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Multinational Pharmaceutical Manufacturers' Opposition to Patent Law Reform in South Africa: A Bitter Moral Pill.

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For Stephen (Steve) Bantu Biko

(18 December 1946 – 12 September 1977)

I am grateful that he lived. And that he wrote what he liked.

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Declaration

I, Kwanele Asante-Shongwe (Student number: 8902830W) am a postgraduate student registered for the Masters of Science Medicine: Bioethics and Health Law degree in the School of Public Health at the University of the Witwatersrand (Wits), in Johannesburg, South Africa.

- I am aware that plagiarism is the use of someone else's work without their permission and/or without acknowledging the original source.
- I am aware that plagiarism is wrong.
- I confirm that the work submitted for assessment for the above course is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.

Signature: _____ Date: _____

Abstract

It is estimated that about two billion people, one-third of the world's population, lack regular access to essential medicines (Forman & Kohler 2012: 26). The situation is worst in Africa and South East Asia, where it is reported that about half the population do not have regular access to potentially life-saving drugs (Forman & Kohler 2012:26). A normative study was undertaken to probe whether legal duties to provide affordable medicines place or ought to place limitations on the exercise of pharmaceutical patents in developing countries. I have used the bioethics theory of justice and the jurisprudence on the right-to-health, enshrined in international human rights law, as my argumentative framework. Like other pro-health equity academics (Forman & Kohler 2012, Cameron 2005, Gostin 2014) I argue that the exorbitant prices charged by the multinational pharmaceutical industry for patented drugs are a barrier to equitable access to essential medicines for the world's poor, most of whom live in developing countries. I concur with (Forman and Kohler 2012:1) that, "access to essential medicines (should be) authoritatively interpreted to constitute a minimum core entitlement under the human right to the highest attainable standard of health (the right-to-health), placing correlative duties on a range of actors to enable and ensure access." In addition, I posit that the interests of social justice ought to justify a partial infringement of private commercial interests in the public interest – to speed up regular and affordable access to essential medicines to all who need them. My argument proceeds as follows:

Firstly, nation states bear the primary responsibility to meet right-to-health responsibilities as espoused in international human rights law and applicable African regional laws. Secondly, I argue that richer states (should) have joint legal and moral responsibilities to assist poorer nations to realize access to the "highest attainable standard of health" which is the legal entitlement of "every person" (WHO 1946, African Charter of Human Rights, 1981). I conclude

by arguing that the multinational pharmaceutical industry ought to assume binding right-to-health human rights obligations, with nation states.

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Last but not least I wish to thank all my lecturers at the Steve Biko Centre for Bioethics, Faculty of Health Sciences, at the University of the Witwatersrand for the teaching, support and enthusiasm afforded me, and particularly my supervisors Professor Ames Dhai and Advocate Yolande Guidozzi for guiding me in the production of this research report. All errors in fact or thinking are mine.

This work is dedicated to the memory of Bantu Steve Biko, my academic *idlozi* (isiZulu for ancestor). I am grateful that he lived, and that he wrote.

List of acronyms

AC AIDS Consortium
ACHPR African Charter of Human and People's Rights
AGOA African Growth and Opportunity Act
ALP Aids Law Project
ANC African National Congress
APN+ Asia Pacific Network of People Living with HIV/AIDS
ARV antiretroviral
AU African Union
BI Boehringer Ingelheim (Pty) Ltd
CC Constitutional Court
DTI Department of Trade and Industry
ESCR Committee for Social, Economic and Cultural Rights
FDA Federal Drug Administration
FTPL *Fix the Patent Laws*
GATT General Agreement on Tariffs and Trade
GSK GlaxoSmithKline
HRC Human Rights Council
ICESCR International Covenant on Economic, Social and Cultural Rights
IP intellectual property
IPASA Innovative Pharmaceutical Association of South Africa
KEI Knowledge Ecology International
MCC Medicines Control Council
MTCT mother to child transmission
NHI National Health Insurance
NRF National Research Foundation
OAU Organisation of African Unity
OHCHR Office of the United Nations High Commissioner for Human Rights
PAE Public Affairs Engagement
PhRMA Pharmaceutical Research and Manufacturers of America
PMA Pharmaceutical Manufacturers Association of South Africa
R&D research and development
SACP South African Communist Party
WHO World Health Organisation
Wits University of the Witwatersrand
WTO World Trade Organisation
TAC Treatment Action Campaign
TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights
TPP Trans-Pacific Partnership
UN United Nations
UNGA United Nations General Assembly

CHAPTER 1

INTRODUCTION: MULTINATIONAL PHARMACEUTICAL MANUFACTURERS' OPPOSITION TO PATENT LAW REFORM IN SOUTH AFRICA: A BITTER MORAL PILL

1.1 Introduction

The issue of pharmaceutical patents and access to essential medicines has gained international significance since the signing of the World Trade Organisation's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Marrakech, Morocco on 15 April 1994. It is estimated that about two-thirds of the world's population lack regular access to the medicines they need. Pharmaceutical patents have been identified as a major barrier to affordability. The status quo has created tensions between two main schools of thought involved in what is commonly referred to as the global access to medicines debate. The two sides differ on whether multinational pharmaceutical manufacturers have or ought to have joint international human rights law obligations, with states for providing access to essential medicines for all persons. It must be borne in mind that, the application of human rights obligations to non-state actors remains unsettled at international law (Forman and Kohler, 2012).

Multinational pharmaceutical manufacturers and their academic supporters argue that the sector does not have legal obligations to safeguard the right-to-health entitlements of global citizens who lack adequate access to essential treatments. It is often argued on behalf of the industry that it is a for-profit sector with the primary objective of maximizing profits for its investors. CL Clemente, the former Pfizer executive senior vice president in South Africa, summarised the

position succinctly when he asserted, ‘We are not the Red Cross. We are a for-profit company’ (Quoted by Cameron 2005).

By contrast, right-to-health activists posit that the exorbitant prices charged by multinational drug-makers for patented drugs act as a barrier to health equity for the global poor. As mentioned above, they argue that drug-makers must be held to strict joint human rights duties, with states to provide access to treatments. The access to medicines debate can best be summarised as a contestation over acceptable levels of legal protections for property rights (pharmaceutical patents) versus the social justice needs of providing essential medicines to the greatest number of patients, worldwide. Legal questions arise on whether it would be desirable, fair or just to limit the exercise of pharmaceutical patents in developing countries in the public interest. Are treatment access campaigners correct to suggest that human rights principles and bioethical theories of justice ought to be used to curtail the legitimate property rights of international drug-makers in the public interest?

The global debate has gained great momentum in the past year largely due to the secrecy surrounding the pharmaceutical patent clauses of trade agreement the Trans-Pacific Partnership (TTP) which was concluded on 5 October 2015. It has been said that the TTP could be the world’s largest free trade agreement. It was concluded by “12 countries including the US, Japan, Canada, Mexico, Australia, Vietnam, Malaysia, and Chile. TPP countries represent 40 percent of global GDP, 25 percent of global exports, and 30 percent of global imports” (Meltzer, 2016)

Key parts of the legal and moral arguments in this debate have been tested in the multinational pharmaceutical manufacturers’ robust court challenges in South Africa and India. Tensions have also been heightened by the exposure of the multinational pharmaceutical industry’s underhanded plans to thwart South Africa’s public interest patent law reforms. Chapter 2

of the South African Draft National Policy on Intellectual Property (IP Policy), 2013 deals expressly with IP and Public Health and contains an extensive list of pro-healthy equity recommendations which seem to have unsettled the drug manufacturers (Government Gazette 2013: 20-21). In their comments on the draft policy, a consortium of mostly South African legal academics noted that the intentions of the drafters were good and that the proposed law "is grounded in a developmental approach appropriate to our country, and seeks to eliminate the many perverse outcomes of IP protection which are detrimental to the broader society" (Schonwetter et al, 2013: 4). They also remarked that the draft document was cognizant of the complex technological questions that attach to the issue and that it sought to maintain a fair balance between competing private and public interests (Schonwetter et al, 2013). However, they were critical that the draft policy "lacks reference to the fundamental rights in the Bill of Rights, which is the framework within which all government in South Africa is to operate"' (Schonwetter et al, 2013: 5) Also that the policy did not incorporate enough of the TRIPS flexibilities that could assist the country with the provision of access to medicines (Schonwetter et al, 2013)

1.2 Background and statement of question

Pharmaceutical drugs are an essential component of healthcare. It is estimated that about two billion people, one-third of the world's population, lack regular access to essential medicines. (Forman & Kohler, 2012, p1) The situation is worse in Africa and Asia, where it is estimated that about half the population do not have regular access to essential medicines. (Forman & Kohler 2012) Exorbitant prices charged by drug manufacturers are the main reason for global medicine disparities. (Treatment Action Campaign) Using cancer treatments as an example, it is reported that low to middle-income countries bear about two-thirds of the global deaths from cancer, "… and yet only 5 percent of the global resources expended on cancer are available to those countries" (Lawrence Shulman cited by David Freedman, 2014). Most patients in high-income

countries are able to afford the high costs of the newest medicines. (Freedman, 2014) By contrast, the majority of cancer patients in developing countries cannot afford them. There "… are sharp inequities in access to care among different populations around the globe" (Freedman, 2014). Country drug estimates show that "(the) United States spends $460 per year per patient on (cancer) treatment and prevention costs, compared to about $US8 in South America, $US4 in China and 50 cents in India." (Freedman, 2014) Pharmaceutical patents have been highlighted as a major barrier to affordable access to essential medicines (Cameron 2005, Hestermeyer 2012, and Klug 2012). Originally intended to reward innovation and to promote drug research and development, treatment access activists argue that pharmaceutical patents influence the high prices of medicines charged by multinational drug manufacturers. (Medecins Sans Frontieres (MSF) &, TAC Online Access Campaigns). All the aforementioned authors claim that the drug industry's insistence on strict compliance with patent protections, gives them an unfair advantage to charge exorbitant drug prices at the expense of poor persons; a claim vigorously denied by the multinational drug industry and their academic supporters. (DiMasi, Hansen and Grabowski, 2003) The multinational pharmaceutical companies have pursued legal action against the Republic of South Africa (in 1989) and the Union of India (in 2008 and 2013) to protect their patent rights (Hestermeyer 2012, Indian Case Laws.org). More recently, sharp tensions between multinational drug manufacturers and the government of South Africa were starkly revealed in an article published in the Mail and Guardian newspaper on 17 January 2014. The article exposed an alleged plot by multinational pharmaceutical companies to run a misinformation campaign to discredit the country's Draft Patents and Intellectual Property (IP) laws (Mail & Guardian, 17 January 2014). It is alleged that two dozen pharmaceutical companies had, in a document entitled "Campaign to Prevent Damage to Innovation from the Proposed Draft

National IP Policy in South Africa", formulated a three-pronged strategy to raise public doubt about the economic and legal merits of the country's proposed IP legislative reforms. Revelations of the alleged plot sparked moral outrage from the Minister of Health Dr. Aaron Motsoaledi and treatment equity campaigners like the Treatment Action Campaign (TAC), Medecins San Frontiers (MSF) and Section27. It is reported that Minister Motsoaledi "accused (the) multinational pharmaceutical companies active in South Africa of conspiring against the state, the people of South Africa and the populations of developing countries - and of planning what amounts to mass murder." Motsoaledi is said to have referred to the alleged plot as "genocide", emphasizing, "I am not using strong words; I am using appropriate words. This is genocide." The incident and the Government's strong worded response to it captures, in my opinion, the salient issues in the 16 years long South African struggle to balance pharmaceutical patent protections and obligations to provide essential medicines. Strong words by either side notwithstanding, it is indisputable that swift and decisive action needs to be taken to settle the law in this area to alleviate the enormous human suffering currently borne by people without dependable access to essential medicines. South African Constitutional Court Judge and treatment access activist, Edwin Cameron, characterizes this slow progress in realizing the state's duty to provide access to essential medicines as a "moral emergency". He argues that progress in the pharmaceutical patents and essential medicines debate will "require new thinking and new flexibility, in both business and politics" (Cameron, 2014, p118).

