access to Medicines: A Global Problem' in E Jackson *Law and the Regulation of Medicines* (2012), 189, 193.

⁸⁷ S Wibulpolprasert *et al* 'Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership' (2011) 7 *Globalisation and Health* 1, 1.

the Agreement as many feel that the TRIPS Agreement places excessive emphasis on private rights and commercial interests rather than public interests.⁸⁸

3.1 Justification for Patents

Most governments from developing countries were afraid that the introduction of strong patents on essential medicines, through the TRIPS Agreement, would increase prices of essential drugs making them less affordable to the poor. However, the patent system has been justified as a mechanism to “reward inventiveness, encourage technical progress and foster the dissemination of innovations.”⁸⁹ It is argued that patents constitute a derogation from the principle of free trade as it gives the inventor exclusive rights to exploit the invention.⁹⁰ Therefore, the underlying principle driving the grant of patents is the need to compensate the inventor.⁹¹

The need for patent protection is significant as it grants the inventor a monopoly in order to recover research and development (R&D) costs. Consequently, this protection encourages future investment into R&D with the assurance of potential profit after all costs have been regained.⁹² Without patent protection, there may be little motivation to invest in expensive and risky research, for example if competitors could enter the market with an identical versions of a new medicine that has reached the market, it may be difficult for the inventor to recover its costs, let alone yield a profit.⁹³

A further justification of patents is known as the *quid pro quo* theory. Essentially, the patent system is regarded as “a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”⁹⁴ The requirements of public disclosure and limited

⁸⁸ Oh (note 19 above).

⁸⁹ CM Correa ‘Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing’ 2011 *South Centre Research Paper* 41 1, 1.

⁹⁰ P Cullet ‘Patents and Medicines: the relationship between TRIPS and the human right to health’ (2003) 79 *International Affairs* 139, 140.

⁹¹ *Ibid.*

⁹² MB Walker ‘Accessing the Barriers to Universal Antiretroviral Treatment Access for HIV/AIDS In South Africa’ (2004-2005) 15 *Duke J. Comp. & Int’l L* 193, 207.

⁹³ Jackson (note 86 above) 192.

⁹⁴ Pesses E ‘Patent and Contribution: Bringing the Quid Pro Quo into eBay v. MercExchange’ (2009) 10 *Student Scholarship Papers* Paper 96 321 available

duration of the patent are aimed at motivating inventors to disclose their innovations so that “the benefit to the public is served.”⁹⁵

It has been argued that market exclusivity caused by patent protection has created artificial market conditions which have resulted in the exploitation of drug prices, thus causing the loss of benefits resulting from scientific developments.⁹⁶ This is contrary to public interest, which demands that such benefits be available and accessible.⁹⁷ Furthermore, despite stronger global patent protection introduced by TRIPS, consumers have not witnessed major increases in the output of new medicines, despite the higher standard of intellectual property protection in place.⁹⁸

Vawda submits that the research programmes of pharmaceutical companies are driven by purchasing power.⁹⁹ The pharmaceutical private sector will not invest in developing essential medicines that treat diseases in those countries with little purchasing power.¹⁰⁰ It is not disputed that financial incentives for research and development for new medicines is vital. However, from a theoretical perspective, it is uncertain whether the intellectual property patent system is effective as an incentive to invent especially in the context of developing countries.¹⁰¹ India, a developing country, was able to establish its pharmaceutical industry in the absence of patent protection on pharmaceutical products.¹⁰²

3.2 THE TRIPS FLEXIBILITIES

The TRIPS Agreement built on the existing standards of the Paris and Berne Conventions under the control of WIPO, introducing new minimum standards of intellectual property protection. These standards include a variety of flexibilities which Member States can utilise in order to mitigate the negative impact of strengthened intellectual property rights protection

at http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1096&context=student_papers, accessed on 15 October 2012.

⁹⁵ *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another* [1998] JOL 3793 (A), page 5.

⁹⁶ E Cameron ‘Patents and Public Health: Principle, Politics and Paradox’ (2004) 1 *SCRIPT-ed* 518, 521.

⁹⁷ *Ibid.*

⁹⁸ United Nations Development Programme (note 84 above) 9.

⁹⁹ YA Vawda ‘Putting the ‘public’ back into ‘private’ law’ (2008) *De Rebus*.

¹⁰⁰ S Musungu ‘Intellectual Property and Access to Medicines’ (2011) *Management Sciences for Health*, 3 available at <http://www.msh.org/resource-center/publications/upload/MDS3-FrontMatter-Nov2011.pdf>, accessed on 16 July 2012.

¹⁰¹ Cullet (note 90 above) 142.

¹⁰² United Nations Development Programme (note 84 above) 11.

on the availability of and access to essential medicines. Article 1.1 states that Member States have the freedom to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. Therefore, Member States “can exploit creative solutions to transpose into national law”¹⁰³ and have a discretion in determining the scope of the concepts that the Agreement simply states but does not define e.g. concepts such as novelty and inventiveness; or of situations of extreme urgency in terms of compulsory licenses.¹⁰⁴ Developing countries can implement this flexibility as a defence against employing stronger intellectual property rights under the Agreement.

This section discusses the TRIPS flexibilities that are most relevant for health.

3.2.1 Patentability Criteria

The TRIPS Agreement obliges all Member States to recognize patents for inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step and is capable of industrial application.¹⁰⁵ The Agreement does not contain any guidelines regarding the application of these criteria, giving Member States the flexibility to define their own patentability standards. This article also requires that patents be available and patent rights be enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.

Correa submits that upon an interpretation of Article 27.1, Member States are not obliged to adopt a specific notion of novelty, consequently they can implement a standard which objectively assesses whether the innovation is new or not.¹⁰⁶ The second requirement that the invention contain a “non-obviousness/inventive step” is essential because it determines the amount of “technical contribution” needed to attain a patent.¹⁰⁷ The Agreement does not provide a definition for this concept, therefore giving Member States the freedom to interpret the requirement in good faith and to adopt more or less strict criteria to apply these patentability criteria. As with the aforementioned requirements, the Agreement fails to define

¹⁰³ World Intellectual Property Organisation ‘Advice on Flexibilities under the TRIPS Agreement’ available at http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html, accessed on 15 October 2012.

¹⁰⁴ Ibid.

¹⁰⁵ Article 27.1

¹⁰⁶ CM Correa ‘Pharmaceutical Inventions: When is the granting of a patent justified?’ (2006) 1 *Int. J. Intellectual Property Management* 1, 5.

¹⁰⁷ Ibid.

what standards should be adopted with regards to industrial applicability. Correa further submits that Article 27.1 does not authorise the exclusion of medicines from patentability; therefore Member States cannot exclude “essential medicines” stated in the WHO from patentability.¹⁰⁸

Articles 27.2 and 27.3 of the TRIPS Agreement contain subject matter that Member States may exclude from patentability. The first is *ordre public*, one of the identified grounds for exclusion from patentability in terms of Article 27.2. Correa and Yusuf have submitted that there is “no universally accepted notion of *ordre public*.”¹⁰⁹ However this provision gives Member States some flexibility to define which situations are applicable. Article 27.2 indicates that this concept relates to among others the protection of “human, animal or plant life or health” and applies to innovations that may cause “serious prejudice to the environment.” Furthermore, this article allows the State to prevent the commercial exploitation of an invention to protect the *ordre public*.

In addition, Article 27.3 permits Member States to exclude diagnostic, therapeutic and surgical methods from patentability. Although this flexibility is not directly linked to pharmaceutical products, countries should adopt it because it prevents patents being granted on items which may inevitably increase the cost of treatment and essential medicines.

This provision also permits Member States to exclude plants and animals other than micro-organisms, and “essentially biological processes for the production of plants or animals other than non-biological and microbiological processes” from the ambit of patent protection. Thorpe submits that the ambit of this provision permits Member States to provide greater exclusion by excluding plant and animal varieties as well as any plant or animal even if it satisfies the requirements for patentability.¹¹⁰

¹⁰⁸ C Correa ‘Integrating Public Health Concerns into Patent Legislation in Developing Countries’ (2000) *The South Centre* 1, 11.

¹⁰⁹ C Correa and A Yusuf ‘Intellectual Property and International Trade: the TRIPS Agreement’ (2008) *The Netherlands Kluwer Law International* 230.

¹¹⁰ P Thorpe ‘Study on the Implementation of the TRIPS Agreement by Developing Countries’ *Commission on Intellectual Property Rights* 18, available at http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf, accessed on 2 September 2012.

In light of TRIPS patentability criteria, many pharmaceutical companies are trying to extend the minimum patent term of existing medicines by acquiring patent protection on new uses of existing medicines. This is known as the “evergreening” of patents. Temmerman submits that evergreening occurs before the expiration of a patent, in this instance a pharmaceutical company files a new application for patent protection over a slight modification of an existing product to resume another 20 years of protection for what is essentially the same product.¹¹¹ The extension of patent protection for another 20 years hinders the development and production of generic medicines. Since the TRIPS Agreement does not provide a definition of what an invention is in terms of Article 27, developing countries have the flexibility to define the scope of what constitutes an invention under their national laws in a manner that excludes new uses from patentability.

Therefore developing countries should adopt strict criteria which specifically exclude the patenting of a new form of a known substance or the new use of known substances from patentability, which would directly limit prospects of “evergreening.” In compliance with the TRIPS Agreement, India introduced patent provisions which explicitly excludes new dosages and different forms of the same medicine from patentability, and in particular known substances which do not display evidence of an increased efficacy.¹¹²

3.2.2 Exceptions to Patent Rights

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

While the exceptions are bound by the above qualifications, the Agreement does not provide a definition for “limited exceptions” and therefore it can be used by developing countries to

¹¹¹ M Temmerman ‘The Legal Notion of Abuse of Patent Rights’ (2011) *Working Paper No. 2011/23*, 5 available at http://www.wti.org/fileadmin/user_upload/nccr-trade.ch/wp3/3.5/The%20Legal%20Notion%20of%20Abuse%20of%20Patent%20Rights.pdf, accessed on 7 September 2012.

¹¹² Ibid.

pursue public health goals. This provision also suggests an intention to strike a balance concerning the interests of the patent holder and that of third parties.¹¹³

One example of allowable exceptions is the so called early working exception. The Dispute Settlement Body of the WTO in the dispute between the European Union and Canada has provided some guidance on the interpretation of this exception.¹¹⁴ In this instance the Settlement Body held that a provision allowing a third party to make and use a patented invention with the intention of acquiring regulatory approval for a similar product was a legitimate exception within the context of TRIPS.¹¹⁵ This exception allows the competitor to use the invention without the consent of the patent holder prior to the expiration of the patent with the sole intention of the seeking regulatory approval for marketing the product upon expiry of the patent.¹¹⁶ This exception is aimed at ensuring that generic versions of the product are available on the market immediately or within a reasonable time after the patent has expired.¹¹⁷

3.2.3 Compulsory Licenses

A “compulsory license” is the non-voluntary authorisation to use an invention. The patentee is obliged to accept the exploitation of his invention by a third person or by the government. It is argued that public interest in terms of access to the patented invention is given more weight than the private interest of the patent holder not to have his exclusive rights infringed.¹¹⁸ Thus, compulsory licenses can be granted to secure the production of generic medicines or allow for the importation from foreign producers. The most important rule governing the use of compulsory licenses is Article 31 of the TRIPS Agreement, which addresses uses “of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.”

¹¹³ Ibid.

¹¹⁴ Thorpe (note 110 above) 21.

¹¹⁵ Ibid.

¹¹⁶ Sector Strategy for Access to Medicine in Comesa ‘Review of Implementation of TRIPS Flexibilities on Patents’ (2011) 1, 27 available at <http://www.comesabusinesscouncil.org/attachments/article/31/0.%20Cover%2031.10.2010.pdf>, accessed on 17 July 2012.

¹¹⁷ SF Musungu ‘Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations’ (2007) 1, 13.

¹¹⁸ J Reichmann and C Hasenzahl ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (2003) *Intellectual Property Rights and Sustainable Development* 1, 10 available at http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf, accessed on 12 September 2012.

Article 31 does not restrict the grounds upon which compulsory licenses can be granted. However, it does impose certain substantive and procedural obligations. Substantively, this provision requires that the adequate remuneration be paid to the patent holder and that license granted be “non-exclusive.”¹¹⁹ Compulsory license applications are to be considered on their individual merits.¹²⁰ This provision provides some flexibility by allowing compulsory licenses to be “fast-tracked” which is especially important when essential lifesaving medicines are needed.¹²¹

Procedurally, applicants should first seek a voluntary license on reasonable terms and conditions from the patent holder, but this provision can be waived on the grounds of “national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use.”¹²² Licenses are subject to termination when the conditions giving rise to the grant are no longer present.¹²³ Furthermore, a successful compulsory license requires expeditious licensing procedures.

Article 31(f) provides that compulsory licenses can be granted “predominantly for the supply of the domestic market” of the Member State allowing them. Abbott suggests that a country with a manufacturing capacity can grant a compulsory license for its local manufacture and can also authorize export of a “non-predominant” part of the production.¹²⁴ Gupta argues that in terms of policy, this provision may be an impediment to less-developed countries which lack infrastructure and technical capabilities to build a domestic market with the ability to supply pharmaceutical products.¹²⁵ The restriction on exports in Article 31(f) is not applicable when a compulsory license is granted to correct anti-competitive practices.¹²⁶

¹¹⁹ Article 31 para d; h.

¹²⁰ Ibid para a.

¹²¹ SF Musungu and C Oh ‘The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?’ (2005) *Commission on Intellectual Property Rights, Innovation and Public Health* 1, 21 available at

<http://www.southcentre.org/publications/SouthPerspectiveSeries/TheUseOfFlexibilitiesInTripsFinal.pdf>, accessed on 12 September 2012.

¹²² Article 31 para b.

¹²³ Ibid para g.

¹²⁴ FM Abbott ‘The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health’ (2005) 99 *The American Journal of International Law* 317, 319.

¹²⁵ A Gupta ‘Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?’ (2003-2004) 2 *Buff.Intell.Pro.L.J.* 127, 138.

¹²⁶ Article 31 para k.

It is clear that Article 31 aims to strike a balance by giving the government a right to authorise compulsory licenses whilst attempting to protect the patent holder's rights whenever applicable.¹²⁷ Thus, compulsory licenses can be an important way for governments in developing countries to make patented pharmaceutical products available at more competitive prices.

The Doha Declaration confirmed that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which it may be granted. "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency."¹²⁸ Although this provision does not supplement the substantive content of Article 31, it provides an authoritative and "unequivocal statement regarding the right of Members to grant compulsory licenses."¹²⁹

3.2.4 Parallel Importation

Parallel importation is a mechanism used to increase access to medicines. It can be defined as "the import and resale in a country, without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner."¹³⁰ A patent holder has the exclusive right to manufacture his invention and place it on the market. Once the patented product is placed on the market, the principle of exhaustion allows the patented product to be resold without the patentee's express authorization.¹³¹ International exhaustion allows the patented product to be imported after the first sale authorized by the patentee even if that sale occurred in another country.¹³² The patent holder is unable to prevent any consequent resale of a pharmaceutical product since their rights over the product have been exhausted by the act of selling it.

¹²⁷ Gupta (note 125 above) 141.

¹²⁸ Para 5(c) of Doha Declaration.

¹²⁹ Reichmann (note 118 above) 16.

¹³⁰ Correa (note 108 above) 72.

¹³¹ Sector Strategy for Access to Medicines in COMESA 'Introduction to WTO Decisions on TRIPS and Public Health' (2011) 1, 12 available at

<http://www.comesabusinesscouncil.org/attachments/article/31/8.%20Strategic%20Analysis%20and%20Implementation.pdf>, accessed on 12 September 2012.