1.3 Thesis statement

Because more than two billion people living in poor countries lack regular access to essential medicines a normative study was undertaken to probe whether legal duties to provide affordable

medicines place or ought to place limitations on the exercise of pharmaceutical patents in developing countries.

1.4 Rationale

Access to essential medicines remains highly contested around the globe and a vital issue in South Africa (Klug, 2012). It is estimated that about half the population in Africa and Asia do not have regular access to essential medicines. In South Africa, a period of 16 years has elapsed since the multinational pharmaceutical manufacturers had tried to sue President Mandela for signing amendments to the Medicines and Related Substances Control Amendment Act, 1997, into the nation's law. (Hestermeyer, 2012) There is growing concern among scholars in global health that substantive action needs to be taken to address the unjust and widening gap of health disparities between citizens of the developed and developing countries. Pharmaceutical patents have singularly been highlighted as a key barrier to the provision of regular and affordable access to essential medicines by poor patients. This research report is a bioethical-legal response to the call to decisively settle health and human rights law on this topic in South Africa, with the hope that work successfully undertaken in this country will contribute to legal reforms in other countries in the developing world.

1.5 Argumentative strategy

I have used the bioethics theory of justice and the jurisprudence on the right-to-health, enshrined in international human rights law and the African Charter of Human and People's Rights (ACPHR) as my argumentative framework. It is argued that, moral and human rights dilemmas arise from the gap in access to medicines created by the unconscionably high prices charged by multinational drug manufacturers for essential medicines. The main argument of my research is based on the premise that "access to essential medicines (should be) authoritatively interpreted to

constitute a minimum core entitlement under the human right to the highest attainable standard of health (the right-to-health), placing correlative duties on a range of actors to enable and ensure access" (Forman & Kohler, 2012, p3). In this report, I have argued the following; firstly, that all states are legally and morally bound to provide access to the right-to-health as stipulated by international and regional human rights laws. Secondly, though individual states bear the primary duty to safeguard their citizens' right-to-health, I submit that richer states ought to have joint legal and moral responsibilities to assist poorer nations to realise access to the "highest attainable standard of health" which is the legal entitlement of every person (WHO Constitution, ACHPR). Globalization and advances in technology have connected national economies and destinies of world populations in ways not previously possible. This interconnectedness creates, in my opinion, shared obligations and legal responsibilities to ensure equitable distribution of the fruit of trade. Legal academics frame this interdependence as "transnational obligations" (Gostin, 2014) and/or "joint responsibilities'/'correlative duties of all actors" (Forman & Kohler, 2012).

1.6 Objectives

1.6a Primary

1. I have critically analyzed South Africa's approach to intellectual property (IP) law with regard to health

2. I have discussed and critiqued the multinational pharmaceutical industry's resistance to intellectual property law reform in South Africa.

3. I have critiqued how international trade agreements, like the TRIPS Agreement (the World Trade Organisation's patent legislative framework) and the TPP, constrain patent legislative reforms in developing countries like South Africa, undermining these states' efforts to meet

their international law right-to-health obligations – which include providing access to essential medicines.

1.6b Secondary

1. I have probed whether rich countries and the multinational pharmaceutical industry have/or ought to have human rights law obligations to help realise the principle of global distributive justice in connection with medicines.

1.7 Methods

Both normative and meta-ethical enquiries were undertaken. Normative ethics probes how we ought to evaluate conduct and the reasons for doing so (Beauchamp & Childress, 2013). Meta-ethics, probes the meanings of terms like justification, responsibility, obligations and virtues. (Sulmasy and Sugarman, 2010) I have utilised the desktop (DTS) research method because doing so enabled me to collate, evaluate and integrate relevant bioethics and global health law information that is already available on my topic of study. (Denis 2012) In addition, the technique has assisted me to achieve the three key research purposes outlined by Raphael Dennis. Firstly, it enabled me to identify key public health data, focusing on access to essential medicines in the South African public health sector and in other developing world jurisdictions currently seized with the issue. Secondly, it helped me to identify data gaps that needed to be filled. Thirdly, it assisted me to identify issues related to my topic that require separate and/or further academic study. (Denis 2012)

1.8 Outcomes

This research report will be offered as a discussion document with recommendations to assist the Department of Trade and Industry in finalising the draft national intellectual property rights policy.

1.9 Structure and Chapter outline

Chapter 1 has set out the background, rationale and objectives of this research report and offered a broad overview of the academic, legal and ethical issues in the global pharmaceutical patents and access to essential medicines debate. Chapter 2 gives a detailed account of how the human rights approach adopted by South African treatment access campaigners during the HIV/AIDS pandemic of the 1990s led to the genesis of that country's human-rights centered health jurisprudence. I have detailed how civil society movements (led by the Treatment Action Campaign), domestic courts, the Competition Commission and the Competition Tribunal leveraged international human rights law provisions - and the Constitution Act of the Republic of South Africa, 1996, to hold the African National Congress (ANC) government accountable to its peremptory right-to-health obligations. I have argued that, the courts' bold pronouncements in the two TAC cases helped to elevate the legal and moral worthiness of the access to medicines debate from a popular campaign to a vexing social justice issue centered on the state's obligation to respect the inherent human dignity of all persons.

Chapter 3 sketches the content and scope of the right-to-health at international law. It further explores the minimum core duties of states in respect of this right and argues that the multinational pharmaceutical manufacturers ought to be held to joint duties with nation states to provide regular access to affordable essential medicines to all who need them. I have also interrogated South African jurisprudence on the right-to-health – and given a detailed analysis on

how the country's domestic law has incorporated international human rights frameworks. (The African Charter of Human and People's Rights also uses similar right-to-health language) In Chapter 4, I have highlighted how bilateral trade and global investment interfere with developing states' ability to respect, protect and promote their international human rights obligations, in respect to health equity. I argue that, the requirements of distributive justice urgently require that this grossly unethical undermining of the health entitlements of large sections of the global population be curtailed. Finally, in Chapter 5 I have argued that the 1946 UN promise that access to the highest attainable standard of health is a fundamental human right for all human beings, remains unrealized. I have argued that all the key stakeholders in the debate are liable for the lack of substantive progress in the South African and global IP and access to medicines debate. Millions of patients without access will continue to die and suffer needlessly until nation states; the multinational pharmaceutical industry and treatment access campaigners join hands to develop win-win solutions.

CHAPTER 2: THE DEVELOPMENT OF HEALTH LAW IN SOUTH AFRICA IN RESPECT OF ACCESS TO MEDICINES: SOME HISTORICAL PERSPECTIVES

2.1 Introduction

The issue of pharmaceutical patents and affordable access to essential medicines has been debated in South Africa since 1997. This chapter will chart the history of the nation's HIV/AIDS pandemic and the related struggle for free antiretrovirals (ARVs) in the public sector to highlight how grassroots action led to the emergence of the nation's AIDS jurisprudence - and how it crystallized the pharmaceutical patents and access to medicines debate in the country and beyond. Substantive legal and policy gains were made in the provision of free access to ARVs in the public health sector. However, efforts to reform the intellectual property (IP) legislative regime in the public interest have resulted in inadequate public health gains over the past 18 years (FTPL, 2015a). Fresh hostilities on the issue of pharmaceutical patents and access to medicines erupted after the Mail and Guardian newspaper (2014) published reports revealing that the multinational pharmaceutical manufacturers had devised a plot to undermine patent law reform in South Africa. The allegations reignited calls for urgent finalization of the country's patent law reform process, in the public interest.

2.2 The legal beginnings of the pharmaceutical patents and access to essential medicines in South Africa

In 1997, a group of 42 multinational pharmaceutical manufacturers filed legal action against former President Nelson Mandela after he had signed the new provisions of the Medicine and Related Substances Control Amendment Act No.90 of 1997 (the Medicines Amendment Act) into law (T'Hoen 2003). The group was later reduced to 39 due to mergers. Section 15c of the Medicines Amendment Act was promulgated to provide the Minister of Health with powers to

use compulsory licensing and parallel importation mechanisms to procure ARV medicines for millions of South African HIV/AIDS patients. The litigants supported by the US Congress, which placed South Africa on its 301 Watch-list of patent infringing nations, argued that the amendments gave the Minister powers to abrogate IP rights (Hestermeyer 2012). The lawsuit turned into an unmitigated public relations fiasco for the pharmaceutical industry, after millions of citizens around the world voiced moral outrage at the litigation (Geffen 2010, Hestermeyer 2012). Treatment activists, led by the South African HIV/AIDS treatment access non-profit organisation the Treatment Action Campaign (TAC), argued that the law suit and the US Congress's interventions on behalf of the multinational drug industry interfered with a developing country's ability to honour its international law right-to-health obligations. The drug manufacturers abandoned their legal action in September 1999. An out of court settlement was reached between the parties and a significant amount of HIV/AIDS drug donations were given to needy patients.

However, the cessation of public hostilities between pharmaceutical manufacturers, the government and civil society (represented by HIV/AIDS organisations) did not bring a permanent resolution to the standoff. Academic writers and global health equity activists argue that the widely publicised South African court proceedings catapulted the issue of pharmaceutical patents and access to essential medicines onto the world stage (Geffen 2010, Halbert 2002, Hestermeyer 2012). Halbert (2002) argues that the litigation highlighted three key issues. Firstly, the lack of adequate research and development funding to deal with the AIDS pandemic ravaging in poor African communities. Secondly, it legitimized the use of AIDS treatments as a prevention strategy, debunking the pharmaceutical industry's claims that this intervention would not work within an African clinical setting. Thirdly, and most importantly in

Halbert's assessment, South African health equity activists led by the TAC "successfully opened a hole in the intellectual property discourse" by asking leading key questions about whether insistence on strict IP protections undermined access to medicines (Halbert 2002:258). She claims that the treatment access campaigners' action created a new language of parallel importations and compulsory licensing agreements which in turn advanced the articulation of the provision of healthcare as a moral and human right (Halbert, 2002).