¹³² Ibid.

The TRIPS Agreement allows for parallel importation. This flexibility is one of the measures that Member States can take to protect public health under Article 8.1 of TRIPS. Article 6 states that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” Therefore, Member States have the freedom to incorporate the international exhaustion of rights principle in its domestic laws. Correa submits that Article 6 gives Member States broad flexibility to implement parallel importation policies.¹³³

Facilitating parallel importation can result in significant cost savings in order to secure essential medicines, which are important in resource-constrained countries. Importation of a patented medicine from a country where it is marketed at a cheaper price enables greater access to the medicine, without depriving the patent holder of his remuneration for the patented invention when the product was first sold. There are no procedural or remuneration obligations in terms of parallel importation.

Paragraph 5(d) of the Doha Declaration has confirmed that each Member State is “free to establish his own regime for such exhaustion without challenge”- this is viewed as an extra measure for Member States wanting to adopt an international exhaustion principle that is authentic and in conformity with the TRIPS Agreement.¹³⁴

3.2.5 Anti-competitive Practices

The TRIPS Agreement “envisages a balance between the promotion of technological innovation and the transfer and dissemination of technology, in addition to a balance in the enjoyment of the benefits accruing to the users and producers of technology.”¹³⁵ These balances are dealt with under Articles 8, 31(k) and 40 of the TRIPS Agreement.

The intention behind competition law is to ensure that markets are effectively contestable, making sure that firms are not engaging in anti-competitive practices for unlimited periods of time.¹³⁶ Anti-competitive practices include a refusal to provide goods or to license

¹³³ Correa (note 108 above) 75.

¹³⁴ Musungu (note 121 above) 28.

¹³⁵ SF Musungu *et al* ‘Utilising TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks’ (2004) 1, 19 available at <http://www.southcentre.org/publications/flexibilities/flexibilities.pdf>, accessed on 8 September 2012

¹³⁶ KE Maskus and M Lahouel ‘Competition Policy and Intellectual Property Rights in Developing Countries’ (2000) 595, 597 available at

technologies on market terms to curb competition, merging with competitors to achieve a monopoly, and agreeing to establish collusive restraints on trade with other firms.¹³⁷

Article 8

Article 8.1 provides that Member States may implement measures necessary for the protection of public health and nutrition and take measures to promote public interests in sectors of vital importance to their socio-economic and technological development. Article 8.2 states that appropriate measures may be required “to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

Article 8.2 is a “principle”, constituting a general rule which provides rights and duties for Member States.¹³⁸ The fact that the Agreement provides a “principle” as opposed to a specific rule indicates that it is not the intention of the treaty-makers to rule on the matter, but to give Member States a broad discretion in terms of implementation.¹³⁹ This provision recognises that Member States are authorized to take steps to deal with the country’s needs and concerns. Furthermore it does not restrain Member States from taking such steps.¹⁴⁰ The second principle should be regarded as an interpretive standard in favour of Member States adopting measures which are considered essential for promoting competition and to prevent patent holders from abusing the monopoly position they hold, which includes engaging in anti-competitive licensing arrangements or practices which adversely affect international transfer of technology.¹⁴¹

However, Article 8.2 also contains a limitation to Member States obligation to prevent the aforementioned practices. It provides that the measures taken must be “consistent with the provisions of this Agreement”, and it must be “appropriate” to prevent such practices.

<http://infojustice.org/download/gcongress/globalarchitectureandthedevelopmentagenda/maskus%20article.pdf>, accessed on 15 August 2012.

¹³⁷ Ibid.

¹³⁸ UNCTAD-ICTSD ‘Intellectual Property Rights and Competition’ (2004) *CY564-Unctad-v1* 539, 546 available at http://www.iprsonline.org/unctadictsd/docs/3.IPRSandCompetition_update.pdf, accessed on 15 September 2012.

¹³⁹ Ibid.

¹⁴⁰ J Berger ‘Advancing Public Health by Other Means: Using Competition Policy to Increase Access to Essential Medicines’ (2004) *ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio* 1, 4.

¹⁴¹ Musungu (note 135 above) 20.

Article 31(k)

This provision is relevant to competition policy, dealing with the granting of compulsory licences whilst recognising that anti-competitive practices involving patents are particularly egregious. Compulsory licenses adopted as a remedy for an anti-competitive practice under this provision does not require any prior negotiations with the patent holder. The only requirement is that the anti-competitive practice is established by a procedure, either administratively or judicially, which exists on a national level. It is submitted that if there is a likelihood that the practice will persist, the competent authorities may refuse to terminate the anti-competitive measure, extending it further.¹⁴² Neither the TRIPS Agreement nor Article 31 provides a definition of the term “anti-competitive practice,” giving Member States the flexibility to determine what they might consider to be anti-competitive.

Article 31 (k) also states the remuneration to the patent holder can be adjusted in light of his anti-competitive practices. The consequences of this provision are that in severe cases of anti-competitive practices, remuneration can be omitted in its entirety. This provision also expressly waives the restrictions for predominant domestic use, thus permitting the exportation of local production to any country where the pharmaceutical product is not under patent or where a compulsory license has been granted.¹⁴³

Article 40

Article 40 establishes a system which regulates anti-competitive practices in contractual licences. Apart from the measures contained in Article 8.2 aimed at improving competitiveness in the pharmaceutical area, Member States can also take further measures to control the licensing practices in terms of this article.¹⁴⁴ Maskus argues that upon a broad interpretation, this provision could extend to any potential abuse of intellectual property rights, which could include “monopoly pricing, refusals to license, effectuating horizontal

¹⁴² United Nations Development Programme (note 84 above) 42.

¹⁴³ Ibid .

¹⁴⁴ Musungu (note 135 above) 20.

cartels through patent pooling, and exclusive vertical arrangements that forestall competition.”¹⁴⁵

3.2.6 The Waiver for Least Developing Countries until 2016

Article 65 and 66 of the TRIPS Agreement granted least developed countries (LDCs) special permission not to implement the TRIPS Agreement until 2006.¹⁴⁶ The Agreement provided for transitional periods that benefited developing countries and economies in transition, including LDCs.

1. Article 65.2 states that any developing country Member State is entitled to delay compliance with the Agreement until January 2000.
2. Article 65.3 states that any other Member State which was “in the process of transformation from a centrally-planned into a market, free enterprise economy and which was undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations,” could also benefit from the same period of delay.
3. Article 65.4 states that to the extent that a Member State was obliged “to extend product patent protection to areas of technology” which was not protectable in its territory upon application of the Agreement, it could delay the application of product patents for an extra term of five years i.e. until 2005.

Furthermore, Article 66.1 provides that in light of the special needs and requirements of least-developed country, such Member States are not required to apply the provisions of the Agreement for a period of 10 years from the date of application. It is submitted that this provision is intended to allow LDCs greater flexibility enabling them to create an efficient technological base, which includes domestic pharmaceutical production.¹⁴⁷

¹⁴⁵ Maskus (note 136 above) 602.

¹⁴⁶ FM Abbott and CM Correa ‘World Trade Organization Accession Agreements: Intellectual Property Issues’ (2007) Global Economic Issues Publication 1, 6 available at: http://frederickabbott.com/uploads/Abbott___Correa_Accession_WTO-IP-English.pdf, accessed 25 August 2012.

¹⁴⁷ UNAIDS Technical Brief ‘Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries’ (2011) 1, 3 available at

It is important to note that this period was extended by the Decision of the Council for TRIPS 2005. In accordance with this Decision, LDCs were obliged to apply the provisions of the Agreement until 2013, or until such a date on which they cease to be a least-developed country Member State, or whichever date comes first.¹⁴⁸ Furthermore, in terms of Paragraph 7 of the Doha Declaration, least developed Member States are granted an additional ten-year extension until 2016, instead of 2006- not to provide or enforce pharmaceutical patent and data protection. The extensions are particularly important because they lengthen the time frame in which Member States may consider the type of pharmaceutical intellectual property law system they want to implement while still being allowed to import and produce generic medicines.¹⁴⁹

The transitional arrangements for LDCs are important regarding access to essential medicines and for the development of research and development capabilities of these countries. The transition period until 2016 in LDCs is an acknowledgement of the consequences of patent protection in the field of public health, and the needs of LDCs to have access to these medicines.¹⁵⁰

3.2.7 The Doha Declaration

The Fourth Ministerial Conference of the WTO was a major breakthrough regarding the implementation of TRIPS and access to medicines. The WTO Ministerial adopted a Declaration on TRIPS and Public Health, which placed public health before commercial interests of patent holders and provided a comprehensive interpretation of the TRIPS Agreement with regards to public health.

The Doha Declaration deals with ‘health problems’ without limitation. The first two paragraphs expressly “recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics . . . and the need for the Agreement to be part of the

http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf, accessed on 13 July 2012.

¹⁴⁸ Abbott and Correa (note 146 above) 10.

¹⁴⁹ t’Hoen (note 8 above) 53.

¹⁵⁰ UNAIDS Technical Brief (note 147 above) 4.

wider national and international action to deal with such problems.” These provisions merely depict some of the problems facing developing countries; it does not limit the use of the Declaration to these three diseases or epidemics only.

Paragraph 3 is an important provision regarding access to essential medicines. It recognizes that intellectual property protection is vital for the development of new medicines and the concerns relating to its effects on prices. t’Hoen stated that this text is significant because it recognises the relationship between patents and exorbitant drug prices and the difficulties it poses to developing Member States.¹⁵¹

Paragraph 4 acknowledged each country’s right to take steps to protect public health. It affirmed that Member States “agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.” It further noted that the Agreement should be interpreted and implemented in a manner supportive of Member States right to protect public health and to promote access to medicines for all. This Paragraph is extremely important because it gives primacy to public health considerations and clarifies that this principle is applicable to the entire TRIPS Agreement. Reference to “measures to protect public health” is not limited to essential medicines only but includes vaccines, diagnostics and other health tools needed to facilitate the use of these products.¹⁵²

Paragraph 5 deals with compulsory licensing, which can be used to overcome intellectual property obstacles to access to medicines. This provision guarantees in 5(b) that each Member State “has the right to grant compulsory licences” and the freedom to establish the grounds upon which they are authorised.

In light of the ineffectiveness of Article 31 and the public health problems facing developing and least-developed nations without manufacturing capability, Paragraph Six of the Doha Declaration called for a solution to the problem inherent in Article 31(f), which stipulated that a compulsory license could only be granted primarily for the supply of the domestic market. In 2003, in attempting to find a solution to legal barriers in exporting essential medicines manufactured under a compulsory licence and ensuring that Member States that depend on import for their medicine supply could gain from compulsory licences, the WTO

¹⁵¹ t’Hoen (note 13 above) 33.

¹⁵² Ibid.

adopted the “August 30th decision.”¹⁵³ This Decision¹⁵⁴ essentially permits a waiver of Article 31(f) for countries that need to import generic medicines.

The Decision permits any Member to export medicines made under compulsory licenses to countries with insufficient or no manufacturing capacity in the pharmaceutical sector. This provision is subject to a number of conditions which includes Member States giving notice to the TRIPS Council, the patent holder receiving remuneration, and safeguards aimed at ensuring that the pharmaceutical products developed under compulsory licenses are not averted from the "public health purposes underlying their importation."¹⁵⁵

Implementation of the Decision has been criticised for a number of reasons:

- Before a generic company can apply to a government to issue a compulsory license, it has to negotiate with the patent holder for a voluntary license. Such negotiations are complex and are a source of delays.¹⁵⁶
- The Decision requires that the drugs be identified through specific labelling and marketing, ensuring that it will be exported to the destination specified in the compulsory license. These measures that generic companies must comply with are burdensome and are a deterrent to their participation in the process.¹⁵⁷
- Furthermore, a potential importing country must send a written notification to the WTO TRIPS Council, affirming its objective to import pharmaceutical products. The requirement may result in pressure from countries whose policy and practice it is to discourage the grant of compulsory licenses. Although the purpose behind the

¹⁵³ t’Hoen *et al* (note 13 above) 5.

¹⁵⁴ World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of the General Council of 30 August 2003, Sept. 1, 2003, WT/L/540 available at www.wto.org/English/tratop_e/trips_e/implement_para6_e.htm, accessed on 5 May 2012.

¹⁵⁵ M McClellan ‘Tools for Success: The TRIPS Agreement and the Human Right to Essential Medicines’ (2005)12 *Washington and Lee Journal of Civil Rights and Social Justice* 153, 159 available at <http://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1193&context=crsj&sei-redir=1&referer=http%3A%2F%2Fwww.google.co.za%2Fsearch%3Fhl%3Den%26sclient%3Dpsy-ab%26q%3DM%2BMcClellan%2B%25E2%2580%2598The%2BTRIPS%2BAGreement%2BAND%2Bthe%2BHuman%2BRight%2Bto%2BEssential%2BMedicines%25E2%2580%2599%2B%26btnG%3D#search=%22M%20McClellan%20%25E2%80%98The%20TRIPS%20Agreement%20Human%20Right%20Essential%20Medicines%25E2%80%99%22>, accessed on 18 August 2012.

¹⁵⁶ Medecins Sans Frontieres ‘Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable’ (2006) 1, 3 available at http://www.doctorswithoutborders.org/news/hiv-aids/WTO_chretien.pdf, accessed on 9 October 2012.

¹⁵⁷ *Ibid.*

notification is to ensure transparency, this condition may discourage importing countries from doing so.¹⁵⁸

Rwanda has been the first country to make use of the August 30th Decision process to import generic ARVs from Canada.¹⁵⁹ This was the only time that the system has been implemented.¹⁶⁰ This mechanism has been critiqued as being difficult and onerous.¹⁶¹ This was due to shipments to Rwanda taking longer than necessary because “the company seeking a compulsory license needed time to find an interested importing country, as well as on account of Rwanda’s procurement tendering procedures.”¹⁶² Due to the length of time taken in Canada’s case, it has been suggested that the system is not working and is too complicated.¹⁶³

¹⁵⁸ Ibid.

¹⁵⁹ Third World Network “Members discuss implementation of TRIPS "Para 6" solution” (2010) *TWN Info Service on Intellectual Property Issues* available at http://www.twinside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.100302.htm, accessed on 9 October 2012.

¹⁶⁰ UNAIDS Technical Brief (note 147 above) 5.

¹⁶¹ Ibid 8.

¹⁶² Third World Network (note 159 above).

¹⁶³ Ibid.

CHAPTER IV: INTELLECTUAL PROPERTY IN SOUTH AFRICA

4.1 Patents Act 57 of 1978

4.1.1 Introduction

When a person invents something, there is a danger that their invention will be copied by others. If it is subsequently copied, the benefit from the product may be enjoyed by the person who copied the product. Before the patent and its protective mechanisms were introduced, this danger was common and it discouraged inventors from pursuing their interests or disclosing them to the world. To safeguard the interests of inventors, patent laws were established to protect inventors' rights and regulate an efficient intellectual property system. The "South African intellectual property framework is well established."¹⁶⁴

The South African Patents Act was amended by the Intellectual Property Amendment Act in order to render intellectual property legislation in conformity with the TRIPS Agreement. Daya & Vink submit that only a small number of substantive changes were involved.¹⁶⁵ In terms of such compliance, it is submitted that South Africa's intellectual property laws contain stronger mechanisms than is necessary in order to protect intellectual property rights. The scope of patent legislation is wide as section 25(1) of the Act specifies that a "patent may be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture". Since South Africa is a not patent examining country- the effect is that the Companies and Intellectual Property Registration Office (CIPRO) does not conduct an investigation into the novelty or inventive requirements of the invention which results in only the documentation being confirmed and not the substantive nature of the product or process.¹⁶⁶ Kaplan submits that the lack of a rigorous patent examination system and the resultant ease of acquiring a patent can result in companies filing a great number of patents domestically.¹⁶⁷ It can be argued that the large

¹⁶⁴ Y Daya and N Vink 'Protecting Traditional Ethno-Botanical Knowledge in South Africa through the Intellectual Property Regime' (2006) 45 *Agrekon* 319, 326.