2.3 Do multinational drug manufacturers have legal and moral duties to provide access to essential medicines for developing countries?

This new language of holding pharmaceutical manufacturers to ethical and human rights obligations to remove barriers to access to essential medicines in the developing world, deepened in 2011. Unsurprisingly, the multinational drug manufacturing sector disagreed with the proposition to potentially decrease pharmaceutical patent protections to advance the provision of affordable access to essential medicines, globally. The drug-making sector also fiercely resisted suggestions that as a multinational industry it had joint-legal duties, at the level of international human rights law, to assist state parties (especially developing countries) with their right-to-health responsibilities (Forman and Kohler 2012). They maintained that they "*did not have right-to-health responsibilities that exceeded those dictated by ethics and the law implicit in shareholder primacy"* (Forman and Kohler 2012) (Emphasis added) - a position many still hold.

Academics allied to the industry have authored numerous articles arguing that the cost of drug development justifies the exorbitant prices charged for pharmaceutical products. Health economists from the Tufts Center for Drug Development have led claims that the astronomical development costs incurred by the multinational pharmaceutical industry justify their insistence on the grant of strict patent protections (DiMasi et al. 2003, DiMasi 2014). They claim that it

cost US$802 million to develop a single drug in 2001. The figure was adjusted upwards to US$2.6 billion (estimate in 2013 dollars) in 2014 (Silverman 2014).

Pro health equity academics and activists have questioned the methodology used in both Tufts studies (Silverman 2014). Other academic critiques have raised concerns about possible research bias pointing out that the Tufts Center, led by DiMasi, receives funding from the pharmaceutical sector. Furthermore, it has been highlighted that the 2014 study relies on proprietary information that was provided by the industry (Baker 2014). American macroeconomist Baker (2014) notes, "whether or not the criticisms of the study are valid, $2.6 billion is not a number that should make the pharmaceutical industry proud. It implies that the cost of developing a new drug increased at an annual rate of almost 8 percentage points above the overall inflation rate".

The real-life effects of the pharmaceutical patents and access to essential medicines debate have played out in South Africa and India. I shall use the South African struggle for treatment access as an illustrative case study. The issue of inadequate equitable access remains as contentious today as it was in the late 1990s. The multinational pharmaceutical manufacturers continue to use the argument about the costs of research and development (R&D) to justify the exorbitant price they charge for patented medicines, with it being argued on their behalf that the costs borne by the sector justify the industry's insistence on stringent IP protections – in the form of pharmaceutical patents.

Relying on international human rights law and moral arguments, treatment access campaigners and their academic supporters robustly assert that the right-to-health is a fundamental human right that should not be constrained by arguments premised largely on the protection of drug makers' pecuniary interests. In my opinion, Lisa Forman, Jillian Clare Kohler and Patricia Illingworth correctly emphasize that access to healthcare is a fundamental human right conferred

by international law. Illingworth's assertion that, "s*hareholder claims do not override the life-and-death claims of the sick and dying"* (Forman and Kohler 2012: 11), poignantly summarizes the point in relation to access to medicines. (Emphasis added) A similar argument was advanced by South Africa's TAC during its struggle for universal access to ARVs.

2.4 The AIDS pandemic and the emergence of HIV/AIDS (health) law and public policy discourse in South Africa

South African AIDS and treatment access activists used the law to facilitate access to affordable medicines for vulnerable populations (Moyle 2015: 21). In the past, the rapid spread of the HIV/AIDS pandemic often led to workplace discrimination against poor foreign mineworkers by mine management. A 1987 study found high levels of sero prevalence among mine workers from Malawi. The then government and the Chamber of Mines started conducting secret HIV testing without consent on unsuspecting employees. Many foreign mine workers were summarily laid off and transported back to their countries of origin with little explanation of why their work permits and employment contracts were not renewed. Rights activists, academics and lawyers banded together to formulate a charter of rights on AIDS and HIV (Moyle 2015: 23) This intervention was the precursor to the establishment in 1992 of the AIDS Consortium (AC) - an amalgamation of 45 civil society organisations – in response to the growing AIDS pandemic and the accompanying widespread human rights abuses (Moyle 2015: 24)

The AC was based at the Centre for Applied Legal Studies at the Faculty of Law of the University of the Witwatersrand, Johannesburg. During its first year, lawyers from the AC drafted the AIDS Charter of Rights which was a twelve clause statement of the human and health rights of South African workers based on the country's social welfare and healthcare systems (Moyle 2015: 24). The Charter was warmly received by the post-democratic South African

government. Didi Moyle (2015: 31) explains that, "the process of dismantling apartheid and the creation of a new legal code on AIDS … flowed from the fact that the new order recognised that all South Africans had rights." Early responses to the AIDS pandemic were developed to honour the bill of rights injunction to "respect, protect and promote" the human rights of all citizens (Constitution of the Republic of South Africa, 1996). Activists and lawyers from the Aids Law Project (ALP) sought to impress on the government that it had positive duties to meet Constitutional obligations related to the right-to-health, as well as to shape new business and employment laws that respected and upheld the principles of "non-discrimination through ethical and legal principles, guided by the AC's Charter of Rights on HIV/AIDS" (Moyle 2015:32)

Before it ascended to power, the African National Congress (ANC) and its allies like the South African Communist Party (SACP) understood the mayhem that an unaddressed AIDS pandemic could have on the country's transition to democracy. In 1990 Chris Hani, then General Secretary of the SACP cautioned during the Maputo AIDS Conference that, "*(w) e cannot afford to allow the AIDS epidemic to ruin the realization of our dreams*." (Moyle 2015: 27) He further noted that,

> "*existing statistics indicate that we are still at the beginning of the AIDS epidemic in our country. Unattended, however, this will result in untold damage and suffering by the end of the century*" (Moyle 2015: 27).

It is estimated that about 74,000 to 120,000 South Africans were living with AIDS then. Hani's words proved prophetic 10 years later when the health impacts of a tardy government response to HIV/AIDS started to be felt. Nkosazana Dlamini-Zuma, a medical doctor, was appointed Health Minister after the first democratic elections in 1994. Her national department sought the legal assistance of the ALP on a number of key public health policies, like the reform of the Medical

Schemes Act, to outlaw barriers that prevented access to medical insurance policies and other health services to individuals deemed too sick to qualify for cover (Moyle 2015: 39). In 1995 the ALP was intricately involved in the drafting of what would become the "HIV/AIDS and Employment: Code of Good Practice" – appended as Regulation 1298 of the Labour Relations Act of 1995 (Moyle 2015: 34).

Unfortunately, the proactive rights based responses to HIV/AIDS lost momentum as the ANC government settled into ruling after the 1994 elections. Frictions between government and the AIDS lobby started to surface. Researcher Jody McNeil (SA History Online, undated) claims that three events strained relations between the then-President Nelson Mandela's administration and the HIV/AIDS civil society mass movement. Firstly, newspaper reports in June 1995 revealed that the National Health Department had spent R14.27 million given by the European Union for HIV/AIDS prevention and control on a play called *Sarafina II*. HIV/AIDS civic organisations complained that they had not been consulted on the commissioning of the play and on the subsequent crafting of its public health messages. Government stopped funding the play in 1996.

The *Sarafina II* debacle was followed by revelations in January 1997 that the government supported research into the South African AIDS drug Virodene. The country's Medicines Control Council (MCC) banned the research drug over toxicity concerns after attention from key officials in government. However, then deputy president Thabo Mbeki and Health Minister Dlamini-Zuma continued to support public trials of the drug overriding its scientific censure by the MRC. Thirdly, in January 1998 treatment access activists and AIDS researchers demanded that the government provide an ARV drug called Zidovudine to pregnant women attending

public healthcare facilities. The WHO had authorized the drug for use to prevent mother to child transmission (MTCT) of the virus at birth or shortly thereafter (Sidley 1998).

Over the years, the ALP broadened its health rights activism. It added a paralegal unit and formed a law and access to treatment unit specializing in medicine pricing, competition law and IP. The TAC, as the new specialized medicines unit became known, was launched on 10 December 1998. The subsequent work of the ALP laid the foundations of the South African AIDS jurisprudence that exists today (Moyles 2015: 32).

2.5 The constitutional struggle for free ARVs in the public health sector and challenges to the Mbeki administration's AIDS denialism

1998 to 1999 were watershed years in the South African national AIDS discourse. Civil society organisations led by the TAC changed their health rights advocacy strategy from seeking to gently influence government's public health policies to utilizing the law to force bureaucrats and politicians to honour the right-to-health claims of millions of poor citizens infected with the HI-virus. It was also during this period that 42 pharmaceutical manufacturers (later reduced to 39 because of mergers) filed legal action against President Nelson Mandela after he had signed section 15C of the Medicines Amendment Act into law as mentioned in Chapter 1 (page 12).

Perhaps the most important event was the ascendency of Thabo Mbeki to the Presidency after Mandela. Dr. Manto Tshabalala-Msimang succeeded Dr. Nkosazana Dlamini-Zuma as Health Minister. Whereas, Mandela's administration has been widely criticised for taking their eyes off the fast rolling HIV/AIDS ball, Mbeki's administration is remembered for actively conspiring to contradict the widely held global scientific consensus that HIV causes AIDS (Cameron 2005, Geffen 2010, McNeil). The president and his Health Minister surrounded themselves with AIDS dissent theorists who argued that socio-economic factors and not the HI-virus were responsible for the rapid spread of HIV/AIDS among poor African populations. They added that good

nutrition and not ARVs (which they deemed too toxic for public consumption) would help reverse the physical and social health impacts of the pandemic. Their contra-scientific views would have been easy to ignore if they were privately expressed. However, the two politicians steamrolled them into national health debates on AIDS. Their belligerence led the TAC to file a legal suit to compel the government to accelerate the provision of the ARV drug Nevirapine in public health facilities. The manufacturers of the drug had offered it free to the government for five years to help curb the rapid rise of MTCT.

The government decided to limit the distribution of the free drugs to health facilities that fell within its designated public sector HIV/AIDS research test sites. In September 1995 the TAC launched a court challenge calling on the government to make Nevirapine freely available to all pregnant women who needed it. On 14 December 1999 the Pretoria High Court found in the TAC's favour and directed the government to make the drugs available as demanded. The Court also granted the government the right to have the matter vindicated in the Constitutional Court (CC). In addition, the CC used the opportunity to further develop South African jurisprudence on the right-to-health as enshrined in section 27 of the national Constitution.