¹⁶⁵ Ibid.

¹⁶⁶ A Pouris *et al* 'Patents and Economic Development in South Africa: Managing Intellectual Property Rights' (2011) *S Afr J Sci* 1, 5 available at [http:// dx.doi.org/10.4102/sajs.v107i11/12.355](http://dx.doi.org/10.4102/sajs.v107i11/12.355), accessed on 16 October 2012.

¹⁶⁷ D Kaplan 'Intellectual Property Rights and Innovation in South Africa: A Framework' (2009) *The Economics of Intellectual Property in South Africa* 1, 3 available at http://www.wipo.int/ip-development/en/economics/pdf/wo_1013_e.pdf, accessed on 15 August 2012.

number of patent applications being granted for medicines can reduce the availability of generic production, restricting access to essential medicine.

In addition, South Africa has made “little use of mechanisms to limit the rights of patent holders in the interests of broader public interest” such as compulsory licensing or parallel importation.¹⁶⁸

4.1.2 Patentability Standards

The purpose behind the Act is to facilitate the registration and granting of patents for inventions and for any related matter. The Act does not define the term “invention” stating that an invention is something that can be patented under section 25.

Despite no express mention in Section 25(1) of the place of invention or manufacture and the fact that the invention can be used or applied in any field of trade or industry or agriculture, it still has to comply with Article 27.1 of the TRIPS Agreement. In order to be patentable, an invention must:

- “be novel,
- involve an inventive step, and
- be capable of being used or applied in trade or industry or agriculture.”

(i) Novelty

Novelty refers to something that is new. Section 25(5) states that a new invention is one which “does not form part of the state of the art immediately before the priority date of any claim to that invention.” The state of art comprises of:

- “all matter that has been made available to the public by written or oral description, by use or in any other way;
- matter contained in an application for a patent which was both lodged and open to public inspection, provided that the priority date of that matter is earlier than that of the invention;
- an invention used secretly and on a commercial scale within the Republic.”¹⁶⁹

¹⁶⁸ Ibid 5.

A substance or composition that is employed in a new method for treatment or diagnosis of humans or animals can be patented even if the substance or composition formed part of the state of art, as long as the substance or composition has not been used before in that new method (section 25(9)).

(ii) Inventive Step

According to section 25(10), an invention is deemed to involve an inventive step “if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art.” Therefore in order to acquire a patent, the invention must be non-obvious. The invention will be regarded as non-obvious or incorporating an inventive step if the enhancement to the innovation is not such that any person in that field could have come up with that invention.¹⁷⁰

The test for “obviousness” can be described as follows:

‘It is to identify the differences that exist between these prior art documents and the alleged invention. And, if there are differences, the question is then whether there has been a step forward. If there is; then the final question is whether it required some inventiveness or would it have been obvious to a man skilled in the art.’¹⁷¹

In the *Ensign-Bickford*¹⁷² case, Plewman JA held that the aforementioned enquiry must proceed further and a more structured enquiry should be undertaken, and that it would be “...appropriate to adopt tests formulated in certain English authorities.”¹⁷³ Citing the case of *Mölnlycke AB and Another vs Procter & Gamble Limited and Others*,¹⁷⁴ a new test for the inventive step was introduced in the form of a four-step inquiry:

1. What is the inventive step said to be involved in the patent in suit?
2. What was, at the priority date, the state of the art (as statutorily defined) relevant to that step?
3. In what respect does the step go beyond, or differ from, that state of the art?

¹⁶⁹ P Ramsden ‘A Guide to Intellectual Property Law’ (2011) 257.

¹⁷⁰ Y Daya and N Vink (note 164 above) 330.

¹⁷¹ *Speedmark Holdings (Pty) Ltd v Roman Roller CC and Another* 1993 BP 397 at 408G–409B

¹⁷² *Ensign-Bickford (South Africa)(Pty) Limited and Others v AECI Explosives and Chemicals Limited* 1998 BIP 271 (SCA).

¹⁷³ *Ibid* page 23.

¹⁷⁴ (No.5) [1994] RPC 49 (CA).

4. Having regard to such development or difference, would the taking of the step be obvious to the skilled man?"

The requirement of inventiveness could also be used to contest a patent application by contending that the content of the patent application is 'obvious' and does not fulfil the requirement of inventiveness as set out in the Act. Furthermore, it could be countered that in terms of section 25(9), the subject matter of an application is lacking an inventive step because they are founded upon existing compounds or discovered the compound, but in a different form.

(iii) Industrial Applicability

Once it is determined that the invention differs sufficiently from the prior art with regard both the new and inventive requirements, the final prerequisite is that the invention's function be implemented. For the invention to be patentable it must be capable of being used or applied in trade or industry or agriculture. It is submitted that the term "capable of being used" can be defined as an invention being capable of creating the result intended by the invention.¹⁷⁵ Where the invention is capable of creating the intended result, it is regarded as "useful", even if that result is not a commercial or a financial success.¹⁷⁶

4.1.3 Exclusions from Patentability:

Various sections in the Act deal with exclusions from patentability. Inventions that are frivolous because they claim something obviously contrary to well-established natural laws do not qualify for patent protection.¹⁷⁷ The Registrar of patents has a discretion to refuse to grant a patent for subject matter that may be used in a way that is contrary to law.¹⁷⁸ Such inventions are not patentable on the grounds of public policy.¹⁷⁹

General exclusions are contained in section 25(11) and 25(4): section 25(11) states that an invention of a method of treatment of the human or animal body by surgery, therapy or of

¹⁷⁵ Ramsden (note 169 above) 262.

¹⁷⁶ Ibid.

¹⁷⁷ Section 36(1)(a).

¹⁷⁸ Section 36(2).

¹⁷⁹ Klopper *et al* (note 24 above) 290.

diagnosis shall be deemed incapable of being used or applied in trade, industry or agriculture. It has been suggested that this exclusion was included on ethical grounds to stop the monopolisation of medical and veterinary methods which entails application by a person.¹⁸⁰

The second exclusion states that a patent shall not be granted-

“(a) for an invention, the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or

(b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.”

Vawda submits that as the “concept of morality and offensive behaviour are relative concepts, particularly in a diverse and evolving society such as South Africa, it is unclear how this provision is to be applied.”¹⁸¹

The Act also provides specific exclusions by distinguishing between inventions that may not be patentable and therefore are not deemed inventions in terms of the Act:

“Anything which consists of—

(a) a discovery;

(b) a scientific theory;

(c) a mathematical method;

(d) a literary, dramatic, musical or artistic work or any other aesthetic creation;

(e) a scheme, rule or method for performing a mental act, playing a game or doing business;

(f) a program for a computer; or

(g) the presentation of information.”¹⁸²

4.1.4 Exceptions to Patentability

The Patents Act does not contain any general provisions relating to the list of exceptions permitted under Article 30 of the TRIPS Agreement. However it is suggested that the provisions regarding infringements provide two instances of exceptions under the Act.¹⁸³ The first exception is contained in section 71(1). It states that a patentee’s rights will not be

¹⁸⁰ Ibid 291.

¹⁸¹ Vawda (note 31) 12.

¹⁸² Section 25(2).

¹⁸³ Vawda (note 181 above) 12.

infringed by the use of a patented invention on board a convention vessel, if the vessel enters territorial waters of the Republic, temporarily or accidentally, and the invention is used exclusively for the actual needs of the vessel.

The second exception is contained in sections 69 and 69A which allows the making, use, exercise, dispose or import a patented product on a non-commercial scale, solely for reasons related to the development, obtaining and submission of information required which regulates the manufacture, production, distribution, use or sale of a product.¹⁸⁴ This is also referred to as the early working exception.

4.1.5 Compulsory Licensing

The granting of compulsory licenses is provided for under dependent patents (under section 55) and in terms of the abuse of patent rights (under section 56).

(i) Dependent Patents

Section 55 provides that, “where the working of a patent (dependant patent) without infringement of a prior patent is dependent on the obtaining of a licence under that prior patent, the proprietor of the dependant patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the Commissioner for a licence under the prior patent.”

The Commissioner may grant such licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of permitting the dependant patent to be worked and for no other purposes. It is further provided that the Commissioner will not grant such a licence unless:

“(a) the invention claimed in the dependant patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;
(b) the proprietor of the dependant patent granted the proprietor of the prior patent on reasonable terms, a cross-licence to use the invention claimed in the dependant patent; and

¹⁸⁴ United Nations Development Programme (note 43 above) 38.

(c) the use authorized in respect of the prior patent is not assignable except with the assignment of the dependant patent.”

(ii) Abuse of Patents

Any interested person who wishes to apply for a compulsory licence may do so if he believes that the rights in the patent are being abused.¹⁸⁵ There are four grounds under section 56(2) whereby an applicant can bring a compulsory licence application:

“(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion Commissioner no satisfactory reason for such non-working;

(b) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(c) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(d) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.”

The patentee or any other person who is deemed an interested party can oppose the application for compulsory licenses. Section 56(4)(a) states that the Commissioner has the authority to consider the application on its merits and can grant or refuse the application and include any conditions, including that the licensee has to manufacture the patented product in South Africa. Subject to protecting the legitimate interests of the licensee, the patentee can

¹⁸⁵ Section 56(1).

make an application to terminate the licence if the circumstances which led to its grant cease to exist and, in the Commissioner's opinion, are unlikely to recur.¹⁸⁶

In South Africa, no compulsory licences have been granted on pharmaceutical products. The State has yet to make use of a statutory power that entitles it to 'use an invention for public purposes.'¹⁸⁷ Cameron submits that if the conditions of this government use – which includes the licensing of generic pharmaceutical companies as a manner in which drug prices can be reduced– cannot be agreed upon, the state should seek judicial assistance.¹⁸⁸

The *Syntheta* case dealt with an application for compulsory licence in terms of section 56 the Patents Act in respect of a registered patent. The Appellant's founding papers was based on s56(2)(a) and (d) of the Act. The Appeal Court dismissed the application as it found that the Appellant's founding affidavit failed to disclose such abuse.¹⁸⁹ The court addressed several deficiencies in Syntheta's application, including the apparent lack of evidence that the license would benefit South African public because the product was intended for export only.¹⁹⁰ The Court was of the opinion that the applicant provided little evidence of the abuse of the patent right, which was the legal foundation for the granting of the compulsory license.¹⁹¹ The ultimate finding by the Court was influenced by the fact that the application was for a license to export the product commercially which did not involve any domestic use in South Africa.

This case is also important as Plewman J referred to the essential *quid pro quo* theory of intellectual property law, acknowledging that patent protection is given in exchange for inventors disclosing their inventions for the benefit of the public.¹⁹²

As noted earlier, the Doha Declaration clarified that Member States have the flexibility to grant compulsory licenses and the power to determine the grounds upon which they may be granted. Furthermore, they can determine what constitutes a national emergency or other

¹⁸⁶ Section 56(4)(c).

¹⁸⁷ s 4 states:

'State bound by patent A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an 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'

¹⁸⁸ Cameron (note 96 above) 528.

¹⁸⁹ *Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd* (note 95 above).

¹⁹⁰ Ibid page 9.

¹⁹¹ Ibid page 11.

¹⁹² Ibid page 5.

circumstances of extreme urgency. However, South Africa's intellectual property laws have not yet been amended to include these important flexibilities especially in the case of public health emergencies.

4.1.6 Government Use

The relevant provisions regarding government use are dealt with in terms of section 4 and 78 respectively. Section 4 authorizes that a Minister of State has the power to use an invention for public purposes in terms of the conditions agreed upon with the patentee, or upon default of such agreement on such conditions as are determined by the commissioner on application by or on behalf of the Minister and after hearing the patentee. In addition, section 78 provides that the Minister can acquire, on terms and conditions agreed upon, any invention or patent on behalf of the State. Section 4 empowers the Minister of Health to grant compulsory licenses for a public purpose, such as ensuring access to a sustainable supply of affordable medicines.¹⁹³

4.1.7 Parallel Importation

Section 45(2) of the Act deals with parallel importation by providing that "the disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article." Vawda submits that this principle is a component of our jurisprudence.¹⁹⁴ In the case of *Commissioner of Patents of Stauffer Chemical Co v Agricura Ltd*, the court "held that all restraints imposed by the patentee's monopoly fall away where the patented article is sold or disposed of by the patentee himself, his assignee or agent; and where the sale is by a licensee, the question of exhaustion would depend on the extent of the authority conferred on the licensee."¹⁹⁵

4.1.8 Disclosure Requirements

¹⁹³ T Avafia *et al* 'The Ability of Select Sub-Saharan African countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries' (2006) *International Centre for Trade and Sustainable Development* 10.

¹⁹⁴ Vawda (note 22 above) 362.

¹⁹⁵ *Ibid.*

Patents grant monopolies to inventors in exchange for public disclosure of the invention. Therefore, the full disclosure of an innovation is an essential principle of patent law.¹⁹⁶ Disclosure is dealt with in section 32 of the Patents Act, which provides that every specification must indicate whether it is a provisional or a complete specification, and shall commence with a title which sufficiently indicates the subject-matter of that invention. Furthermore, a complete specification must include an abstract; the inventions must be sufficiently described, ascertained and, where necessary, illustrated or exemplified and the manner in which it is to be performed in order to enable the invention to be performed by a person skilled in the art of such invention; and it must end with a claim(s) defining the invention for which protection is claimed (section 32(3)).

Although the Act provides for disclosure requirements, it is submitted that this provision is rendered redundant in light of South Africa's non-existent patent examination system. As a result, "the system may allow the granting of patents which fall into excluded categories, it may create social costs through the monitoring of non-novel patents by the various stakeholders, it may create market power for particular patent holders, and it may provide obstacles for further research and development in certain technological fields."¹⁹⁷

4.1.9 Opposition procedures and Examination System

Upon analysis, the Patent Act does not contain any provisions permitting opposition to the grant of patents. Section 23 of the 1952 Patents Act stated that "any person may within three months from the date of the advertisement of the acceptance of a complete specification... given written notice at the patent office of opposition to the grant of a patent on any" of the grounds listed therein. The 1978 Act abolished opposition proceedings. A person who wishes to object to a particular grant has to wait until the patent has been issued. According to section 34, the Registrar of Patents is obliged to examine every patent application and every complete specification accompanying the application before acceptance. In addition, the Registrar must examine the patent application in the prescribed manner, and upon compliance with the Act he must accept it. The examination is of a formal nature only.

¹⁹⁶ Correa (note 108 above) 75.

¹⁹⁷ Pouris (note 166 above) 5.

Vawda submits that the present patent registration system lacks transparency, in that the Act simply requires the Registrar to conduct the prescribed “tick-box approach” to all patent applications.¹⁹⁸ Patent offices in many developing countries lack the capacity to conduct comprehensive investigations into patent applications.¹⁹⁹ They may also be hindered by laws and regulations that do not establish patentability standards with adequate specificity.

A possible option which would improve transparency is to allow interested parties—such as the public—to oppose patent applications. It is interesting to note that the 2005 amendments to the Indian Patent Act retained its previous patent opposition procedures. It permits a pre-grant opposition to be filed after the patent application is published and before the patent is granted. A further provision allows for the filing of an opposition after the date of publication of the grant, before the expiry of one year.²⁰⁰

4.1.10 Revocation of Patents

The Act lists 9 grounds upon which a patent can be revoked under section 61. Fraudulent conduct on the part of the patent holder, which includes theft of the patented invention from another person, is a ground for revocation.²⁰¹ In terms of patent documentation, the fact “that the complete specification concerned does not sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be carried out by a person skilled in the art of such invention” can result in revocation.²⁰² When the invention “as illustrated or exemplified in the complete specification concerned cannot be performed or does not lead to results and advantages set out in the complete specification” the patent granted on it is revocable.²⁰³

When the content of a patent is obvious, the patent may be revoked because it relates to an unpatentable subject matter.²⁰⁴ The fact that the patent holder is not the inventor or a person who acquired the patent rights from the inventors serves as a ground for revocation.²⁰⁵

¹⁹⁸ Vawda (note 181 above) 11.

¹⁹⁹ Correa (note 108 above) 99.

²⁰⁰ Section 25 of 2005 Indian Patent Amendment Act.

²⁰¹ Section 61(1)(b).

²⁰² Section 61(1)(e).

²⁰³ Section 61(1)(d).

²⁰⁴ Section 61(1)(c).

²⁰⁵ Section 61(1)(a).

4.2 Medicines and Related Substances Control Act 101 of 1965

In 1997, the Medicines and Related Substances Act Control Amendment Act was passed by the South African government in response to the HIV/AIDS and other epidemics and to make medicines more affordable.²⁰⁶ The context of this amendment was to allow the use of cheaper generic drugs on a mass scale. In South Africa, over a brief period of time, millions of citizens had been infected with HIV/AIDS and it had been estimated “that the loss of these human resources will increase poverty, potentially causing the South African economy to lose approximately twenty percent of its GDP within twenty years.”²⁰⁷ Thus the driving force behind this legislation was to access generic medicines for domestic use due to the HIV/AIDS crises in the country.

The Act provides for (1) parallel importation of patented medicines; “(2) generic substitution of off patent medicines and medicines imported and produced under compulsory licenses and (3) a transparent pricing system through the establishment of a pricing committee.”²⁰⁸ In terms of the amendments the Minister of Health is empowered to use parallel importation to protect the public health.

4.2.1 Parallel Importation

The relevant provision facilitating parallel importation is section 15(C). It states:

15C. Measures to ensure supply of more affordable medicines.

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

(a) notwithstanding anything to the contrary contained in the 1978 Patents Act, determine that the rights with regard to any medicine under a patent granted shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

²⁰⁶ C Lumina ‘Free Trade or Just Trade? The World Trade Organization, Human Rights and Development (Part 2)’ (2010) 14 *Law, Democracy and Development* 1, 12.

²⁰⁷ WP Nagan ‘International Intellectual Property, Access to Healthcare, and Human Rights: South Africa v United States’ (2001-2002) 14 *Fla. J. Int’l L.* 155, 162.

²⁰⁸ SR Sekalala ‘Beyond Doha: Seeking Access to Essential Medicines for HIV/AIDS Through the World Trade Organisation’ 1, 4 available at <http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf>, accessed on 1 September 2012.

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

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

The parallel importation measure has been the cause of confusion surrounding the Medicines Act. Section 15(C)(a) has caused confusion as it is unclear what "acts" are excluded from patent protection, since the provision only addresses medicines which have been "put onto the market".²⁰⁹ Upon a broad interpretation, the law could deny patent protection for patented medicines that have been exploited commercially, once patent holders begin to sell their drugs.²¹⁰ In essence, once a patented medicine is sold, pharmaceutical companies have put their patented medicines "onto the market," and the Minister of Health may then authorize the parallel importation of the patented product.²¹¹

In addition, it has been argued that allowing parallel importation eliminates the obligation of a medicine being registered separately.²¹² Therefore, a generic drug produced in another country does not need to go through the patent registration system before entering the South African market.²¹³ Essentially, "a medicine may be imported from another country and sold in competition with a locally registered product."²¹⁴

4.2.2 International Response to Section 15(C)

South Africa came under intense pressure internationally and domestically, when it passed the amendments to its Medicine and Related Substances Control Act authorising parallel

²⁰⁹ DB Snyder 'South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?' (1999-2000) 18 *Dick. J. Int'l L.* 175, 184.

²¹⁰ *Ibid.*

²¹¹ *Ibid.*

²¹² KM Bombach 'Can South Africa Fight AIDS? Reconciling the Medicines and Related Substances Act with the TRIPS Agreement?' (2001) 19 *B.U. Int'l L.J.* 273, 278.

²¹³ *Ibid.*

²¹⁴ *Ibid.*

importation, amongst other things. The U.S. government contended that the law be rescinded, and in 1998, the Pharmaceutical Manufacturers Association of South Africa²¹⁵ and 39 pharmaceutical corporations instituted legal proceedings in the High Court against the government, to have the legislation repealed. The debate was focused on whether the South African government would utilise its powers under these amendments to avoid patent protections granted under the TRIPS Agreement and national patent laws.²¹⁶

In 1998, the USA government placed South Africa on the watch list for those countries that disrespected international intellectual property rights with respect to US products. Thereafter, the US Office of Trade instituted trade pressures against South Africa in the belief that the 1997 Act contravened the TRIPS Agreement.

Domestically, the drug companies argued that the provisions of the 1997 Medicines Act infringed their property rights and was therefore unconstitutional. It was further alleged that the Act infringed South Africa's international commitments under the TRIPS Agreement.²¹⁷ In a Notice of Motion,²¹⁸ the companies requested the court to strike down the new sections 15(C), 22F and 22G. These amendments allowed for parallel importation of medicines, generic substitution of patented and off -patent drugs and pricing control measures. The inclusion of these provisions would ensure the availability of affordable medicines to those who need them the most.

Furthermore, the PMA claimed that the aforementioned sections in the Act were unconstitutional as it "enables and authorizes the Minister of Health, in conflict with section 25 of the Constitution, to deprive owners of intellectual property in respect of pharmaceutical products of such property, alternatively to expropriate such property without any provision for compensation to be paid in respect thereof."²¹⁹ The companies further alleged that section 15C was discriminatory in respect of the enjoyment of patent rights in the field of

²¹⁵ The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa and Others. Unreported case no: 4183/98, High Court of South Africa (Transvaal Provincial Division) March 2001.

²¹⁶ Walker (note 92 above) 211.

²¹⁷ DW Muriu 'Third World Resistance to International Economic and Structural Constraints: Assessing the Utility of the Right to Health in the Context of the TRIPS Agreement' (2009) 11 *International Community Law Review* 409, 413.

²¹⁸ Notice of Motion filed in the PMA Case available at <http://www.cptech.org/ip/health/sa/pharmasuit.html>, accessed on 5 July 2012.

²¹⁹ Ibid para 2.3.

pharmaceuticals, contrary to Article 27 which was binding on South Africa. In addition, the companies contended that section 22F discriminated unfairly against holders of pharmaceutical patents and in favour of manufacturers of generic medicines contrary to section 9 of the Constitution.

Heywood submits that the measures adopted by South Africa were customary practice in developed countries and complied with international agreements such as the TRIPS Agreement.²²⁰ It can be argued that the legal action by the PMA was an attempt to use the Constitution to seize supplementary powers and safeguards for intellectual property that were not included under TRIPS; to interpret several ambiguities contained in the TRIPS Agreement especially in terms of ‘parallel importation’; and to caution other developing countries.²²¹

The South African government released a press statement affirming the agreement between itself and the United States, which emphasised its ability to use parallel importing under section 15C, while simultaneously promising to follow through upon its obligations under the TRIPS Agreement.²²² After the agreement was announced, the PMA decided that it would settle the matter out of court. However, about a year later, the PMA abandoned settlement talks and was prepared to return to court. Then, in April 2001, intense domestic and international pressure forced the PMA to withdraw their lawsuit, and the US government to reach an agreement with the South African government.²²³

4.3 Competition Act 98 of 1998

4.3.1 Background and Relevant Provisions

The South African Competition Act’s Preamble expresses an intention to create a competitive economic environment “focussed on development”, which is aimed at “balancing the interests of workers, owners and consumers.” The purpose behind the Act is “to promote the efficiency, adaptability and development of the economy” and “to provide consumers with

²²⁰ M Heywood ‘Debunking ‘Conglomo-talk’: A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation’ (2001) *AIDS Law Project* available at www.tac.org.za/.../MedicineActCourtCase/Debunking_Conglomo.rtf, accessed on 17 September 2012.

²²¹ Ibid.

²²² Walker (note 92 above) 211.

²²³ Lumina (note 265 above) 12.

competitive prices and product choices.”²²⁴ There are a number of sections in the Act which provide a foundation upon which anti-competitive practices can be challenged.

Prohibited practices are dealt with in terms of Chapter 2: Part A deals with restrictive horizontal practices,²²⁵ such as price fixing between competitors, collusive tendering or dividing markets by allocating customers, suppliers, territories or specific types of goods or services.²²⁶ It also makes provision for restrictive vertical practices,²²⁷ which includes agreements relating to minimum resale prices entered into between supplier and customer.²²⁸

The Act defines an essential facility as “an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.”²²⁹ Excessive price is defined as “a price for a good or service which bears no reasonable relation to the economic value of that good or service; and is higher than the value referred to in subparagraph (aa).”²³⁰

Section 8 is an important provision dealing with the abuse of dominance; this section is particularly significant with regard to access to essential medicines. It states:

8 It is prohibited for a dominant firm to:

- (a) charge an excessive price to the detriment of consumers;
- (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
- (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive, gain; or
- (d) engage in any of the following exclusionary acts, unless the firm can show technological, efficiency or other pro-competitive, gains which outweigh the anti-competitive effect of its act:
 - (i) requiring or inducing a supplier or customer to not deal with a competitor;

²²⁴ Section 2(a);(b).

²²⁵ Section 4.

²²⁶ Section 4(1)(b).

²²⁷ Section 5.

²²⁸ Section 5(2).

²²⁹ Section 1(viii).

²³⁰ Section 1(ix).

- (ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
- (iii) selling, goods or service on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
- (iv) selling goods or services below their marginal or average variable cost; or
- (v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

There are many reasons why developing countries should use the regulatory tools available in terms of competition law and policy to ensure access to affordable essential medicines. Competition law can be used to penalise companies who have engaged in monopolisation and forms of anti-competitive practices that has resulted exorbitant prices or limited the availability of essential medicines.²³¹

The TRIPS Agreement recognises and accords Member States flexibility when dealing with anti-competitive practices. The international trade law framework under TRIPS is important because it provides some guidance for determining when competition policy can be invoked in order to increase access to essential medicines.²³²

Competition law and policy is significant when implemented by an “independent competition authority vested with strong investigative powers.”²³³ Competition law can encourage interested parties with a mechanism whereby parties are not required to invest considerable resources in risky litigation. Alternatively, “the regulatory authority may pursue the matter in the public interest simply on the basis of a third party complaint.”²³⁴

In addition, TRIPS has granted Member States increased powers to permit the “use of the subject matter of a patent without the authorisation of the right holder”, i.e. through a compulsory license, where there has been an administrative or judicial determination that the patent-holder’s practice has been anti-competitive, in terms of Article 31(k).

²³¹ L Hawkins ‘Competition Policy’ *Politics of Medicine* available at <http://www.politicsofmedicines.org/articles/competition-policy>, accessed on 20 October 2012.

²³² Avafia (note 193 above) 30.

²³³ Ibid.

²³⁴ Ibid.

Section 8 has successfully been used in at least two cases to challenge anti-competitive practices by pharmaceutical companies. Flynn submits that in these cases, civil society demanded licenses based on the high prices of drugs combined with the refusal of the patent holders to grant licenses authorizing generic competition.²³⁵ The Competition Commission in South Africa issued an order finding that the refusals of drug suppliers to license competitors' whilst maintaining extraordinarily high prices were illegal abuses of dominance under its competition law.

4.3.2 Hazel Tau v GlaxoSmithKline and BoehringerIngelheim

In 2002, a group of eleven individuals infected with HIV/AIDS, health care workers, AIDS organizations and a trade union filed a complaint against two multinational pharmaceutical companies GlaxoSmithKline and BoehringerIngelheim (GSK, BI) before the South African Competition Commission.²³⁶ It was argued that these companies were engaging in anti-competitive practices through excessive pricing of their patented ARVs in contravention of Section 8 of the Act. The complainants argued that taking into account R&D costs, costs of production, reasonable profit, and other anticipated costs, the prices that the companies charged were excessive and unjustifiable.²³⁷ Thus, it was argued, the prices charged by GSK and BI for their essential medicines were directly responsible for the "premature, predictable and avoidable loss of life."

The Competition Commission agreed with this argument and held in favour of the complainants and found that the companies had infringed the said Act by engaging in excessive pricing and were found to have violated their dominant positions in their respective ARV markets.²³⁸ In addition, the Commission stated that such conduct denied generic

²³⁵ SM Flynn 'Using Competition Law to Promote Access to Medicines' (2008) *Programme on Information Justice and Intellectual Property* 8.

²³⁶ t'Hoen (note 12 above) 52.

²³⁷ United Nations Development Programme (note 84 above) 44.

²³⁸ Media Release from the Competition Commission 'Competition Commission finds pharmaceutical firms in contravention of the Competition Act' (16 October 2003) available at <http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=6&ved=0CDsQFjAF&url=http%3A%2F%2Fwww.wcl.american.edu%2Fpjjip%2Fdocuments%2FMediaRelease.doc&ei=u8uOULS2EYOThgfp4YCoAg&usg=AFQjCNHNt6eBg9owScvllah8onRSzwucMQ&sig2=d7ne0sAK1WkQNFJEJEJp-w>, accessed on 19 October 2012.

competitors with an “essential facility”, and therefore recommended the matter to the South Africa’s Competition Tribunal to request the following:

- Compulsory licenses on the patented medicines to allow any person to exploit the patents to market generic variations of GSK’s and BI’s patented medicines or fixed-dose combinations that require these patents, in exchange for the payment of a reasonable royalty.
- A penalty of 10% of the annual turnover of GSK’s and BI’s ARVs in South Africa for each year that they are found to have contravened the Act.²³⁹

Before the matter could be heard by the Competition Tribunal, the companies agreed to grant voluntarily licenses on the contested patents to generic producers for both private and public sector markets, at a royalty not exceeding of 5% of the sale price of the generic versions.

In 2007, South Africa’s Treatment Action Campaign (TAC) brought a complaint against the multinational Merck Sharp & Dohme (MSD) for refusing to license its patent on an ARV on reasonable terms. Again, MSD and TAC reached a settlement whereby MSD agreed to grant multiple licenses on its efavirenz patent to generic producers, for supply of both the public and private sectors.²⁴⁰

The South African experience shows that the use of competition laws and policies can be used to secure access to essential medicines. It is important to recognise the role played by civil society, who took the lead in advancing a public health, which was “not constrained by the failure to take appropriate action on the part of both the state and generic pharmaceuticals companies.”²⁴¹

²³⁹ Ibid.

²⁴⁰ United Nations Development Programme (note 84 above)44.

²⁴¹ Berger (note 140 above) 18.

CHAPTER V: TRIPS PROVISIONS TRIPPED UP ON INDIA'S INGENUITY

5.1 India

5.1.1 Historical Background

In 1947 after its independence, India retained the Indian Patent Act of 1911, a statute modelled on British law, as was law prior to independence.²⁴² The 1970 Patent Act was an improvement over the British Patent Act of 1949, as its amendments were essential to creating a weaker intellectual property system than its stronger predecessor.²⁴³

The primary objectives of the 1970 Act were contained in section 83 which stated that:

- “(a) The patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and
- (b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.”