The CC conducted a robust legal inquiry into key issues – among them, the values of the Constitution and their applicability in socio-economic rights litigation, the state's Constitutional and international law duties and obligations in respect of socio-economic rights – probing the legal meaning of "to provide access to basic needs", the legal content of "minimum core entitlements", the reasonableness of state action (probing in this case whether the government's decision to limit free drug distribution to designated test sites was rational) and finally the CC explored whether the doctrine of separation of powers precluded it from pronouncing on the conduct of the legislature. Throughout its judgment, the CC emphasized that the state "must

respect, protect, promote and fulfil the rights in the Bill of Rights". It noted the strained relationship between the government and treatment activists with concern. Remarking that, "it is regrettable (to note) the degree of animosity and disparagement" between the parties. "(The) animosity on the papers bedevil(s) future relations between Government and non-government agencies that will perforce have to join in combating the common enemy." (TAC Con Court case, at para 20)

In interpreting the scope of the section 27 right, the Court emphasized that due regard must be paid to South Africa's historical and social context when interpreting socio-economic rights. It highlighted that these rights exist to address the basic needs of people first, quoting Yacoob, J's averments in the *Grootboom* case:

"…The Constitution obliges the State to *act positively* to ameliorate…the deplorable conditions people live in throughout the country" (TAC Con Court case at para 31).

The judge explained that,

> As far as the rights of access to housing, health care, sufficient food and water, and social security for those unable to support themselves and their dependants are concerned, the State is obliged to go beyond available resources or to realise these rights immediately…(TAC Con Court case at para 31).

He emphasized that the,

"State must foster conditions to enable citizens to gain access (to basic services) on an equitable basis…" and that "those in need have a corresponding right to demand that this be done" (TAC Con Court case at para 31). It is worth highlighting that Yacoob, J, argues that citizens have a right to demand socio-economic entitlements – which are often, almost dismissively, referred to as service delivery protests.

Throughout its judgment the Court emphasized the duties of the state (both positive and negative) to provide for vulnerable and marginalized citizens, as well as the negative duty to desist from irrationally denying citizens access to basic health needs, such as free Nevirapine. It pronounced that sections 26 and 27 conveyed self-standing rights and obligations on the state to act in pursuit of section 7 (2) as explained above.

Like the drafters of the Constitution, the CC acknowledged resource restrictions borne by developing countries like South Africa. It held that though citizens are entitled to vindicate their individual or group rights, "the state is not obliged to go beyond available resources to immediately realize socio-economic rights claims". It granted that provision of social services by the state had to meet the standard of "minimum core entitlements", a notion first formulated in the United Nations (UN's) International Covenant on Economic, Social and Cultural Rights (ICESCR) in 1966. About 164 countries were bound by the ICESCR in March 2015 (Lee 2015). Article 2(1) of the ICESCR stipulates that each signatory state must "progressively realize" its socio-economic rights obligations "to the maximum of its available resources".

Notwithstanding the qualification of the scope of the right, the CC highlighted that states can only successfully rely on the doctrine if they meet the peremptory onus of "[being able to] show proof that all reasonable steps were taken within [their] available resources to meet minimum core requirements." (TAC Con Court case at para 26) Turning to the Constitutional text, the CC reminded the government of its section 9(2) duty. The subsection states that "(e)quality includes the full and equal enjoyment of all rights and freedoms." It further provides that "(t)o promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken." The CC read the notion of human dignity into its exposition of the notion of "minimum core entitlement".

It held, that "minimum core must be consistent with human dignity…No one should be condemned to a life below the basic level of dignified human existence" (TAC Con Court case at para 28).

2.6 Constitutional supremacy and the importance of socio-economic rights

Pronouncements of the South African CC in the TAC case served to further entrench socio-economic rights and the entitlements they bestow. Through its deliberate argumentation the CC clarified that the Constitution is the supreme law of the land. It also emphasized its role as the enforcer of constitutional values and principles even against the executive arm of government. Furthermore, the CC showed that the doctrine of separation of powers would not make it shy away from issuing, where appropriate, mandamus orders against the government in instances where there is clear evidence that the latter's policies unreasonably exclude a significant segment of society from equal enjoyment of fundamental human rights (TAC Con Court case paraphrase para 33). In a landmark decision, the CC upheld the TAC's constitutional challenge to the government's dogged refusal to implement Nevirapine treatment to combat MTCT of HIV/AIDS (Kriegler 2014). Reflecting on the events of 15 December 2002, Kriegler, J, who was one of the judges in the matter, states;

> Were it not for the efforts (of the TAC) the happy outcome for many thousands of mothers and their babies might well have been different and many more could have been condemned to a painful and lingering death by mindless government policy (Kriegler 2014, 47).

Writing on occasion of the tenth anniversary of the free ARVs treatment programme in South Africa Kriegler, J, recalls

> The manner of the TAC's victory over the forces of obstruction was an example for human rights activists everywhere. The genius lay in the two-pronged strategy of combining dignified and disciplined public demonstration with skilled and sharply focused constitutional litigation: thousands of marchers proclaimed their HIV status (or sympathy) while their rights were being forcefully asserted in court
>
> (Krieger 2014: 47).

2.7 Hazel Tau challenges multinational pharmaceutical patents through the Competition Commission

On 19 September 2002 Hazel Tau and 10 other applicants filed a complaint with the Competition Commission against GlaxoSmithKline SA (Pty) Ltd (GSK) and Boehringer Ingelheim (Pty) Ltd (BI) and/or their related companies in South Africa. (Section27, 2003b) The applicants included the TAC, trade union federation the Congress of South African Trade Unions, the Chemical Energy Paper Printing Wood Allied Workers Union, the AIDS Consortium, Hazel Tau and three other people living with HIV/AIDS, and four healthcare workers. Their complaint alleged that the respondents were charging excessive drug prices for ARVs and that their prices denied poor patients access to essential medicines. The complainants also alleged other infringements of section 8 of the Competition Act of 1998.

After reviewing the allegations and supporting evidence before it, the Competition Commission agreed that there was a case to be answered for abuse of dominance per sub sections 8(a)-(c) of the Act. It referred the matter to the Competition Tribunal. The respondents entered into settlement negotiations with the applicants a year after proceedings had commenced. Legal agreements were concluded with both respondents in exchange for the withdrawal of the matter from the Competition Tribunal. GSK and BI agreed to several ground-breaking undertakings that

extended access to essential ARVs to millions of poor HIV/AIDS patients in South Africa and other sub-Saharan countries. The key gains were;

(a) significant reductions in medicines prices;

(b) the number of voluntary licences issued to generic drug manufacturers rose from one to seven - the licences authorized generic manufacturers to produce and/or import, sell and distribute the ARV medicines AZT and lamivudine;

(c) royalty fees were capped at no more than 5% - marking a significant decrease from the 30% and 15% demanded by GSK and BI respectively for their HIV patents;

(d) the patent holders permitted generic manufacturers to export ARVs to other sub-Saharan African countries;

(e) generic manufacturers were also allowed to distribute their products to both the public and private health sectors in South Africa and;

(f) licensees were granted permission to manufacture triple-drug fixed dose combination tablets – which made it easier for patients to be treatment compliant ("*Hazel Tau & Others"* Section27.org.za, 2003)

2.8 Conclusion

The issue of pharmaceutical patents and access to essential medicines is a vexing challenge in South Africa and other developing countries. About two-thirds of the world's population lacks regular access to affordable medicines. The exorbitant prices charged by multinational pharmaceutical companies for patented drugs exacerbate global treatment disparities. The issue has been sharply highlighted by the South African HIV/AIDS epidemic and the subsequent struggle for ARVs. Human rights lawyers and other supporters established the AIDS Consortium and other key HIV/AIDS organisations to develop human rights approaches to employment law

and national law generally. The deft use of the law, by the TAC, as a tool for health equity and social justice is said to have "laid the foundation of the current [global dialogue on] pharmaceutical patent and access to medicines" (Halbert 2002).

Big gains were made after the Pretoria High Court and CC directed the ANC government to provide free access to ARVs in the public sector. Subsequent anti-monopoly challenges to the Competition Commission and Competition Tribunal led to significant pro-public interest compromises between treatment activists and the multinational pharmaceutical manufacturers. However, the tensions of 1997 to 2001 were reignited in January 2014 after the (Mail and Guardian newspaper , 2014) published the contents of a leaked industry email detailing an alleged plot by a group of 24 multinational pharmaceutical manufacturers to subvert South Africa's Draft Patents and Intellectual Property laws. This new standoff creates an opportunity for new research to explore how the exercise of pharmaceutical patent rights ought to be balanced with public interests responsibilities of providing access to essential medicines to all who need them. The news story, popularly knowns as *pharmagate*, and its ramifications will be discussed in detail in Chapter 3, as will be the domestication of the international law pertaining to the right-to-health and the impediments imposed by international trade agreements and trade policies.

CHAPTER 3: THE DIS-EASE BETWEEN INTERNATIONAL HUMAN RIGHTS LAW, RIGHT-TO-HEALTH PROVISIONS AND TRADE AGREEMENTS. WHY DOES PATENT LAW REFORM IN SOUTH AFRICA UNSETTLE MULTINATIONAL DRUG-MAKERS?

1.2 Introduction

Good health and well-being are desired by most human beings. For many people being happy is synonymous with freedom from mental and physical disease. Poor health is undesirable because it diminishes people's enjoyment of life – because it can interfere with their ability to achieve their goals and aspirations. This conception of the value of good health in human development led to the establishment of the right-to-health at international human rights law. The right is classified by the UN Office of the High Commissioner for Human Rights (OHCHR) as a fundamental human right and an essential component of human dignity (OHCHR 2008). It was first articulated in the Constitution of the WHO in 1946 (OHCHR 2008).

The preamble of the WHO Constitution frames health holistically as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (OHCHR 2008:1). Furthermore, international law confers the right-to-health equally on all human beings, without unjustifiable discrimination based on amongst others class, gender, geographic location or race. Regrettably, this comprehensive understanding of the right-to-health and the universal entitlements it confers on world citizens tend to be lost in modern global and public health discourses. The WHO Constitution stipulates that *"*everyone has the right to the enjoyment of the highest attainable standard of physical and mental health*"* (OHCHR 2008:1) In addition, right-to-health entitlements are contained in other international law instruments like Article 12 of the ICESR adopted in 1966 and its General Comment 14 adopted in 2000. Most of

these key international instruments have been adopted into the regional and domestic laws of many countries, including South Africa.

The Organisation of African Unity (OAU) - the predecessor on the African Union (AU) adopted and introduced the international law right-to-health provisions into African regional law on 27 June 1981. The right is contained in Article 16 of the African Charter of Human and People's Rights (ACHPR). It was entered into force on 21 October 1986 (Kiapi, 2005:1). Article 16(1) is almost a verbatim rendition of the WHO's notion of equitable access to the highest standard of health for all right bearers. Article 16(2) obligates member states to take steps to protect the health of their citizens. (Kiapi, 2005) Reading Sandra Kiapi's interpretation of the right-to-health in the African Charter shows how closely the content and scope of the regional right-to-health provisions mirror the key international health law instruments named above. As a member state of the UN and the AU, South Africa is bound by the health duties imposed by both legal institutions.