In terms of section 2(j) of the 1970 Act, a patent may be obtained for an invention that is “new and useful.” It must relate to an “art, process, method or manner of manufacture; machine, apparatus or other article.”²⁴⁴ The term of patent protection was reduced from sixteen to fourteen years.²⁴⁵ Section 5 listed the following exclusions to patentability: food, medicines, drugs, or chemical substances. The Act allowed process patents but in terms of food, medicines, or drugs, the term of protection was five years from the date of the grant or seven years from the date of filing, whichever came first.²⁴⁶ The result of this provision was minimal patent protection.²⁴⁷

The Act also made provision for the issuance of general compulsory licenses, which stated that the Controller had the power to grant compulsory licenses where the patent rights had not

²⁴² MJ Adelman ‘Patent Law in India’ (1996) 1 *Int'l Intell. Prop. L. & Pol'y* 131, 131.

²⁴³ MJ Adelman and S Baldia ‘Prospects and Limits of the Patent Provision in the TRIPS Agreement: the Case of India’ (1996) 29 *Vand. J. Transnat'l L.* 507, 519.

²⁴⁴ Section 2(j).

²⁴⁵ Section 53(1)(b).

²⁴⁶ Section 5.

²⁴⁷ Adelman (note 242 above) 132.

been commercially exploited by the patentee or available to the public in India at a reasonable price.²⁴⁸ In terms of this section, an application to the Controller for a compulsory license would be made by any person three years after sealing, limiting patent protection to three years only. Thus, a potential violator of a process patent for food, medicine, or drugs could be granted a license of right, after the patentee's three years of protection had expired.

India was one of the signatories of the TRIPS Agreement in the Uruguay Round in 1995. Under the Uruguay Round, India was required to bring its domestic laws into conformity with the Agreement.

5.1.2 Steps Taken by India to Comply with the TRIPS Agreement

In 2005, India amended the Patent Act of 1970 to comply with its commitments under the TRIPS Agreement. It introduced patent protection for drugs, food and chemical products and the patent term was increased to 20 years. The amendments were seen in a negative light under the premise that increased patent protection would hamper the growth of the local pharmaceutical industry by limiting the industry's ability to reverse engineer and export drugs. As a result, the Indian pharmaceutical industry grew swiftly by producing cheaper versions of patented medicines for domestic use and eventually supplied the international market with generic medicines upon expiration of the international patents.²⁴⁹

As mentioned earlier, TRIPS requires Member States to safeguard pharmaceutical products by granting patents on all classes of products (including medicines), to grant patent protection for a minimum term of 20 years, and to allow patent rights to be satisfied by either importing the drug or by domestically producing the drug.²⁵⁰

As a developing country that previously failed to recognized patent protection on pharmaceutical products, India was entitled to take advantage of a ten-year transition period

²⁴⁸ Section 84(1).

²⁴⁹ N Zacharias *et al* 'Patents and the Indian Pharmaceutical Industry' (2002) *Business Briefing: Pharmatech* 42, 44 available at <http://www.nishithdesai.com/Research-Papers/Patents-and-the-Indian-Pharmaceutical-Industry-NZ%26SF.pdf>, accessed on 21 October 2012.

²⁵⁰ BK Baker 'India's 2005 Patent Act: Death by Patent or Universal Access to Second- and Future-Generation ARVs?' (2005) *Background Paper* available at http://www.healthgap.org/press_releases/05/091905_HGAP_BP_India_patent_baker.html, accessed 16 August 2012.

in which to implement the obligations to introduce pharmaceutical product patent protection (TRIPS Arts. 65.2, 65.4). It is submitted that whilst India made the amendments to its Patents Act in order to fulfil its TRIPS obligations, the amendments also included vigorous application of public health safeguards which potentially has the effect of restricting the patented market and maintaining a considerable avenue for generic competition.²⁵¹

A detailed overview of the 2005 amendments will follow:

(i) Inventions not patentable

One of the important concerns related to the introduction of product patent protection is the patenting of known substances. Many pharmaceutical companies exploit the law to seek patents on known substances, claiming slight modifications to the known substance as inventions. This practice is known as “evergreening” of patents whereby pharmaceutical companies file new patents over the process, method of administration, or dosage form rather than the main ingredient itself in an attempt to extend patent protection.²⁵² “Evergreening” is aimed to delay the entry into the market of generic medicines by obtaining as many patents on the known substance.²⁵³ Therefore, application of a strict patentability standard, which rejects patent protection for minor improvements on known substances is essential to guarantee early entry of generic medicines.²⁵⁴

As already explained (under 3.3.1), patents must be granted for inventions, which are “new, involve an inventive step and are capable of industrial application.” TRIPS does not provide a definition for these terms. There are two ways in which the scope of patentability can be limited: (1) to increase the threshold limit of patentability standards by providing a definition of patentability criteria and (2) to omit certain types of inventions, which do not satisfy any of the patentability standards.²⁵⁵ These measures would allow Member States some flexibility in determining their patentability standards.

²⁵¹ S Chaudhuri *et al* ‘Five Years into the Product Patent Regime: India’s Response’ (2010) *United Nations Development Programme* 1, 24.

²⁵² LL Lee ‘Trials and TRIPS-ulations: India Patent Law and Novartis AG v. Union of India’ (2008) 23 *Berkeley Technology Law Journal* 281, 285.

²⁵³ KM Gopakumar ‘Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime’ (2010) 3 *Law and Development Review* 325, 332.

²⁵⁴ *Ibid* 332.

²⁵⁵ *Ibid*.

The Indian Patents Act utilises both measures to limit patentability by enactment of section 3(d)²⁵⁶ in its amended patent legislation, which has the effect of restricting product patents. Section 3 excludes categories of inventions from patent protection because they are not deemed inventions within the definition of the term. Furthermore, this provision does not authorise the grant of patents for new uses, nor will patents be authorized for new formulations, combinations or chemical derivatives “unless they differ significantly in properties with regard to efficacy.”

An explanatory note supporting the above provision states that “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”²⁵⁷

This provision excludes new forms of a known substance, discovery of new property of a known substance, and new use of a known substance. Further, it treats “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance”²⁵⁸ as the same substance. Therefore, secondary patenting in any of the aforementioned forms is forbidden.

The use of the phrase “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy” has been incorporated into the Amendment Act to prevent frivolous claims being processed.

(ii) Immunity to ongoing generic production

The TRIPS Agreement gave India and some other countries an extension until January 2005 to grant pharmaceutical product patents. However, it was required to make provisions for receiving patent applications from the date of general application of the TRIPS Agreement.

²⁵⁶ Section 3(d) has been amended to read:

”the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant”.

²⁵⁷ Ibid.

²⁵⁸ Ibid.

This transitional provision is often called the 'mailbox'.²⁵⁹ Therefore the Act allows generic manufacturers to continue producing generic versions of new medicines which are in the mailbox.²⁶⁰ However, this is only applicable to generic producers who have made substantial investments, provided they were producing and marketing the generic version prior to 2005. Furthermore, generic companies are required to pay a reasonable royalty to the patent holder.

(iii) Pre-grant Opposition

The 1970 Patents Act contained strong pre-grant opposition mechanisms. It lists several grounds upon which a patent could be opposed including the lack of novelty, inventive step or utility; that the claimed invention does not fall within qualified subject matter; or the specification does not disclose the source.²⁶¹

The 2005 amendment has retained the ability of any interested person to oppose patent applications prior to its grant. There are 11 grounds listed in section 25(1) upon which "any person" can file opposition and seek recourse to challenging frivolous and legally dubious patents. The amendment also provides post-grant opposition within one year from the date of publication on the grant of patent. The grounds are similar to pre-grant opposition.

A competitor who fails to challenge a patent application at the pre-grant/post-grant stage has an extra opportunity in that he can seek revocation of the patent in terms of section 64 of the Act. Basheer submits that the amalgamation of a pre-grant opposition mechanism, a post-grant opposition mechanism and a revocation mechanism makes India's intellectual property system effective in curbing frivolous claims.²⁶²

(iv) Compulsory Licences

²⁵⁹ t'Hoen (note 12 above) 58.

²⁶⁰ Section 11 A(7) states:

Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises.

²⁶¹ S Basheer 'India's Tryst with TRIPS: The Patents Amendment Act, 2005' (2005) 1*The Indian Journal of Law and Technology* 15, 26.

²⁶² Ibid 26.

The 1970 Patent Act has been comprehensively amended in terms of the grant of compulsory licence to comply with the requirements of TRIPS. It is important to note that the efficient and successful authorisation of compulsory licences is necessary to restrain the abuse of patent rights by the patentee.

Section 84(1) of the 2005 Act states that after the expiry of three years from the date of grant of a patent, any interested person can make an application to the Controller to facilitate a compulsory license alleging that the reasonable requirements of the public with respect to the patented invention is not satisfied; the patented invention not available at a reasonable price to the public and the patented invention not being worked in India. Section 84(6) deals with matters that need to be taken into account in granting compulsory licenses, such as “the nature of the invention, the measures already taken by the patentee to make full use of the invention, the ability of the applicant to work the invention to public advantage, and the capacity of the applicant to undertake the risk in providing capital and working the invention if the application were granted...”

In order to incorporate the August 30th Decision, a new ground was introduced by the 2005 amendment to facilitate export to countries with insufficient manufacturing capabilities. Section 92A states that compulsory licences will “be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.”

The term ‘shall’ is significant as it indicates that compulsory licenses granted in terms of the August 30th Decision will be granted automatically without separate scrutiny or procedural requirements.²⁶³ The consequence of this provision is that since many developing countries do not have manufacturing capacities, Indian generic companies can supply these countries with essential medicines.

²⁶³ t’Hoen (note 12 above) 59.

(v) The Early Working Exception

The 2005 amended Act provides for an early working exception in section 107A(a) which legitimises “any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.”

Absent this exception, generic manufacturers would be forced to wait for the expiration of patents before facilitating tests required for regulatory approvals.²⁶⁴ This provision helps to encourage competition amongst Indian generic manufacturers, ensuring the availability of affordable medicines for domestic and international use.²⁶⁵

5.1.3 Novartis v AG and another v. Union of India and others²⁶⁶

The 2005 amendments of the Indian Patent Act became the centre of attention when Novartis’ patent application regarding the anticancer drug Glivec was rejected. The rejection was based on section 3(d) which prevents “ever-greening” by prohibiting the patenting of new forms of known substances that does not display increased “efficacy.” Novartis requested the Madras High Court to clarify this important provision in India’s 2005 patent legislation, contending that it infringed the TRIPS Agreement and violated the Indian Constitution.

5.1.3.1 Constitutional validity of section 3(d) upheld by Madras High Court (2007)

In 2006, Novartis AG challenged the constitutional validity of Section 3(d) of the amended Act. The primary contention in its challenge to the constitutional validity of section 3(d) was that the term “efficacy” was vague and ambiguous, therefore contravening the equality provision (Article 14) of the Indian Constitution.

²⁶⁴ P Ram ‘India’s New TRIPS Compliant Patent Regime Between Drug Patents and the Right to Health’ (2006) 5 *J. Intell. Prop.* 195, 204.

²⁶⁵ *Ibid.*

²⁶⁶ *Novartis AG and another v. Union of India and others*, W.P. Nos. 24759 and 24760 of 2006, High Court of Madras.

The Madras High Court declined to examine whether Section 3(d) violated requirements contained in the TRIPS Agreement and stated that the court lacked jurisdiction to decide upon the validity of the amended provision. The Court further held that section 3(d) was neither vague nor arbitrary and did not breach the Indian Constitution.

In terms of the meaning of the term “efficacy”, the court stated that “efficacy is independent of potency of the drug,” and went on to hold that “the Patent applicant should show that the substance so discovered has a better therapeutic effect.”²⁶⁷ With regards to efficacy and therapeutic effect, the court noted that what “the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body?”²⁶⁸ Therefore, the court held that the patent applicant has to demonstrate an improved therapeutic effect in order to obtain a patent for a new form of an existing substance or for its derivatives.

In coming to the last holding, the Court observed, “we have borne in mind the object of (Section 3(d)), namely ... to provide easy access to the citizens of this country to life saving drugs and to discharge the Constitutional obligation of providing good health care to its citizen.”²⁶⁹

5.1.3.2 Appeal on merits rejected on the ground of section 3(d) (2009)

After a series of litigation, Novartis’ appeal challenging the Patent Controller’s order was heard by the Intellectual Property Appellate Board (IPAB) in 2008. In its decision issued in 2009, the IPAB reversed the Patent Controller’s findings on novelty and inventive step and found that the invention was new and involved an inventive step. However, the IPAB held that Novartis’ alleged invention did not meet the standard required by section 3(d). In addition, Novartis was not able to prove that the invention demonstrated significantly improved therapeutic efficacy over the existing substance.²⁷⁰

²⁶⁷ Ibid para 13.

²⁶⁸ Ibid.

²⁶⁹ Ibid para 19.

²⁷⁰ Lawyers Collectively ‘Novartis Case: Background and Update- Supreme Court of India to Recommence Hearing’ (6 September 2012) available at <http://www.lawyerscollective.org/news/archived-news-a-articles/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html>, accessed on 21 October 2012.

The IPAB rejected Novartis' appeal and declined to grant it a patent for Glivec.²⁷¹

5.1.3.3 Proceedings before the Supreme Court (2011)

Challenging the IPAB's order, Novartis came before the Indian Supreme Court contesting the IPAB's analysis and application of section 3(d) to its patent application.

Novartis' main argument is that section 3(d) that relates to "discoveries" is does not apply to its patent application which, having fulfilled the criteria of novelty, inventive step and industrial application, is an "invention" in terms of Indian patent law. Counsel argued that upon establishing that Glivec was an "invention", section 3(d) could not have been applied by the IPAB to reject Novartis' patent application. It was argued that the IPAB's holding indicated a complete non-application of mind.²⁷²

Disputing the IPAB's holding that the term "efficacy" in section 3(d) means therapeutic efficacy, it was argued that the IPAB erroneously relied on the Madras High Court's interpretation of the term "efficacy". Restating Novartis' pleadings before the IPAB on the interpretation of the term "efficacy", it was contended that enhanced bioavailability and thermodynamic stability are properties that improved efficacy and that the beta-crystalline form of imatinibmesylate displayed both these properties.²⁷³

It was further contended that once a patent application satisfies the requirements of novelty, inventive step and industrial application, section 3(d) could not be interpreted or applied in a manner to destroy the primary purpose of patent law. Therefore using section 3(d) to disallow patents for inventions would sound the death knell for patents and affect research and development for the entire sector.²⁷⁴

This matter is proceeding.

²⁷¹ Ibid.

²⁷² The Indian Express: Journalism of Courage 'Novartis argues for Glivec Patent at Supreme Court' (12 September 2012) available at <http://www.indianexpress.com/news/novartis-argues-for-glivec-patent-at-supreme-court/1001329/2>, accessed on 20 October 2012.

²⁷³ Ibid.

²⁷⁴ Ibid.

CHAPTER VI: ATTEMPT TO TRIP “TRIPS” BY OTHER JURISDICTIONS

6.1 Thailand

6.1.1 Thailand’s Patent Laws

Since 1975, the US pharmaceutical industry has maintained that the absence of product patent protection has acted as an obstacle to market entry in Thailand. The US government has placed trade pressure on the Thai government to implement stronger patent protection, through trade sanctions, “representing US\$165 million in lost export revenue for Thailand.”²⁷⁵ As a result of such pressure, Thailand introduced measures which emphasized the interests of the pharmaceutical industry at the expense of the rights of patients, with minimal advantage to the national industry in respect of technology transfer and foreign investment.²⁷⁶

In 1992, Thailand enacted the Thai Patent Act which created a legal framework for intellectual property protection, including pharmaceutical products. This Act introduced pharmaceutical product patents and extended patent life from 15 to 20 years. It permitted patent protection for drugs for the first time in Thailand but provided liberal opportunities for compulsory licensing and parallel importing to soften the impact of patent protection on drug prices.²⁷⁷ The Thai Patent Act was further amended in 1999 to comply with the TRIPS Agreement.

6.1.2 Compulsory Licenses:

The 1999 amendments reintroduced compulsory licences into the patent system. Section 46(2) states that compulsory licenses can be granted on a product after 3 years “from the grant of a patent or 4 years from the date of application, whichever is later,” where there are no patented products for sale in the domestic market, where they are sold “at unreasonably high prices or does not meet the public demand without any legitimate reason.”

²⁷⁵ N Ford *et al* ‘The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand’ (2004) 363 *The Lancet* 560, 560.

²⁷⁶ *Ibid* 560.

²⁷⁷ R Sweeney ‘The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision’ (2000) 9 *Pac. Rim L. & Pol’y J.* 445, 449.

It also eliminated the Director-General's authority to issue a public invitation for compulsory license applications.²⁷⁸ The 1999 amendments also removed the powers of the Patents Board, which was empowered to require the disclosure of the production costs of medicines.²⁷⁹ The absence of the Patents Board made it difficult to ascertain whether drug prices were reasonable, “a determination that justifies the issuance of a compulsory license.”²⁸⁰

Section 51 of the 1999 Act provides that any ministry, bureau or department of the government may exercise the compulsory-licensing right in order “to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realisation of natural resources or the environment or to prevent or relieve a severe shortage of food, drug... or any other public service.” The objectives of this provision are aimed at non-commercial purposes and public interest i.e. the public health service.²⁸¹

6.1.3 Government Use Licences in Thailand

In 2006, the Thai government issued government use order for a select number of drugs such as efavirenz, which is an essential ARV. These orders were based on Thai government use provisions. In 2007 Thailand issued such orders for a number of pharmaceutical products such as Ritonavir+Lopinavir (ARVs) and Clopidogrel (heart disease medicine). This decision resulted in widespread protests from multinational pharmaceutical companies. In 2008, the Thai Government issued additional orders for Docetaxel, Letrozole and Imatinib.

In 2007, the Thailand government decided to issue a compulsory license on an essential ARV called Kaletra (manufactured by Abbott). This decision resulted in a lobbying attack by Abbott, “a large number of pharmaceutical industry supported groups, industry-funded consultants and experts.”²⁸² Accordingly, an Abbot representative stated that since the Thai government “decided not to support innovation by breaking the patents, Abbott will not

²⁷⁸ Ibid 452.

²⁷⁹ Ibid.

²⁸⁰ Ibid.

²⁸¹ UNDP ‘The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health’ (2011) *Discussion Paper* 1, 25.

²⁸² Love J ‘Abbott Sought Compulsory License While Criticising Thai License’ (2007) TWN Info Service on Intellectual Property Issues (May07/03) available at http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.050703.htm, accessed on 15 November 2012.

submit applications or register new medicines and will withdraw current applications in Thailand until the government changes its position."²⁸³

Abbott has kept its promise and has withdrawn the registration applications for the new form of Kaletra, and six other medicines that it had provided for marketing approval.²⁸⁴ Abbott submitted that it would not register its new products unless Thailand agreed to not issue further compulsory licenses.²⁸⁵

It is submitted that Abbott's conduct of refusing to provide Kaletra and six other medicines undermines the steps taken by the Thai government to ensure access to essential medicines. Abbott's conduct can be construed as placing a greater emphasis on making profits than on protecting the health of citizens. If Abbott's threats are left unchallenged, the consequent result is that the grant of future compulsory licenses by developing countries will be threatened, impeding access to essential medicines.

6.1.4 Bristol-Myers Squibb taken to court

In 2001, the AIDS Access Foundation and two HIV positive patients filed a lawsuit against Bristol-Myers Squibb (BMS). In 1992, BMS licensed the rights to didanosine (ddl) from the US Government.²⁸⁶ BMS then filed a derivative patent application in Thailand for the purpose of protecting a particular dosage formulation. In this patent application, the invention was restricted to a specified dosage range of 5mg to 100mg per dosage unit.²⁸⁷ Thereafter, BMS amended its patent application to remove the limitation in the dosage range, which was subsequently granted by the Thai Patent office.²⁸⁸

This unlimited patent prevented generic companies from developing any form of ddl. After a campaign to try to encourage the government to authorise a compulsory licence, ddl was

²⁸³ Ibid.

²⁸⁴ BK Baker 'Standing Up To Abbott's Decision to Withhold Registration and Marketing of Life-Saving Medicines - A New Variant of Pharmaceutical Apartheid' (2007) available at <http://www.twinside.org.sg/title2/health.info/twninfohealth080.htm>, accessed on 12 November 2012.

²⁸⁵ Love (note 282 above).

²⁸⁶ MSF Access Campaign 'Revoking An Invalid Patent: The Case of Didanosine in Thailand' available at http://patentoppositions.org/case_studies/500e9b8c7718ea0002000018, accessed on 21 October 2012.

²⁸⁷ Ibid.

²⁸⁸ Ibid.

manufactured in a powder form instead (which had an unpleasant taste and side effects).²⁸⁹ As a result, civil society decided to dispute the grant of the patent itself. The Plaintiffs demanded that BMS adjust their patent claim back to the restricted dosage range originally asked for.²⁹⁰

One of the main questions before the court was whether individuals have the right to challenge a patent. In giving judgment, the court held that “medicine is one of the fundamental factors necessary for human beings, as distinct from other products or other inventions that consumers may or may not choose for consumption” and that “lack of access to medicines due to high price prejudices the human rights of patients to proper medical treatment”.²⁹¹ In coming to this conclusion, the Thai court explicitly referred to the Doha Declaration on TRIPS and Public Health.

6.1.5 Exceptions to patent rights

Section 36 of the 1999 Act provides for a number of exceptions, these include:

- Research exception: “any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner;
- Parallel Importation: “the use, sale, having in possession for sale, offering for sale or importation of a patented product when it has been produced or sold with the authorisation or consent of the patentee.”
- Early Working Exception: “any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term.”

The mention of “importation” in this provision constitutes an application of the international exhaustion of rights principle, which is not prohibited by the TRIPS.

²⁸⁹ Ibid.

²⁹⁰ Ibid.

²⁹¹ Ibid.

6.1.6 Opposition

Section 31 of the 1999 Act states that any person who may lodge an opposition to the application at stake within 90 days from the date of publication of the application. Where an opposition has been initiated and has succeeded, the new applicant shall file the request for examination either within five years after publication, as in the normal case, or within one year after the final decision concerning the opposition has been reached, depending on which period expires last (section 29).

6.1.7 Revocation

According to section 54 of the 1999 Act, the invalidity of a patent may be challenged by any person. It further states that a petition to cancel an invalid patent may be submitted to the Court or the public prosecutor by any interested party.

6.2 Brazil

Before 1994, Brazilian patent legislation did not acknowledge or implement patents on pharmaceuticals, thus upon acceptance of the TRIPS Agreement, Brazil began to amend its patent laws so that it would fulfil its international obligations. Brazil did not make use of the 10-year transition period granted under the TRIPS Agreement to recognize patents in the field of medicines. This transition period was offered to developing countries that did not recognize pharmaceutical patents previously.²⁹² Chaves submits that the Brazilian legislation failed to adopt certain flexibilities allowed under TRIPS and, in some areas, went further than what was expected under the Agreement.²⁹³

The Industrial Property Law was promulgated in 1996, which authorised patent protection for medicines developed after that time as long as the manufacturer conducts some part of the medicines production in Brazil.²⁹⁴ Lazzarini notes that this "local working" requirement

²⁹² GC Chaves *et al* 'Access to Medicines and Intellectual Property in Brazil: reflections and strategies of civil society' (2008) *Human Rights University Network* 163, 167.

²⁹³ *Ibid* 167.

²⁹⁴ Article 68.

excludes drugs in existence prior to 1994 from patent protection, enabling the government to license generic local production of essential medications.²⁹⁵

Compulsory licensing has been incorporated into Brazilian legislation in Article 68 which stipulates that a patent shall be subject to compulsory licensing if its owner exercises the patent right in an abusive manner or exploits economic power. Further, it may be granted when the patented product is not exploited inside Brazil or when the sale of the protected product fails to meet the needs of the market (the “failure to work” requirement). Compulsory licenses may also be issued in cases of dependent patents, under the terms provided for in Article 70. Article 71 states that a compulsory license may be issued in cases of national emergency or public interest declared by the Federal Executive Authorities.

The early working exception is significant as it promotes quicker entry of generic medicines into the market and enables information on the invention to be used for research.²⁹⁶ This flexibility is contained in Article 43. According to Article 68, parallel imports can be utilised in a limited way- its use is restricted to situations in which a compulsory license has been issued in virtue of abuse of economic power or in cases of national emergency and public interest.

Given the importance of pharmaceutical products, Brazilian lawmakers considered the grant of patents important enough for each individual case to warrant the most rigorous and technical examination possible by the State. Therefore prior consent by ANVISA (Brazilian Health Regulatory Agency) is required before a patent can be granted.²⁹⁷ The rationale is essentially, patent protection should pursue a stricter standard ensuring genuine innovations and preventing “monopolistic practices on products that are already known, hindering access by delaying the entry of generic drugs on the market.”²⁹⁸

In 1999, the President of Brazil issued a decree regarding principles regulating compulsory licensing using an additional provision in the 1996 Act which allows the grant of compulsory

²⁹⁵ Z Lazzarini ‘Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil’ (2003) 6 *Yale Hum. Rts. & Dev. L.J.* 103, 129.

²⁹⁶ Chaves (note 292 above) 169.

²⁹⁷ *Ibid* 170.

²⁹⁸ Working Group of Intellectual Property ‘Private interests and the connivance of the State: the case of pharmaceutical patents and ANVISA’s role’ (2011) 1, 1 available at http://patentes.org.br/media/file/nota%20anuencia%20ingles_ing_jan11.pdf, accessed on 24 October 2012.

licensing in the event of national emergency, including situations where there is an imminent public health crisis.²⁹⁹

In Brazil, the threat of compulsory licenses was a significant strategy employed to pressure drug companies in price negotiations for essential medications.³⁰⁰ For example, in 2001 the Brazilian Health Minister proclaimed that the government would issue a compulsory license for the production of the ARV nelfinavir, to a Brazilian pharmaceutical producer.³⁰¹ On August 28, the Brazilian Health Minister and Roche resumed talks and reached an agreement whereby the drug would be sold at an additional 40% discount and that Brazil will not issue the license.³⁰² In 2007 Brazil granted its first compulsory license to import efavirenz, a patented medicine in Brazil.³⁰³

6.3 Lessons that can be learnt from India, Thailand and Brazil:

6.3.1 India:

India's patent legislation has set an excellent example of the creative manner in which the TRIPS Agreement can be implemented in domestic systems. It has adopted into their national legislation many of the flexibilities allowed under the TRIPS to protect medicine access. South Africa has failed to follow suit. It is submitted that the introduction of section 3(d) has created stricter criteria for obtaining product patents, resulting in fewer patent monopolies being created and creating more space for generic competition to enter the market.

South Africa can learn from India's example by rejecting new use and new formulation patents, as currently being employed in section 3(d) of India's patent laws. Currently South Africa's patent legislation does not exclude new uses and new patents from patentability; this

²⁹⁹ Lazzarini (note 295 above) 130.

³⁰⁰ R Reis *et al* 'Access to Medicines and Intellectual Property in Brazil: A Civil Society Experience' (2009) *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South* 1, 29.

³⁰¹ JP Love 'Recent Examples of the Use of Compulsory Licenses on Patents' (2007) *KEI Research Note* 2 1, 15 available at http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf, accessed on 24 October 2012.

³⁰² Ibid.

³⁰³ A Nunn *et al* 'AIDS Treatment in Brazil: Impacts And Challenges Brazil's accomplishments in treating AIDS are unprecedented and have profoundly influenced global AIDS and health policy' (2009) 28 *Health Affairs* 1103, 1105.

may result in many patent applications being granted and has a direct impact on the cost of essential medicines in South Africa, whereas in India affordable generics are available.

South Africa should also follow India's lead with regards to procedures relating to opposition by third parties. The Indian experience has shown us that opposition to the grant of patent applications especially secondary patent applications can help curb the number of such applications being granted. A prime of example of this is the Novartis case. Should Novartis win in the matter; the consequent result would be patents being granted for minor changes to patented inventions, therefore blocking the competition among multiple generic producers. It would also allow other pharmaceutical companies have pending patent applications to easily pursue patents on new forms of these medicines.

India's patent law allows for interested persons to apply for a compulsory license, which may be granted if the patented invention is not available to the public at a reasonable price. The 2005 amendment Act also provides that compulsory licenses for manufacture and export are allowed for countries without sufficient manufacturing capacity. South Africa allows for compulsory licenses to be granted to prevent the abuse of a patent but does not explicitly allow them as a way of protecting public health. In addition, South Africa's Patents Act does not clearly permit compulsory licenses for export.

6.3.2 Thailand:

Thailand has been exemplary with regards to compulsory licensing. Lessons that can be learnt from Thailand's experience in compulsory licensing include: "middle-income countries are unable to pay the high prices of multinational pharmaceutical companies; compulsory licensing has brought treatment with newer ARVs within reach in Thailand, but has resulted in pressure from industry and the US government; and an informed and engaged civil society is essential to support governments in putting health before trade relations."

6.3.3 Brazil:

In South Africa, the patent office does not examine the merits of each patent application. As a consequence, patents are granted for inventions even though they do not amount to a real innovation. The South African Patents Act needs to follow the measures taken by Brazil, to

compel the Patent Office to carry out full, rigorous and thorough reviews of all patent applications relating to medicines. In addition, the requirement of prior consent by the Brazilian health authority before a patent application is granted has played an important role in ensuring that a stricter patent standard is maintained and that truly genuine inventions are patented.

CHAPTER VII: RECOMMENDATIONS AND CONCLUSION

The TRIPS Agreement sets international standards of intellectual property protection that Member States are required to uphold in their domestic legislation. It obliges Member States to provide patent protection on pharmaceuticals and all other products for a minimum term of 20 years. During this period the patent holder is granted a monopoly and exclusive rights to market the medicine. Given that pharmaceutical companies face no competition during the patent period, they often charge extremely high prices in order to maximize profits.

Given the fact that most developing countries were afraid that the introduction of patents on essential medicines through the TRIPS Agreement would increase prices of essential medicines making them less affordable, the Doha Declaration on the TRIPS Agreement and Public Health was concluded in 2001. The Doha Declaration is significant because it affirmed each government's right to implement measures to protect public health and that the TRIPS agreement "should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicine for all."

It is submitted that South Africa has not fully utilised the public health flexibilities contained in the TRIPS agreement in its intellectual property legislation. For example, under the South African Patents Act, the patentability criterion is weaker as it grants patents for so-called "new use" and "new formulation" of existing medicines. By allowing new patents to be granted on existing medicines, pharmaceutical companies are given a monopoly ensuring that they have market exclusivity beyond the 20 years required under TRIPS. In addition, South Africa's does not implement a patent examination system, this results in patents being granted as long as administrative requirements are met. The Act also makes provision for the grant of compulsory licenses which has never been utilised. Furthermore, in light of the subsequent Doha Declaration which elevated public health over intellectual property rights, South Africa has failed to take steps to realise these flexibilities in its legislation.