This chapter will critically appraises the domestication of the international law right-to-health into South African law, highlighting how the country's courts have interpreted the state's duties and responsibilities in respect of the right-to-health. Secondly, it will critically appraise how international trade agreements and investment policies can interfere with a state's ability to fulfil its right-to-health duties – from both legal and moral perspectives. Thirdly, it will discuss the fall-out caused by the publication of a leaked e-mail that revealed the multinational pharmaceutical manufacturers' extensive plot to undermine IP law reforms in South Africa. The underhanded plot is popularly known as *pharmagate* – a term that will be used in this report.

3.2a Background to the right-to-health in international law

The right-to-health, at international law, first finds expression in the preamble of the WHO Constitution of 1946. Also, Article 25(1) of the Universal Declaration of Human Rights recognizes the right-to-health as an essential part of an adequate standard of living. The Article grants universal entitlements to the right and expressly offers non-discriminatory inclusion for all. On 15 March 2006 the United Nations (via resolution 60/251) established the Human Rights Council (HRC) which replaced the Commission for Human Rights. In recent years the HRC has placed greater focus on promoting and safeguarding the right to the highest attainable standard of health (OHCHR 2008). Its predecessor had created "the mandate of Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health" in 2002 (OHCHR 2008). It also adopted new measures to delineate the right and to map out relevant legislative and public policy frameworks which signatories to right-to-health treaties ought to incorporate into their national health and other health related laws.

3.2b Scope and content of the right-to-health in international law

According to the UN OHCHR, many tend to conceive of the right-to-health solely as the provision of access to healthcare and the provision of healthcare infrastructure (OHCHR 2008). The UN body outlines the its key aspects of the right-to-health, namely that it is an inclusive right, which contains freedoms and entitlements, as well as a peremptory requirement of the provision of health services, goods and facilities to all without discrimination.

Furthermore, it mandates that all goods and facilities must be available, accessible and of good quality (OHCHR 2008) (Emphasis added). At its core, the right-to-health requires close consideration of all key factors that are essential to assisting individuals to have an adequate quality of life. The Committee on Social, Economic and Cultural Rights (the monitoring agency

for the ICSER) refers to these building blocks as the underlying determinants of health (OHCHR 2008). They include: safe drinking water and adequate sanitation, safe food, adequate nutrition and housing, healthy working and environmental conditions, health related education and information and gender equality (OHCHR 2008).

Equally important, healthcare recipients have entitlements which include the freedom to withhold consent to treatments, freedom to withhold consent to forced sterilization, freedom to decline to participate in medical research that violates their right to bodily integrity and the freedom not to be subjected to cruel, inhuman and degrading treatment or punishment (OHCHR 2008). They are also entitled to the provision of "equitable opportunities that give them access to the highest standard of health, rights to disease prevention, treatment and control, access to essential medicines, provision of adequate maternal, child and reproductive health services and participation in health decision-making." (OHCHR 2008)

The WHO (1946) mandates that everyone must be granted access to timely, acceptable and affordable healthcare of appropriate quality. It enjoins states to take proactive measures to meet the four fundamental requirements of the right-to-health, namely availability, accessibility, acceptability and quality. The availability requirement stipulates that states must provide "a sufficient quantity of functioning public health and healthcare facilities". The accessibility requirement stipulates that healthcare must be accessible to all who need it free from barriers like unjustified discrimination, high costs, physical inaccessibility or inadequate information. The acceptability requirement safeguards respect for health ethics, cultural and gender sensitivities (WHO: 2015, Factsheet No 323). Finally, the quality requirement stipulates that health services and products must be medically and scientifically appropriate and of good quality (WHO: 2015, Factsheet No 323).

International law right-to-health provisions further impose three key duties on state parties, namely to respect, protect and fulfil their right-to-health obligations (WHO). The duty to "respect" forbids governments from acting in ways that infringe on the right-to-health. By contrast, the duty to "protect" obligates states to ensure that third parties do not infringe the right-to-health. Finally, the duty to "fulfil" requires states to take proactive measures to ensure the realization of the right-to-health. General Comment 14 of the ICESCR expressly outlines the "core content" of the right. It lists the healthcare basics that governments must provide.

Other core obligations include a peremptory requirement that states develop and implement national public health strategies that meet the health needs of all citizens. International law right-to-health obligations are progressively realisable within each state's available resources. This means that, even though the right-to-health is a core human right entitlement of every person, states do not have a duty to immediately meet all healthcare needs. The drafters of the health-related international law instruments were cognisant of other socio-economic obligations and the resource constraints that governments operate under, particularly in developing and least developed countries.

3.3 The right-to-health in South African law, domestication and application of international law right-to-health precepts

Section 231 of the Constitution Act of the Republic of South Africa, 1996 makes provision for international agreements the Republic has signed to be incorporated into domestic law, once they have been approved by Parliament - such agreements then become binding on the country once they have been thus enacted (Constitution, 1996). In the same vein, section 232 prescribes that customary international law is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament. The right-to-health provisions enshrined in various global health law

and international human rights instruments like the WHO Constitution, Article 12 of the ICESCR and in General Comment 14 are domesticated into national law through section 27 of South Africa's constitution. Like its international law sources, South African right-to-health entitlements include universal access to basic health and human welfare services like reproductive health (section 27(1)(a)), sufficient food and water (section 27(1)(b)) and social security, including social assistance for those who are unable to support themselves or their dependants (section 27(1)(c)).

State obligations in respect of the right-to-health are expressly set out in section 27(2) – which stipulates that "the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights". Section 27(3), further, outlaws the refusal of emergency medical treatment to anyone who needs it. The scope and applicability of the right-to-health has been vindicated in the two landmark CC cases of *Soobramoney* and *Treatment Action Campaign* - heard in 1997 and 2002 respectively. (The latter case was dealt with extensively in Chapter 1). In Soobramoney both the Court of first instance and the CC explored the scope and reach of section 27 - adjudicating the matter by closely relying on the right-to-health provisions provided for at international human rights law. Briefly, the facts of the case were as follows: The appellant Mr. Soobramoney was an unemployed man with multiple severe and advanced stage health conditions. He sought the Courts' assistance in compelling the Province of KwaZulu-Natal to enroll him on a renal dialysis treatment programme offered at a public hospital. Soobramoney based his claim on section 27(3) – which stipulates that "*no one* may be refused access to emergency medical treatment", and section 11 of the Constitution – which grants everyone the right to life (Emphasis added).

In its judgment, the CC acknowledged that,

> [South Africa is a] society in which there are great disparities in wealth. Millions of people are living in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services" (Soobramoney CC at para 8). The Court further noted that gross social disparities existed before the Constitution was formally adopted in 1996. It emphasised that it recognised the post democratic government's commitment to transformation and social justice (Soobramoney CC at para 8). In addition, it highlighted that the state had limited resources and that an "unqualified obligation to meet (health and other socio-economic) needs would not presently be capable of being fulfilled (Soobramoney CC at para 11).

In keeping with international law health provisions the CC highlighted that section 27(3) does not impose a duty on the state to protect citizens from the natural ravages of ill health and human decay by providing terminally ill patients like Mr. Soobramoney with access to emergency treatment in order to prolong their lives (Soobramoney CC at para 12). The applicant had sought to have the right to life, entrenched in section 11 of the Constitution, read into the state's duty to provide him with emergency medical care as stipulated in section 27(3). The CC held that the right to life does not entitle financially destitute terminally ill patients to compel the state to grant them free access to life-saving treatments they cannot afford (Soobramoney CC para 14). The Court emphasized that reading the right to life (section 11) into the right-to-health (section 27), as the appellant asked it to, would impose obligations on the state that were not intended by the drafters of the Constitution.

The bench proclaimed that the drafters of the Constitution developed the document mindful of the country's historical and social contexts and of the resource constraints the new democratic

administration would have to urgently attend to (Soobramoney CC: 8-9) In its judgment, the CC undertook a delicate balancing of rights, expressly probing the state's obligations and simultaneously highlighting the difference between negative and positive duties. The Court held that broader health and social interests necessitated that the state should not expand its limited resources to ameliorate the human suffering of an individual to the potential detriment of "everyone" owed right-to-health entitlements, per sections 27(1) and (2). Furthermore, the Court pronounced on the actual costs of providing dialysis treatment. Arriving at the conclusion that seeking to meet the medical needs of "*all patients claiming access to expensive medical treatment or expensive drugs, (would necessitate that) the health budget (be) dramatically increased to the prejudice of other needs which the state has to meet*" (Soobramoney CC at para 28). Delineating the reach of its mandate, the CC in *Soobramoney* expressed its reluctance to meddle with the independence of doctors and public health policy-makers to develop evidence-based public health policies and to make essential treatment decisions. It stressed that would be "slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with (these matters)" (Soobramoney CC at para 29).

The Court commented on the adverse impacts of prevailing South African wealth disparities on access to healthcare. It stated that "(t)he hard and unpalatable fact is that if the appellant were a wealthy man he would be able to procure such treatment from private sources; he is not and has to look to the state to provide him with the treatment" (Soobramoney CC at para 31). The afore-going statement eloquently summarises the Court's appreciation of how high costs act as barriers to access to essential treatments for poor and gravely ill patients who do not qualify for state assistance. It held that though it was sympathetic to the plight of Mr. Soobramoney and his family, its judicial duty was to be mindful that "the state's resources are limited" and that the

department of health in KwaZulu-Natal has clear guidelines for which patients qualify for state sponsored renal dialysis treatments. It confirmed that the appellant did not meet the criteria for admission to its programme. The Court also acknowledged that Mr. Soobramoney was not unique in his lack of financial resources to purchase the private healthcare which might prolong his life. It also acknowledged that "many others . . . need access to (other essential services) like housing, food and water, employment opportunities, and social security – services which the state is obligated to provide" (Soobramoney CC at para 31).

I have discussed the Soobramoney judgment in detail to illustrate how closely the South African right-to-health jurisprudence follows the precepts of international human rights law. It is clear from its pronouncements that the CC denied the relief sought by following the letter of international health jurisprudence and the relevant provisions as incorporated into domestic law by section 27.

The Court expressly pronounced on how wealth disparities, chronic poverty and inability to procure expensive treatments denied Mr. Soobramoney and other poor patients affordable access to healthcare. Below is a discussion of how widespread the problem is globally, and claims of how pharmaceutical patents and the exorbitant prices of essential drugs aggravate global health disparities.

3.4 How a lack of regular and dependable access to affordable medicines impacts poor patients

Forman and Kohler estimate that about two billion people around the world lack access to essential medicines. They claim, "this deprivation causes immense and avoidable suffering, ill health, pain, fear and loss of dignity and life" (Forman and Kohler 2012: 26). The authors argue

that gross inequality in access to medicines is an overriding feature of the pharmaceutical situation.