One of the most significant factors affecting access to essential medicines is that of cost. The consequences of weak patentability criteria and a non-examining patent system (amongst others things) is the subsequent ease of patent applications being granted. The likely effect thereto is that drug prices will dramatically increase because generic production will be halted. Therefore, amending our intellectual property laws to incorporate public health

safeguards and adopting stronger patent examination mechanisms which allow patents to be granted for truly genuine innovations, will not only reduce the cost of essential medicines but will increase access to these medicines overall.

The following amendments should be made to the South African Patent Act 1978, whilst still complying with the TRIPS Agreement:

7.1 Standards of patentability

In terms of the patentability criteria under the TRIPS Agreement, South Africa has the flexibility to determine its own criteria for assessing patentability, therefore it has the freedom to set stricter standards for patentability than it does at the moment (as in the case of India). Adopting stricter criteria would have a direct influence on the number of patent applications currently being granted.

In terms of the practice of “evergreening”, pharmaceutical companies are ever ready to file patent applications for slight modifications to known substances thereby extending the term of patent protection to another 20 years. India has been exemplary in combating this practice by introducing section 3(d) of the 2005 Indian Patent Amendment Act, which excludes new forms, new uses and new formulations of existing medicines that do not enhance therapeutic efficacy from patentability.

It is submitted that South Africa should include a provision, similar to that of India’s, explicitly prohibiting new forms, new uses and new formulations of already existing medicines from patentability.

7.2 Patent examination

Kaplan submits that the lack of proper search and examination prior to the grant of a patent results in the absence of an assurance that the patent is in fact valid.³⁰⁴ The absence of a patent examination system and the consequent ease of acquiring patents results in companies

³⁰⁴ Kaplan (note 167 above) 3.

filing a large numbers of patents on a local scale.³⁰⁵ A further consequence of a weak examination system is the granting of patents with a broad scope.³⁰⁶ As a result of not having an examination system, Vawda submits that this results in a large number of ‘weak’ patents being granted and “closes the opportunity for pre- and post-grant opposition proceedings.”³⁰⁷

7.3 Compulsory licenses

As mentioned earlier in this dissertation, compulsory licenses are an important flexibility which does not only curtail patent monopolies but also facilitates access generic medicines. The use of compulsory licenses has been clarified in the Doha Declaration, which affirmed each Member’s right to issue compulsory licenses and the freedom to determine the grounds upon which such licenses are to be granted.

The Patents Act makes provision for compulsory licenses which are limited to two grounds in the case of dependant patents (section 55) and four grounds in terms of abuse of patents (section 56). It is therefore submitted that the Patents Act should create more grounds upon which compulsory licenses can be granted, for example a provision relating to the inaccessibility of essential medicines because of cost implications, public health, nutrition, emergency etc.

It is important to note that the South African has not been pro-active in issuing any compulsory licenses thus far.

7.4 Prior Consent by Health Authorities

As noted earlier, Brazil’s patent laws require that pharmaceutical patent applications are reviewed by a health regulatory agency to ensure that they do not unduly impact on the country’s ability to achieve the right to health. This ensures a higher and stricter standard of patentability which has decreased the number of pharmaceutical patents being granted annually.

³⁰⁵ Ibid 3.

³⁰⁶ Ibid 3.

³⁰⁷ Vawda (note 31 above) 27.

It is therefore submitted that the Act must be amended to make provision for a rigorous examination of patent applications. A proper examination system will ensure that frivolous patents are not granted, thereby reducing the number of patents granted. In addition, provision should be made for prior consent by the Department of Health.

7.5 Pre and post grant opposition

The Patents Act does not make provisions for pre- or post-grant opposition of patents by any members of the public. The only way to challenge a patent is through court procedures. As noted above, India makes provision for both pre- and post- grant opposition. Accordingly, “any person” can oppose a patent while the application is pending, for a period of one year after it is granted. It is submitted that South Africa should amend its Patents Act to allow for both pre- and post-grant opposition procedures.

7.6 Voluntary Licenses

Although South Africa has not issued a compulsory license for patented medicines, there has been a trend towards voluntary licenses and use of competition laws and policies to control high prices of medicines.³⁰⁸ The issue surrounding voluntary licenses is that requests can “easily be rejected by patent-holding companies.”³⁰⁹ Thus, government should not place over reliance on this mechanism and use it as an excuse not to issue compulsory licenses.

In the light of the aforementioned deficiencies in our patent law, it is submitted that various legislative amendments need to be made to make essential medicines more affordable to those who need it the most. This dissertation has looked closely at the manner in which India has creatively utilized TRIPS provisions to not only strengthen intellectual property laws but also keep medicines affordable. As discussed earlier, India has adopted many of the flexibilities allowed under the TRIPS into their national legislation to protect access to medicine. The flexibilities used by India include using the extension period prior to 2005, granting compulsory licenses, patent opposition mechanisms and rejecting patents on new

³⁰⁸ O Sibanda ‘Parallel importation and compulsory licensing in Kenya and South Africa as measures to access HIV/AIDS medicine’ (2009) 41 *Acta Academia* 184, 197 available at www.ajol.info/index.php/pelj/article/view/81300/71485, accessed on 24 October 2012.

³⁰⁹ *Ibid.*

formulations of existing medicines. South Africa has not taken effective steps to follow suit. Partly as a result of this, medicines in India are much more affordable than in South Africa.

In conclusion, it is submitted that South Africa's intellectual property legislation has failed to support the government's constitutional commitment to realise the right to health. Section 27 of our Constitution obliges the State to take reasonable legislative and other measures to progressively achieve the right of access to health care services.

It is further submitted that the South African legislative framework has not been effective in making access to essential medicines more affordable. Although South Africa has signed the TRIPS Agreement, it has not taken advantage of the significant number of flexibilities contained in the Agreement. By amending its patent legislation to include these flexibilities, South Africa would ensure that stricter patentability standards are met, which would result in the grant of patents on inventions that are truly innovative. The consequent result of fewer patents being granted is that it would allow greater generic versions of medicines to enter the local market. This will have a direct impact on the prices of essential medicines, allowing for affordable prices.

In essence, South Africa should implement the following flexibilities into its legislation:

- Employing a stricter patentability standard will have a direct influence on the number of patent applications being granted. In addition, its patent legislation should be amended to exclude new forms, new uses and new formulations of existing medicines that do not enhance therapeutic efficacy from patentability.
- The Patents Act should make provision for a rigorous patent application examination system which will ensure that all pharmaceutical patent applications are properly examined. This will have the effect of curbing the large number of weak patents being granted.
- It should create more grounds upon which compulsory licenses can be granted, for example a provision relating to the inaccessibility of essential medicines because of cost, implications, public health, nutrition, emergency etc. It is further submitted that the South African government needs to become more proactive with regards to the issuance of compulsory licenses.

- Legislative provision should also be made for the inclusion of prior consent by the Department of Health. This will ensure that frivolous patents not granted, thereby reducing the number of patents being granted.
- The Patents Act should be amended to make provision for both pre- and post-grant opposition. This should also include disclosure requirements to allow third parties to review patents that are pending or granted.

It is submitted that the Novartis case is illustrative of the pro-active stance the Indian judiciary has taken when dealing with issues pertaining to intellectual property and access to medicines. It is important to note that if Novartis is successful, it will have disastrous consequences on the Indian generic industry. It may also set a negative standard for other countries when determining the patentability criteria that it should adopt and attempting to strike a balance between public health and intellectual property protection.

Given the significant health needs of the country, the South African government should amend its patent legislation to take full advantage of the flexibilities contained in the TRIPS Agreement, including those contained in the Doha Declaration, to safeguard public health.

REFERENCES

BOOKS

1. Brand D 'Introduction to Socio-economic Rights in the South African Constitution' D Brand and C Heyns (2005) 1,132.
2. CESCR General Comment No 3 The Nature of States Parties' Obligations (art 2(1) of the ICESCR) (5th session, 14 December 1990) available at <http://www.unhcr.org/refworld/pdfid/4538838e10.pdf>, accessed on 3 August 2012.
3. International Covenant on Economic, Social and Cultural Rights, 16 December 1966, 999 UNTS 3, 3 January 1976.
4. Jackson E 'Funding and Access to Medicines: A Global Problem' in E Jackson *Law and the Regulation of Medicines* (2012), 189, 193.
5. Klopper H et al *Law of Intellectual Property in South Africa* (2011).
6. Ramsden P 'A Guide to Intellectual Property Law' (2011).
7. The Right to the Highest Attainable Standard of Health, General Comment No. 14, U.N. CESCR, 22nd Sess. Agenda item 3, E/C.12/2000/4 (2000) paragraph 12 available at [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument), accessed on 23 July 2012.
8. World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of the General Council of 30 August 2003, Sept. 1, 2003, WT/L/540 available at www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm, accessed on 5 May 2012.

CASE LAW

1. Ensign-Bickford (South Africa) (Pty) Limited and Others v AECI Explosives and Chemicals Limited 1998 BIP 271 (SCA).
2. Government of the Republic of South Africa v Grootboom 2001 (1) SA 46 (CC); Minister of Health v Treatment Action Campaign No 2 2002 (5) SA 721 (CC).- Constitution of the Republic of South Africa, 1996 (1996 Constitution).

3. Mölnlycke AB and Another vs Procter & Gamble Limited and Others (No.5) (1994) RPC 49 (CA).
4. Notice of Motion filed in the PMA Case available at <http://www.cptech.org/ip/health/sa/pharmasuit.html>, accessed on 5 July 2012.
5. Novartis AG and another v. Union of India and others, W.P. Nos. 24759 and 24760 of 2006, High Court of Madras.
6. Residents of Bon Vista Mansions v Southern Metropolitan Local Council 2002 (6) BCLR 625 (W).
7. Speedmark Holdings (Pty) Ltd v Roman Roller CC and Another 1993 BP 397 at 408G–409B.
8. Syntheta (Pty) Ltd previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutical NV and another [1998] JOL 3793 (A).
9. The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa and Others. Unreported case no: 4183/98, High Court of South Africa (Transvaal Provincial Division) March 2001.

STATUTES

1. Competition Act 98 of 1998.
2. Indian Patent (Amendment Act) 2005.
3. Indian Patent Act 1970.
4. Medicines and Related Substances Control Act 101 of 1965.
5. South African Patents Act 57 of 1978.
6. Thai Patent (Amendment Act) 1999.
7. Thai Patent Act 1992.

ARTICLES

1. Abbott FM 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 The American Journal of International Law 317.
2. Abbott FM and CM Correa 'World Trade Organization Accession Agreements: Intellectual Property Issues' (2007) Global Economic Issues Publication 1, 6 available

at: http://frederickabbott.com/uploads/Abbott___Correa_Accession_WTO-IP-English.pdf, accessed 25 August 2012.

3. Adelman MJ 'Patent Law in India' (1996) 1 Int'l Intell. Prop. L. & Pol'y 131.
4. Adelman MJ and S Baldia 'Prospects and Limits of the Patent Provision in the TRIPS Agreement: the Case of India' (1996) 29 Vand. J. Transnat'l L. 507.
5. Anderson AJ "Global Pharmaceutical Patent Law in Developing Countries- Amending TRIPS to Promote Access for All" (2006).
6. Avafia T et al 'The Ability of Select Sub-Saharan African countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries' (2006) International Centre for Trade and Sustainable Development.
7. Baker BK 'Standing Up To Abbott's Decision to Withhold Registration and Marketing of
8. Basheer S 'India's Tryst with TRIPS: The Patents Amendment Act, 2005' (2005) 1 The Indian Journal of Law and Technology 15.
9. Berger J 'Advancing Public Health by Other Means: Using Competition Policy to Increase Access to Essential Medicines' (2004) ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio.
10. Bombach KM 'Can South Africa Fight AIDS? Reconciling the Medicines and Related Substances Act with the TRIPS Agreement?' (2001) 19 *B.U. Int'l L.J* 273, 278.
11. Chaudhuri S et al 'Five Years into the Product Patent Regime: India's Response' (2010) United Nations Development Programme.
12. Chenwi L 'Monitoring the progressive realisation of socio-economic rights: Lessons from the United Nations Committee on Economic, Social and Cultural Rights and the South African Constitutional Court' (2010) Research paper written for Studies in Poverty and Inequality Institute.
13. Chenwi L and R Hardowar 'Promoting Socio-Economic Rights in South Africa through the Ratification and Implementation of the ICESCR and its Optional Protocol' (2010) 11 ESR Review.
14. Chirwa DM 'The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicine' (2003) 19 SAJHR 541.

15. Correa CM 'Integrating Public Health Concerns into Patent Legislation in Developing Countries' (2000) The South Centre.
16. Correa CM 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' 2011 South Centre Research Paper 41.
17. Correa CM 'Pharmaceutical Inventions: When is the granting of a patent justified?' (2006) 1 Int. J. Intellectual Property Management.
18. Correa CM and A Yusuf 'Intellectual Property and International Trade: the TRIPS Agreement' (2008) The Netherlands Kluwer Law International 230.
19. Flynn SM 'Using Competition Law to Promote Access to Medicines' (2008) Programme on Information Justice and Intellectual Property.
20. Ford N et al 'The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand' (2004) 363 The Lancet 560.
21. Forman L 'Ensuring Reasonable Health: Health Rights, the Judiciary, and South African HIV/AIDS Policy' (2005) Journal of Law, Medicine & Ethics 711.
22. Gopakumar KM 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 Law and Development Review 325.
23. Gupta A 'Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?' (2003-2004) 2 Buff. Intell.Pro. L.J. 127.
24. Hason AK and JE Shimotake 'Recent Developments in Patent Rights for Pharmaceuticals in China and India' (2006) 18 Pace Int'l L. Rev.
25. Hestermeyer HP 'Access to Medication as a Human Right' (2004) Max Plank UNYB.
26. Lazzarini Z 'Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil' (2003) 6 Yale Hum. Rts. & Dev. L.J. 103, 129.
27. Lee LL 'Trials and TRIPS-ulations: India Patent Law and Novartis AG v. Union of India' (2008) 23 Berkeley Technology Law Journal 281, 285.
28. Life-Saving Medicines - A New Variant of Pharmaceutical Apartheid' (2007) available at <http://www.twinside.org.sg/title2/health.info/twninfohealth080.htm>, accessed on 12 November 2012.
29. Lumina C 'Free Trade or Just Trade? The World Trade Organization, Human Rights and Development (Part 2)' (2010) 14 Law, Democracy and Development.
30. Muriu DW 'Third World Resistance to International Economic and Structural Constraints: Assessing the Utility of the Right to Health in the Context of the TRIPS Agreement' (2009) 11 International Community Law Review 409.

31. Nagan WP 'International Intellectual Property, Access to Healthcare, and Human Rights: South Africa v United States' (2001-2002) 14Fla. J. Int'l L. 155, 162.
32. Pechacek JT 'The Past, Present, and Future of South Africa's Patent System' (2012) 3 Intellectual Property Law Review 188.
33. Pesses E 'Patent and Contribution: Bringing the Quid Pro Quo into eBay v. MercExchange' (2009) 10 Student Scholarship Papers Paper 96 321.
34. Ram P 'India's New TRIPS Compliant Patent Regime Between Drug Patents and the Right to Health' (2006) 5 J. Intell. Prop. 195, 204.
35. Snyder DB 'South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?' (1999-2000) 18 Dick. J. Int'l L.175, 184.
36. Sweeney R 'The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision' (2000) 9 Pac. Rim L. & Pol'y J. 445.
37. Vawda YA 'Tripped Up on TRIPS: The Story of Shrinking Access to Drugs in Developing Countries' (2002) 13 Stellenbosch L. Rev. 325.
38. Walker MB 'Accessing the Barriers to Universal Antiretroviral Treatment Access for HIV/AIDS In South Africa' (2004-2005) 15 Duke J .Comp. & Int'l L193.
39. Wibulpolprasert S et al 'Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership' (2011) 7 Globalisation and Health 1, 1.
40. Yamin AE 'Not Just a Tragedy: Access to Medications as a Right Under International Law' (2003) 21 B.U. Int'l LJ 325.

INTERNET SOURCES

1. Adukia SR 'Handbook on Intellectual Property Rights in India' (2012) 11 available at www.caaa.in/Image/34_Hb_on_IPR.pdf, accessed on 24 October 2012.
2. Baker BK 'India's 2005 Patent Act: Death by Patent or Universal Access to Second- and Future-Generation ARVs?' (2005) Background Paper available at http://www.healthgap.org/press_releases/05/091905_HGAP_BP_India_patent_baker.html, accessed 16 August 2012.

3. Balasubramaniam K 'Access to Essential Medicines as a Human Right' (2011) *Politics of Medicine* available at <http://www.politicsofmedicines.org/articles/access-to-essential-medicines-as-a-human-right>, accessed on 3 August 2012.
4. Cameron E 'Patents and Public Health: Principle, Politics and Paradox' (2004) 1SCRIPT-ed.
5. Chaves GC et al 'Access to Medicines and Intellectual Property in Brazil: reflections and strategies of civil society' (2008) *Human Rights University Network* 163.
6. Cullet P 'Patents and Medicines: the relationship between TRIPS and the human right to health' (2003) 79 *International Affairs*.
7. Daniels L 'Health Advocates Eye Proposed changes to Patent Law in South Africa' available at <http://www.fixthepatentlaws.org/?p=383#more-383>, accessed on 30 August 2012.
8. Daya Y and N Vink 'Protecting Traditional Ethno-Botanical Knowledge in South Africa through the Intellectual Property Regime' (2006) 45 *Agrekon* 319.
9. Forman L "'Rights" and wrongs: What utility for the right to health in reforming trade rules on medicines?' (2008) 10 *Health and Human Rights* 2, 45 available at <http://www.hhrjournal.org/index.php/hhr/article/view/80/165>, accessed on 25 on June 2012.
10. Grabowski H 'Patents and New Product Development in the Pharmaceutical and Biotechnology Industries' (2002) 1, 4 available at <http://www.dklevine.com/archive/grabow-patents.pdf>, accessed on 14 October 2012.
11. Grover A *et al* 'Pharmaceutical companies and global lack of access to medicines: strengthening accountability under the right to health' (2012) *Journal of Law, Medicine & Ethics* available at <http://business.highbeam.com/6391/article-1G1-298171392/pharmaceutical-companies-and-global-lack-access-medicines>, accessed on 28 September 2012.
12. Hawkins L 'Competition Policy' *Politics of Medicine* available at <http://www.politicsofmedicines.org/articles/competition-policy>, accessed on 20 October 2012.
13. Heywood M 'Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation' (2001) *AIDS Law Project* available at www.tac.org.za/.../MedicineActCourtCase/Debunking_Conglomo.rtf, accessed on 17 September 2012.

14. Hogerzeil HV et al 'Access to Essential Medicines as part of the Fulfilment of the Right to Health: Is it Enforceable Through the Courts?' (2006), 305 available at http://www.who.int/medicines/news/Lancet_EssMedHumanRight.pdf, accessed on 25 July 2012.
[http:// dx.doi.org/10.4102/sajs. v107i11/12.355](http://dx.doi.org/10.4102/sajs.v107i11/12.355), accessed on 16 October 2012.
15. Kapczynski A 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1571, 1577.
16. Kaplan D 'Intellectual Property Rights and Innovation in South Africa: A Framework' (2009) The Economics of Intellectual Property in South Africa 1, 3 available at http://www.wipo.int/ip-development/en/economics/pdf/wo_1013_e.pdf, accessed on 15 August 2012.
17. Lawyers Collectively 'Novartis Case: Background and Update- Supreme Court of India to Recommence Hearing' (6 September 2012) available at <http://www.lawyerscollective.org/news/archived-news-a-articles/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html>, accessed on 21 October 2012.
18. Love JP 'Recent Examples of the Use of Compulsory Licenses on Patents' (2007) *KEI Research Note* 2 1, 15 available at http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf, accessed on 24 October 2012.
19. Love J 'Abbott Sought Compulsory License While Criticising Thai License' (2007) TWN Info Service on Intellectual Property Issues (May07/03) available at http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.050703.htm, accessed on 15 November 2012.
20. Marks SP 'Access to Essential Medicines as a Component of the Right to Health' (2009) *Health: A Human Rights Perspective*.
21. Maskus KE and M Lahouel 'Competition Policy and Intellectual Property Rights in Developing Countries' (2000) 595 available at <http://infojustice.org/download/gcongress/globalarchitectureandthedevelopmentagenda/maskus%20article.pdf>, accessed on 15 August 2012.
22. McClellan M 'Tools for Success: The TRIPS Agreement and the Human Right to Essential Medicines' (2005) 12 Washington and Lee Journal of Civil Rights and Social Justice 153, 159 available at <http://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1193&context=crsj>

&sei-

redir=1&referrer=http%3A%2F%2Fwww.google.co.za%2Fsearch%3Fhl%3Den%26sc
lient%3Dpsy-

ab%26q%3DM%2BMcClellan%2B%25E2%2580%2598The%2BTRIPS%2BAgreem
ent%2Band%2Bthe%2BHuman%2BRight%2Bto%2BEssential%2BMedicines%25E2
%2580%2599%2B%26btnG%3D#search=%22M%20McClellan%20%25E2%80%98Th
e%20TRIPS%20Agreement%20Human%20Right%20Essential%20Medicines%25E2%
80%99%22accessed on 18 August 2012.

23. Medecins Sans Frontieres 'Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable' (2006) 1, 3 available at http://www.doctorswithoutborders.org/news/hiv-aids/WTO_chretien.pdf, accessed on 9 October 2012.
24. Media Release from the Competition Commission 'Competition Commission finds pharmaceutical firms in contravention of the Competition Act' (16 October 2003) available at <http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=6&ved=0CDsQFjAF&url=http%3A%2F%2Fwww.wcl.american.edu%2Fpijip%2Fdocuments%2FMediaRelease.doc&ei=u8uOULS2EYOThgfp4YCoAg&usg=AFQjCNHnt6eBg9owScvllah8onRSzwucMQ&sig2=d7ne0sAK1WkQNFJEJp-w>, accessed on 19 October 2012.
25. MSF Access Campaign 'Revoking An Invalid Patent: The Case of Didanosine in Thailand' available at http://patentoppositions.org/case_studies/500e9b8c7718ea0002000018, accessed on 21 October 2012.
26. Musungu S 'Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations' (2007) 1, 13.
27. Musungu S 'Intellectual Property and Access to Medicines' (2011) Management Sciences for Health, 3 available at <http://www.msh.org/resource-center/publications/upload/MDS3-FrontMatter-Nov2011.pdf>, accessed on 16 July 2012.
28. Musungu SF and C Oh 'The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?' (2005) Commission on Intellectual Property Rights, Innovation and Public Health 1, 21 available at

- <http://www.southcentre.org/publications/SouthPerspectiveSeries/TheUseOfFlexibilitiesInTripsFinal.pdf>, accessed on 12 September 2012.
29. Musungu SF, S Villanueva and R Blasetti 'Utilising TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks' (2004) 1, 20 available at <http://www.southcentre.org/publications/flexibilities/flexibilities.pdf>, accessed on 8 September 2012.
 30. Notice of Motion filed in the PMA Case available at <http://www.cptech.org/ip/health/sa/pharmasuit.html>, accessed on 5 July 2012.
 31. Nunn A et al 'AIDS Treatment In Brazil: Impacts And Challenges Brazil's accomplishments in treating AIDS are unprecedented and have profoundly influenced global AIDS and health policy' (2009) 28 Health Affairs.
 32. Office of the United Nations High Commissioner for Human Rights available at <http://www2.ohchr.org/english/law/cescr.htm>, accessed on 14 September 2012.
 33. Oh C et al 'TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform'. Third World Network Briefing Paper (2001) available at <http://www.twinside.org.sg/title/drugs2.htm>, accessed on 15 August 2012.
 34. Phillips R 'South Africa's Right to Healthcare: International and Constitutional Duties in Relation to the HIV/AIDS Epidemic' (2004) 11 Human Rights Brief 1,9 available at <http://www.wcl.american.edu/hrbrief/11/2phillips.pdf>, accessed on 19 July 2012. asubramaniam 'Access to Essential Medicines as a Human Right' (2011) Politics of Medicine available at <http://www.politicsofmedicines.org/articles/access-to-essential-medicines-as-a-human-right>, accessed on 3 August 2012.
 35. Pillai M *et al* 'Patent Procurement in India' *Chair of the Intellectual Property Owners Association ("IPO") Asian Practice Committee* 1,3 available at <http://www.ipo.org/AM/Template.cfm?Section=Patents&Template=/CM/ContentDisplay.cfm&ContentID=22900>, accessed on 15 October 2012.
 36. Pouris A *et al* 'Patents and Economic Development in South Africa: Managing Intellectual Property Rights' (2011) *S Afr J Sci*1, 5 available at
 37. Ramanna A 'India's Patent Policy and Negotiations in TRIPS: Future Options for India and other Developing Countries (2002) available at www.iprsonline.org/ictsd/docs/ResourcesTRIPSanita_ramanna.doc, accessed on 10 October 2012.
 38. Regional Issues Brief: Intellectual Property Rights and Access to Medicines (2011) Global Commission on HIV and the Law.

39. Reichmann J and C Hasenzahl 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA' (2003) *Intellectual Property Rights and Sustainable Development* 1, 10 available at http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf, accessed on 12 September 2012.
40. Reis R *et al* 'Access to Medicines and Intellectual Property in Brazil: A Civil Society Experience' (2009) *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South* 1, 29.
41. Saha R 'Management of Intellectual Property Rights in India' (2005) 1, 3 available at <http://www.pfc.org.in/workshop/workshop.pdf>, accessed on 25 September 2012.
42. Sector Strategy for Access to Medicine in COMESA 'Review of Implementation of TRIPS Flexibilities on Patents' (2011) 1, 27 available at <http://www.comesabusinesscouncil.org/attachments/article/31/0.%20Cover%2031.10.2010.pdf>, accessed on 17 July 2012.
43. Sector Strategy for Access to Medicines in COMESA 'Introduction to WTO Decisions on TRIPS and Public Health' (2011) 1, 12 available at <http://www.comesabusinesscouncil.org/attachments/article/31/8.%20Strategic%20Analysis%20and%20Implementation.pdf>, accessed on 12 September 2012.
44. Sekalala SR 'Beyond Doha: Seeking Access to Essential Medicines for HIV/AIDS Through the World Trade Organisation' 1, 4 available at <http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf>, accessed on 1 September 2012.
45. Sheppard DF 'Patent Law in South Africa with Particular Reference to the TRIPS Agreement' *The Journal of World Intellectual Property*.
46. Sibanda O 'Parallel importation and compulsory licensing in Kenya and South Africa as measures to access HIV/AIDS medicine' (2009) 41 *Acta Academia* 184, 197 available at www.ajol.info/index.php/pelj/article/view/81300/71485, accessed on 24 October 2012
47. Statistics South Africa: Statistical Release 'Mid-Year Population Estimates 2010' (2010) 1, 3 available at www.statssa.gov.za/publications/P0302/P03022010.pdf, accessed on 6 October 2012.

48. t'Hoën EFM 'The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health' (2009).
49. t'Hoën EFM 'TRIPS, pharmaceutical patents and access to essential medicines: Seattle, DOHA and Beyond' (2003).
50. t'Hoën EFM et al 'Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines to All' (2011) 14 Journal of International AIDS Society 1, 5 available at <http://www.jiasociety.org/content/14/1/15>, accessed on 18 August 2012.
51. Temmerman M 'The Legal Notion of Abuse of Patent Rights' (2011) Working Paper No. 2011/23, 5 available at http://www.wti.org/fileadmin/user_upload/nccr-trade.ch/wp3/3.5/The%20Legal%20Notion%20of%20Abuse%20of%20Patent%20Rights.pdf, accessed on 7 September 2012.
52. The Indian Express: Journalism of Courage 'Novartis argues for Glivec Patent at Supreme Court' (12 September 2012) available at <http://www.indianexpress.com/news/novartis-argues-for-glivec-patent-at-supreme-court/1001329/2>, accessed on 20 October 2012.
53. Third World Network "Members discuss implementation of TRIPS "Para 6" solution" (2010) TWN Info Service on Intellectual Property Issues available at http://www.twinside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.100302.htm, accessed on 9 October 2012.
54. Thorpe P 'Study on the Implementation of the TRIPS Agreement by Developing Countries' Commission on Intellectual Property Rights 18, available at http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf, accessed on 2 September 2012.
55. UNAIDS Factsheet available at <http://www.unaids.org/en/resources/campaigns/togetherwewillendaids/factsheets/>, accessed on 15 July 2012.
56. UNAIDS Technical Brief 'Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries' (2011) 1, 3 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf, accessed on 13 July 2012.

57. UNCTAD-ICTSD 'Intellectual Property Rights and Competition' (2004) CY564-
Unctad-v1 539 available at
http://www.iprsonline.org/unctadictsd/docs/3.IPRSandCompetition_update.pdf,
accessed on 15 September 2012.
58. United Nations Development Programme 'Good Practice Guide: Improving Access to
Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement'
(2010), 5 available at
<http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf>, accessed on 3
August 2012.
59. United Nations Development Programme 'The Doha Declaration Ten Years on and
Its Impact on Access to Medicines and the Right to Health' (2011) Discussion Paper.
60. Van Gulik C 'Impact of TRIPS on Access to Medicines and the Right to Health of
Children' (2004).
61. Vawda YA 'Pharmaceutical Innovation, Incremental Patenting and Compulsory
Licensing Country Case Study: South Africa' (2011) 12 available at
<http://www.tac.org.za/userfiles/file/Vawda%20SA%20patenting.pdf>, accessed on 17
August 2012.
62. Vawda YA 'Putting the 'public' back into 'private' law' (2008) De Rebus.
63. Working Group of Intellectual Property 'Private interests and the connivance of the State: the
case of pharmaceutical patents and ANVISA's role' (2011) 1, 1 available at
http://patentes.org.br/media/file/nota%20anuencia%20ingles_ing_jan11.pdf, accessed on 24
October 2012.
64. World Health Organization Fact Sheet No. 31 'The Right to Health' 25, available at
www.ohchr.org/Documents/Publications/Factsheet31.pdf, accessed on 15 August
2011.
65. World Intellectual Property Organisation 'Advice on Flexibilities under the TRIPS
Agreement' available at [http://www.wipo.int/ip-
development/en/legislative_assistance/advice_trips.html](http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html), accessed on 15 October
2012.
66. World Trade Organisation 'Doha Declaration on the TRIPS Agreement and Public
Health' (2001) para 4 available at
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm,
accessed on 15 September 2012.

67. World Trade Organisation available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, accessed on 10 October 2012.
68. Zacharias N *et al* 'Patents and the Indian Pharmaceutical Industry' (2002) *Business Briefing: Pharmatech* 42, 44 available at <http://www.nishithdesai.com/Research-Papers/Patents-and-the-Indian-Pharmaceutical-Industry-NZ%26SF.pdf>, accessed on 21 October 2012