A WHO report (2004: 151) found that in 1999, "15% of the world's population who live in high-income countries purchased and consumed about 90% of total medicines, by value". The UN body further states that the growth in sales and consumption in rich countries reported in the intervening period was in contrast with dropping sales and consumption in low-income countries. Several health equity writers and activists argue that these gross global disparities in access to essential treatments are caused by the multinational pharmaceutical manufacturers' insistence on stringent patent protections (Cameron 2005, Geffen 2010, Forman and Kohler 2012). Some have asked whether would be legally right to limit the exercise of pharmaceutical patents in developing countries to facilitate the provision of regular and affordable access to essential medicines for life-threatening diseases like HIV/AIDS (Cameron 2005: 168). They argue that such legal infringement might be justifiable because of the special nature of pharmaceutical patents (Cameron 2005, Forman and Kohler 2012) Secondly, do or should public interest considerations – to give provide essential treatments to all who need them, trump demands for stringent pharmaceutical patent protections in developing countries? These questions address the tensions inherent in seeking to balance the pecuniary interests of drug makers and the need to uphold the health and human rights of all persons. Patricia Illingworth poignantly captures the ethical-legal tensions in the patents and access to medicines debate through her assertion that, "shareholder claims do not override the life-and-death claims of the sick and dying" (Forman and Kohler 2012: 11).

3.5 The health impacts of pharmaceutical patents, bilateral trade and investment agreements

Unlike the health equity activists above, multinational pharmaceutical manufacturers and their supporters argue for stringent IP protections. These they claim will encourage more innovation in their industry. Roy Levy and Abraham Wickelgren of the Federal Trade Commission argue that "it is hard to think of many industries that have contributed as much to human welfare as the pharmaceutical industry. The importance of the industry makes the job of the competition authorities that much more difficult and important" (cited by Grabowski 2002: 849). Grabowski (2002: 851) claims that there is accumulating empirical evidence to prove that the introduction of new drugs has substantively improved human beings' quality of life. In his detailed exploration of the value of pharmaceutical patents in drug development the author asserts that a survey of UK R&D managers conducted by economists Taylor and Silberston "estimated that pharmaceutical R&D expenditures would be reduced by 64% in the absence of patent protections. By contrast, the corresponding reduction was only 8% in other industries". Grabowski (2002) further states that, Edwin Mansfield's survey of a 100 US research directors noted the same trends. In his 2003 study with research colleagues Joe DiMasi and Ron Hansen, Grabowski posits that patents are essential in the pharmaceutical industry because they offer necessary and legitimate compensation for the high costs of R&D – which leads to innovation and ultimately to the manufacture and sale of new drugs (DiMasi et al. 2003).

Grabowski (2002: 851) elaborates,

> The explanation why patents are more important to pharmaceutical firms in appropriating the benefits from innovations follows directly from the characteristics of the pharmaceutical R&D process. In essence, it takes several hundred million dollars to discover, develop and gain regulatory approval for a new medicine. Absent patent

> protection, or some equivalent barrier, imitators could free ride on the innovator's FDA [Federal Drug Administration] approval and duplicate the compound for a small fraction of the originator's costs. In essence, imitation costs in pharmaceuticals are extremely low relative to the innovator's costs for discovering and developing a new compound.

It is worth noting the singular importance that Grabowski places on investment costs and the need to protect the commercial interests of innovators from what he characterises as wanton encroachment from generic manufacturers. Grabowski (2002: 853) further highlights that "most countries with innovative industries" (including the US) have enacted "patent term restoration laws" to compensate originators for commercial benefit time lost in the FDA approval process. These restoration laws are necessary he explains, because an average new drug enjoys monopoly protection of an average effective lifespan of 12 years – shaving 8 years off the legal patent validity term of 20 years (Grabowski 2002: 853).

Attention is drawn to the fact that Grabowski's exposition of the notion of patents does not as vigorously highlight the (equally important) value of innovation in the public interest. His omission is in sharp contrast to Edwin Cameron's (2005) deep defence of the import of the notion of public interest inherent in the patent system. Cameron, a South African CC judge and world acclaimed legal scholar, explains, "patents are created for the public benefit: the theory is that the state grants a patentee a limited statutory monopoly so as to encourage inventors to put their inventions into practice (because by doing so they obtain the financial rewards their inventive efforts warrant) (Cameron 2005: 68). He ruefully observes that, "…*current advocates of extended enforcement of patent rights do not always emphasise the benefit to the public – which is an essential part of the theory*" (Emphasis added). Applying the legal intention which

led to the development of patent law to the access to affordable medicines debate, Cameron (2005: 168) continues,

> (s)o the important question in access to AIDS medications is not whether there should be patent protection – on this everyone agrees – but whether patent protection has become too great. *And the question is whether the profits patents earn for their inventors are not disproportionately vast, given the public benefit that underlies the system, and the terrible suffering and death that results from too-stringent protection* (Emphasis added).

In response to sympathetic arguments proffered on behalf of the multinational pharmaceutical manufacturers, Cameron (2005: 168) notes, "[t]he pharmaceutical industry is not only defensive of its 'turf' but aggressive about expanding its 'turf' throughout the world."

It is interesting to juxtapose Cameron's protection of "turf" observation with Grabowski's (2002: 851) earlier statement that "without patents imitators could free ride on the innovator's FDA approval" and that they would reap undue pecuniary benefits from the innovator's high capital investment in R&D.

The discussion above illustrates the different emphasis the two sides in the pharmaceutical patents and access to medicines debate places on the value of patents. Defenders of patents place primary value on the legal protections patents offer patent holders. By contrast, treatment equity activists invoke the public interest value of pharmaceutical patents – namely to create knowledge for the production of new medicines.

Regardless of where one's sympathies lie, it is important to remember that, in law, a patent is a licence issued by a state entity under stipulated conditions. It is not an entitlement owed the applicant or a patentee. They can be revoked by the grantor. It is important to emphasis that,

patents grant "limited statutory monopoly to encourage inventors' inventions into practice so that they can derive financial reward for the fruit of the intellectual capital" (Cameron 2005: 168). They are "an exclusive right to use knowledge" – created by law.

Cameron (2005: 168) further highlights that IP differs from other tangible forms of property that enjoy legal protection. He writes,

> it is misleading to equate patent rights with traditional forms of property such as land. For one thing, and and other resources are limited. And vulnerable: most movable forms of property can be destroyed. *Knowledge by contrast is unlimited in time and extent – it can be replicated indefinitely and cannot be destroyed*. For one person to have a finite resource such as food or land another must not have it. This exclusivity of possession requires implied or express force – in order to keep others out. But knowledge is entirely different. Once an idea is publicly known, no force is needed to appropriate it. It is intangible. And it is replicable. So ideas are susceptible to non-coercive appropriation through copying. *It is only by creating exclusive property rights in knowledge – and thus creating scarcity – that knowledge is transformed into a limited resource. Knowledge can command a price only once it is accorded commodity status. But unlike other forms of property, scarcity is not physical – it is created by the laws that the state enacts. So patent rights have less moral force than other forms of property rights* (Emphasis added).

His argument that commodification of knowledge creates its monopoly exploitation for profit, is compelling. The business meaning of the term is aligned with Cameron's legal framing. In a business context a patent is a,

> (r)evocable written (formal) or implied agreement by an authority or proprietor (the licensor) not to assert his or her right (for a specific period and under specified

> conditions) to prevent another party (the licensor) from engaging in certain activity that is normally forbidden (such as selling liquor or making copies of a copyrighted work). Intellectual property licences generally mean that the licensor will not invoke ownership protection laws if the licensed property (art, design, patent, etc.) is copied, sold or used by the licensee. A license is not a right, because the licensor may not have the legal power to give all necessary permissions that constitute a legal right... (Business Dictionary.com)

The Patent Office of England claims that, "Britain has the longest patent tradition in the world" (cited by Cameron 2005: 161). Modern day tensions about "the advantages and disadvantages of patents were familiar to thinkers in sixteenth and seventeenth century England. Those wanting to start businesses in competition opposed the system" (Cameron 2005: 161). He elaborates: "(i)n 1623, the Statute of Monopolies outlawed the grant of exclusive industry rights. But there was one exception - for inventions: inventors were granted exclusive rights for fourteen years" (Cameron 2005: 161). Today the time period has been extended to a minimum of 20 years in Europe and South Africa.

In South Africa patents are regulated by the Patent Act No 57 of 1978 and Patent Regulation of 1978. According to the Act, "a patent confers on the patentee for the duration of the patent, the right to exclude all other persons in South Africa from making, using, exercising, disposing of or offering to dispose of, or importing the patented invention, so that the patentee shall have and enjoy the whole profit accruing by reason of the invention" (Adams and Adams 2012: 501). A patent can be revoked by an application launched by any person. Patentees many assign or licence (through a voluntary licence) their rights to another party (Adams and Adams 2012: 506). Rights assigned to a third party terminate when the original patent expires, lapses or is revoked.

3.6 Patent protections and responsibilities in international law: A brief overview of the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Rights (TRIPS)

In international law, patents are governed by a regulatory framework introduced by the WTO. The system is known as TRIPS, which was signed in Marrakesh on 15 April 1994 (Cameron 2005). WTO members who are signatories to TRIPS are obliged "(to) progressively implement …minimum standards of protection for intellectual property" (Cameron 2005: 166). Most developed nations already had established patent systems. By contrast, explains Cameron (2005: 166), many developing countries would have "to introduce substantial changes" to their legal systems. Health equity writers have argued that TRIPS introduced a global IP regulatory system to pressurize developing countries to implement stringent patent legal mechanisms that are not in their national interests. Obijiofor Aginam, cited by Forman and Kohler (2012: 9), argues that the introduction of TRIPS "firmly pitted corporate profit against vulnerable populations living with HIV/AIDS globally, human rights to life against intellectual property rights, and civil society groups against transnational pharmaceutical corporations". Cameron (2005: 166) adds that, displeasure with the TRIPS compliance obligations led developing countries to mount fierce challenges to the newly introduced global IP framework, culminating in the signing of the Doha Declaration in in November 2001. The latter extended the TRIPS related law reform deadline in least-developed nations to 2016. It also introduced the right of countries to compel patent-holders to allow competition, when faced with public health emergencies. Explaining the courts' power to issue compulsory licences under the Doha Declaration, Cameron writes,

> Under this power, a pharmaceutical company can be compelled to licence a competitor to produce, import or sell generic versions of a patented medicine" (Cameron 2005:

> 167). The Doha Declaration also introduced a key pronouncement on IP and public interest by affirming that the "TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all (Cameron 2005: 167).

Cameron (2005: 167) states, "this (addition) enshrines the principle the WHO publicly advocated and advanced – the right of WTO members to make full use of the safeguard provisions of the TRIPS Agreement to protect public health and enhance access to medicines".

I have given a detailed history of the legal system of patents, and of the domestic and international law frameworks within which patents are meant to operate, as well as sought to highlight how differently patent holders and treatment access activists frame the primacy of pharmaceutical IP protections. The tensions between the parties are not always politely framed. Health equity advocates claim that multinational pharmaceutical manufacturers do not always conduct themselves fairly when exercising their patent rights. As mentioned in paragraph 5 on page 43, Cameron (2005: 168) maintains that the industry is "defensive of its 'turf'" and "aggressive about expanding throughout the world". The industry's legal proceedings against the Republic of South Africa in 1999 (extensively dealt with in chapter 1) and against the Union of India in 2008, 2013 and 2015 for alleged patent infringements, seem to strongly support Cameron's assessment (Hestermeyer 2012, Indian Case Laws.org website, Médecins Sans Frontières website, Anand 2015).

Pharmaceutical patents litigation has been seen in other parts of the world too, for example in India, where Switzerland's Novartis and Roche and Germany's BI have mounted ferocious legal challenges against the nation similar to what they did against South Africa. The Indian cases also attracted scathing moral outrage from global treatment access campaigners. India's dogged

refusal to recognize patents on some of the multinational pharmaceutical manufacturers' most profitable medicines has led to diplomatic tensions with its European and US counterparts. The litigants and their supporters have accused the Union of India of failing to adhere to global IP rules. Some have cautioned that India's tough stance is starting to affect its foreign direct investment opportunities. Wall Street Journal writer Geeta Anand notes, "(t)here can be no denying that being tough on patents could cost India substantially in foreign investment—and that means lost jobs and growth" (Anand, 2015).

3.7 Multinational pharmaceutical manufacturers wage a new patent turf war in South Africa through an underhanded transnational plot popularly known as "pharmagate"

It is an open secret that the South African and Indian governments have come under increased pressure from US investment, political leaders and the multinational pharmaceutical industry over their proposed IP law reforms in the public interest. South Africa's draft IP policy was circulated for public comment in September 2013. Some key aspects of it did not find favour with multinational drug manufacturers. In January 2015 Knowledge Ecology International (KEI), a US non-profit organisation specializing in IP and access to medicines, obtained a copy of a leaked email dispatched on 10 January 2014. It was sent by Michael Azrak, Merck's Managing Director for Southern and East Africa, to 24 multinational drug and medical devices companies operating in South Africa (Love 2014). This writer had reliably learned, from a senior public official, that the *pharmagate* email was first leaked to government before it was circulated to KEI and the Mail and Guardian newspaper – the latter then publicized it and thereby getting the pharmaceutical industry's underhanded intentions in the public domain. In his now infamous email Michael Azrak outlined the industry's detailed plot to delay the passage of South Africa's "Draft National Policy on Intellectual Property" legislation. The email further bought to light that

a Washington based consultancy and lobbying firm called Public Affairs Engagement (PAE) had devised a nine page media plan titled 'Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa'. This plan was shared with more than two dozen key companies in the pharmaceutical sector. PAE specifically sought to undermine the treatment access advocacy work of international non-profit Médecins Sans Frontières (MSF) and two of its South African counterparts - TAC and Section 27 (Love 2014).

Under the heading "key objectives of the campaign" the email stated that, "(t)he overall campaign is aimed at delaying the finalization of the IP policy by the Cabinet until after the 2014 election." The contents reveal an equally calculated intention to instill public fear about the trumped up adverse repercussions of the proposed IP reforms. Azrak informed his pharmaceutical sector colleagues that the key element of the campaign was to "(m)obilize voices inside and outside South Africa to send the message that the proposed IP policy threatens continued investment and thus economic well-being". He explained that the US lobby group PAE, in cahoots with the Innovative Pharmaceutical Association of South Africa (IPASA) and its industry ally the Pharmaceutical Research and Manufacturers of America (PhRMA), aimed to run an "energetic campaign" to mobilize grassroots support for the sector's resistance to South African IP reform. Azrak explained that the aim was to make the messaging of the drug manufacturers' plot "fee(l) like a political campaign". The timing of the public misinformation campaign was designed to coincide with other public events held during the lead up to the country's general elections scheduled to be held on 7 May 2014.

The Mail and Guardian newspaper's publication of the leaked email sparked outrage from the Minister of Health Dr. Aaron Motsoaledi and the three non-profits targeted for discrediting by pharma. (Mail and Guardian 2014) According to the newspaper, Minister Motsoaledi "accused

(the) multinational pharmaceutical companies active in South Africa of conspiring against the state, the people of South Africa and the populations of developing countries - and of planning what amounts to mass murder." It was further reported that Motsoaledi referred to the alleged plot as "genocide", emphasising, "I am not using strong words; I am using appropriate words. This is genocide" (Mail and Guardian, 2014).

IPASA issued a media statement a day later disputing that it had engaged PAE's services. It also said that the agency's proposal had been rejected. It maintained that "[t]he draft IP Policy is a matter of vital importance to the future of the healthcare sector in our country and to all other innovative industries in South Africa." In short, the pharmaceutical industry body vigorously sought to reassure Minister Motsoaledi and the Department of Trade and Industry (DTI) of its support for the "broad objectives of the draft national policy on IP" (Love 2014).

In turn, the TAC, Section 27 and MSF each issued a media statement, on 18 January 2014, condemning what they collectively characterized as the multinational pharmaceutical manufacturers' "unethical undermining of South African law reform aimed at improving access to essential medicines" (*Fix the Patent Laws Campaign* website, 2014).

Robust media exchanges between the drug manufacturers and treatment access activists continued for a number of days after the plot was publicised. The TAC issued an updated statement on 21 January 2014 rebutting IPASA's claim that it had rejected the PAE proposal. The non-profit vociferously asserted that the leaked email "provides damning evidence that IPASA had been misleading the public on three key points since the story broke on Friday." The TAC's highlighting IPASA's flagrant dishonesty with the public further undermined its claim that it "…was formed from a desire for a credible, respected (South African pharmaceutical) association to engage with stakeholders in both the private and public sectors" (IPASA website).

Furthermore, the TAC rebuttal cast aspersions on IPASA's stated commitment to *"ethical conduct and practices*" (Love 2015).

Rather than showcase IPASA's business leadership and ethical ethos the TAC statement starkly highlighted the lengths the association was willing to go to protect its public image – even if doing so involved spreading blatant falsehoods. Perusal of the "Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa" strategy document further lays IPASA moral integrity bare in that two critical points stand out. Firstly, the PAE proposal was expressly prepared for IPASA and PhRMA. Secondly, the author of the now infamous leaked *pharmagate* email, Michael Azrak, was the head of IPASA's Intellectual Property Committee and he enthusiastically endorsed the dubious *pharmagate* plot - and sought its implementation with "... *urgency"*. It is highly unlikely that Azrak would have reached advanced negotiations with PAE without authorization from his employers Merck and his IPASA industry colleagues. The contents of the strategy document make it patently clear that PAE, IPASA and PhRMA considered the sector hugely threatened by South Africa's proposed IP reforms. Its overriding message was that collective, decisive, international and immediate action was needed to stop South Africa from committing its "IP folly" (Azrak email 2015). The general consensus was that the industry's collective pecuniary interests needed vigorous protection.

Nothing material had been said publicly about *pharmagate* or where the IP law reform process was by August 2015, except for continued calls on government to show moral courage by enacting the proposed law reforms to speed up the provision of access to affordable medicines to all South Africans who need them. In the interim, the TAC issued a media statement on 2 June 2015 to announce that "twelve patient groups and leading organisations" had formally joined the

Fix the Patent Laws Campaign (FTPL) and that this significantly increased the social movement's base of supporters from three to fifteen (TAC website). On 26 October 2015, the FTPL Campaign addressed a formal letter to Minister Rob Davies, of the DTI, noting that two years had elapsed and no official public update had been issued on where the legislative reform process was. A detailed discussion on this and the DTI's overall handling of the reforms will be undertaken in Chapter 4.

3.8 Conclusion

This chapter explored the content and scope of the right-to-health in international law by highlighting some of the key global instruments related to it. It also provided a detailed analysis of how international law right-to-health provisions have been domesticated into South African law via the country's Constitution and judicial cases. I highlighted notable legal and ethical tensions that exist between international health law provisions and some global trade agreements, particularly TRIPS. My overall intention was to illustrate how the 1946 UN promise of the provision of the highest attainable standard of health to all, free from unjust discrimination, remains unrealized and unattainable for most patients and vulnerable communities around the world. Finally, I used events in South Africa, both historic and current, to illustrate how multinational pharmaceutical manufacturers' pecuniary interests can at times hamper developing states' ability to honour their UN and WHO right-to-health obligations, often with dire consequences for persons who cannot afford to purchase potentially life-saving treatments and medicines.

Chapter 3 will deal with some of the key moral challenges posed by multinational pharmaceutical manufacturers' (aided by the US government) sustained trade and foreign direct investment pressure on South Africa and India to compel them to abandon attempts to reform

their IP laws in the public interest (*"Don't Trade Away Our Health"* section27.org.za, 2015, Health Gap - Global Access Project, 2015).

CHAPTER 4: THE ADVERSE HEALTH IMPACTS OF MULTINATIONAL PHARMACEUTICAL MANUFACTURERS' INSISTENCE ON STRICT PATENT PROTECTIONS IN DEVELOPING COUNTRIES: A BITTER MORAL PILL

4.1 Introduction

Gross global health disparities lead to immense yet preventable human suffering. The WHO estimates that "at least a billion people suffer each year because they cannot obtain the health services they need" (WHO 2014). In addition, "about 150 million users of health services are plunged into financial catastrophe annually, and 100 million are pushed below the poverty line as a result of paying for the services they receive" (WHO 2014). The scale of deprivation and the ruinous economic effects of unaffordable health services and products pose pertinent ethical and legal questions, with the most important being, what joint duties key global health providers (public and private) have to ensure that the promise of the right to access to the highest standard of health is realized. Put differently, the access disparities invite everyone concerned with global health equity to frankly examine whether the right-to-health guaranteed in the preamble of the WHO Constitution of 1946, and later espoused in other UN human rights instruments, is enjoyed equally by all?

This leads to other pertinent questions such as: (1) whether state parties are substantively fulfilling their duty to respect and protect the right-to-health, as enshrined in the UN Constitution (1946), Articles 22 and 25.1 of the Universal Declaration of Human Rights of 1948, as well as the closely related right to life as provided for in Article 6(1) of the ICESCR, (2) whether states (as primary right-to-health duty bearers) can justifiably expect that non-state entities (like multinational pharmaceutical manufacturers) be held to joint duties to provide essential medicines to the world's poorest. Finally, (3) whether based on the widely held view that the prices charged by multinational drug-makers for patented drugs are

exorbitant and a barrier to health equity for the chronically poor, it would be ethically and/or legally justifiable to limit the exercise of pharmaceutical patents in developing countries to facilitate access to treatments. These key moral challenges are discussed in this chapter.

4.2 Reframing the language of global health to advance health equity

The right to the enjoyment of the highest standard of health "is *one of the fundamental rights of every human being*" (Gostin 2014: 20). However, careful scrutiny of the global health landscape shows that the UN's 1946 promise of universal health coverage for all has not been realised. Using South Africa as an example, it is reported that the country has a $29 billion healthcare industry, which is an estimated 8.5% of the country's GDP, yet 84 percent of the nation's population has no access to health insurance. About 14 percent (most of whom are relatively wealthy and white) have access to private health insurance – giving them preferential access to 70 percent of the country's medical specialists (Page 2015). The afore-mentioned in-country health disparities illustrate legal academic Lawrence Gostin's (2014: 13) assertion that the "health gap between the rich and the poor is pervasive and unjust, with few signs of improvement".

Health disparities in most areas of the world are rooted in social disadvantage (Gostin 2014) - meaning, those denied the enjoyment of the highest standard of health are often members of vulnerable groups – i.e., the majority of black South Africans, women and children, the old, the physically and mentally disabled, and the chronically poor in developing countries. Gostin (2014) argues that the status quo raises pertinent questions of social justice, inviting the questions posed above on the necessity of a moral enquiry into what ought to be done to transform global health to uphold the human dignity of persons currently denied equitable healthcare. In answer to the ethico-legal questions posed above, Gostin proposes that

"transforming global health law could dramatically improve health for all and reduce health inequalities" (Gostin 2014: 17). He envisages a robust exercise that interrogates the norms, institutions and processes that collectively inform current responses to the health needs of the world's population. He notes that at the moment global health governance systems are detrimentally and unfairly influenced by non-health international regimes – like trade, intellectual property and finance policies – and he posits that these external impacts need remediating (Gostin 2014). Legal academic Heinz Klug makes a similar argument in paragraph 5 below.

Gostin (2014: 18) advises health equity activists to invoke the law's language of rights – which he argues is useful because it confers entitlements, duties, rules of engagement, core standards and frameworks to measure compliance. He adds that substantive equality will be attained only when legal norms are twinned with moral obligations. Use of the language of rights, he argues, should be followed by a reorganization of governance structures and a robust interrogation of current normative values and practices in global health.

Gostin invites those of us concerned with current health disparities to perform a critical appraisal of the unequal power relationships created by the *concept of "health aid*" – by this term he means, the healthcare assistance given by rich countries to poor countries (Gostin 2014: 18). The notion of "health aid" is problematic, Gostin argues, because it "*presupposes and imposes an inherently unequal relationship in which one side is a benefactor and the other a dependent. This leads affluent states and other donors to believe that they are giving "charity", which means that financial contributions and programs are largely at their discretion*" (Gostin 2014: 18). His argument is similar to the one advanced by South African black consciousness writer Stephen Bantu Biko (1987) who robustly challenged the dependency syndrome created by black South

Africans' reliance on the benevolent interventions of white South Africans who sought to lead the liberation movement working to end apartheid. Writing in the 1970s, Biko – like Gostin – maintained that a radical overhaul of prevailing white power structures was required to ameliorate the power disequilibrium inherent in the South African society of his time. He maintained that the oppressed had to "question old (Western) concepts, values and systems" to effectively challenge their nation's social injustices. He added that "(blacks) have to evolve (their) own schemes, forms and strategies to fit the need and situation, always keeping in mind (their) fundamental beliefs and values" (Biko 1987: 137).

Both authors argue for a global paradigm shift (thought-transformation) which is predicated on the theory of distributive justice. At core, the requirements of justice impose obligations on the rich and poor, black and white, to take hands to remediate gross disparities – in whatever sphere of human life they occur (Biko 1987, Gostin 2014). They unequivocally assert, in the 1970s and 2010s respectively, that it is high time that interventions based on the notion of "aid" (benevolent assistance) be jettisoned in favour of a social justice approach to end human-dignity-sapping social disparities.

Access to medicines academics Forman and Kohler (2012), make a similar argument about what is required to substantively remedy the current gross disparities in access to drugs between the rich and the poor, the global north and south. They argue that global medicines disparities will not be remediated through the drug donations schemes (social responsibility programs) run by multinational pharmaceutical manufacturers. They propose instead, that the sector's human rights duties in respect of the right-to-health should be made legally binding – and that the drug-makers should be held to "joint responsibilities" ("correlative duties") with states to provide access to essential medicines for all who need them (Forman and Kohler

2012: 3). Gostin (2014: 30) uses the term "mutual responsibilities" to refer to a similar notion of shared obligations rich countries (*qua* the home countries of the world's largest drug manufactures) have to assist poor countries to meet their international law right-to-health responsibilities.

4.3 Why a justice approach is necessary to remedy global wealth and health disparities

Improving access to existing medicines could save ten million lives each year - four million of the people who lack access to essential medicines reside in Africa and Southeast Asia (WHO 2014). Medicine consumption and purchase rates differ greatly between rich and poor countries. On average high income countries have a per capita spending on medicines that is 100 times higher than in low income countries. High income countries reportedly spend about US$400 billion on medicines, compared to low income countries, which spend about US$4 billion (Forman and Kohler 2012: 26). Gross global disparities in medicines are unfair and unjust – and lead to unnecessary deaths and disabilities. Using cancer as an example, it is estimated that developing countries bear about two-thirds of the global deaths from cancer, "…and yet only 5 percent of the global resources expended on cancer are available to those countries" (Lawrence Shulman cited by Freedman 2014) The exclusion of large sections of humanity from equal enjoyment of right-to-health entitlements is an omission which contravenes international human rights law and ethical norms.

In his address to attendees of the African Breast and Prostate Cancer Summit held in Kenya, Kenyan President Uhuru Kenyatta noted that "it is estimated that of the African region's 804 million inhabitants**,** 12.4% will develop cancer before the age of 75 and that 90% of these cancer cases will occur after the age of 40" (Kenyatta 2015). He noted that due to lack of health information and early detection facilities on the continent, most Africans get diagnosed with late

stage disease at first consultation. "Worse still**,** most cancer patients in Africa have limited access to treatment**,** palliative care or even pain relief" (Kenyatta, 2015, website article).

Gross inequities in access to essential medicines call for urgent reforms of the current multinational pharmaceutical system – focusing on the issues of patents and drug R&D funding. The global access to medicines movement has grown steadily since the signing of TRIPS and the Doha Declaration, in 1994 and 2001 respectively. Civil society formations have formed global alliances to push back against perceived gluttonous profiteering by multinational pharmaceutical manufacturers. Prominent academic writers, human rights campaigners and global equity campaigners have added their voices to the struggle – contributing compelling ethical and legal arguments on why the global drug-making industry ought to be required to assist with providing regular and affordable access to essential medicines to the poor, especially to citizens of developing countries. Like Biko (1987), Gostin (2014), Forman and Kohler (2012), legal academic Joo-Young Lee (2015) emphatically argues in favour of an overhaul of the legal systems currently governing global health. She recommends the adoption of a new governance structure infused with ethical values to promote universal access to essential medicines. Lee notes that, "international human rights instruments provide a *positive legal order to a set of moral values*" (Lee 2015: 66) (Emphasis added). Further, she argues that "international human right instruments can provide a normative framework" for the regulation of the IP system (Lee 2015: 67) (Emphasis added). She points out that the UN Committee for Social, Economic and Cultural Rights (ESCR) also supports a human rights approach to IP reform. Lee states that the ESCR supports a justice-based approach because it would,

> *encourage…the development of intellectual property systems and the use of intellectual property rights in a balanced manner that meets the objective of providing protection for*

> *the moral and material interests of authors* [the term includes inventors], *and at the same time promotes the enjoyment of (all) human rights.* (Lee 2015: 66) (Emphasis added).

Morality requires fair and just dealing with all people throughout the world. It requires inclusion, fairness, and respect for the inherent human dignity of all. The global movement for equity and fairness in *all human relations* has grown significantly in the past decade and a half. Supporters of the new mass movement for social justice come from all walks of life, proving that right thought and right action are not the stale preoccupations of academics, human rights lawyers, philosophers or public policy-makers - who are at times dismissed as utopian thinkers from ivory towers.

The most prominent global citizen to add his voice to the struggle for equity and human dignity in 2015 was Pope Francis of the Holy Sea. In his 25 September 2015 address to the 70th meeting of the United Nations General Assembly (UNGA) – attended by 150 world leaders, Pope Francis stressed the value of justice in global development and international human rights law. He lauded the UN for its role in "the codification and development of international law, the establishment of international norms regarding human rights, and advances in humanitarian law…as well as (in conflict resolution)" (Pope Francis 2015). He called for "greater equity" and said that this could be attained through just reform of global structural and economic power relations. His remarks echoed those made by Biko (1987), Gostin (2014), Forman and Kohler (2012) and Lee (2015) for more egalitarian sharing of power and material between developed and developing nations.

Pope Francis cautioned that UN institutions charged with addressing economic crises should "help limit every kind of abuse and usury, especially where developing countries are concerned." (Pope Francis 2015). He ruefully observed that some global aid interventions do not promote

progress but instead, "subject people to mechanisms which *generate greater poverty, exclusion and dependence."* (Pope Francis 2015).

Francis' speech was perfectly timed. The world needed a collective moral wake-up call. He focused global attention on the adverse impacts of political and economic indifference. His Holiness also noted how defective compliance with international law instruments can at times do more harm than good. Noting how the UN's administrative structures operate, Francis cautioned against the lulling effects of routine legal processes. He cautioned that, "solemn commitments…are not enough, even though they are a necessary step toward solutions". Pope Francis (2015) drew the UNGA's attention to "the classic definition of justice … (which) contains as one of its essential elements a constant and perpetual will; *iustitia est constans et perpetua voluntas jus sum cuique tribuendi"* (which means, giving "to each his due"). In a direct ethical injunction he told politicians that,

> (o)ur world demands of all government leaders a will which is effective, practical and constant, concrete steps and immediate measures…for improving (social justice) thus putting an end as quickly as possible to the phenomenon of social and economic exclusion, with its baneful consequences...(Pope Francis 2015).

He continued that the global community needed to be mindful that conflicts and disparities wear a human face. Pope Francis' remarks based on justice and moral rightness, reminded us that the principle of justice matters, not for mere diplomatic politeness – but because millions of innocent lives are at stake. He highlighted that many of the hungry or sick will perish or continue to endure lives devoid of human dignity. The interests of justice and fairness require, he argued, political leaders and all key stakeholders to take active and deliberate actions to end unnecessary human suffering.

Warning against moral passiveness, which is often masked by political rhetoric, Pope Francis implored, "we must avoid every temptation to fall into a declarationist nominalism ... *(*to) assuage our consciences." (Pope Francis 2015). He recalled that the primary intentions of the UN preamble and the first Article of the UN Charter were the "development and the promotion of the rule of law, based on the realization that justice is an essential condition for achieving the ideal of universal fraternity" (Pope Francis 2015). Justice (in its original meaning), the Pontiff reminded the General Assembly, imposes on leaders a moral duty to "give each his own" – which "*means no human individual or group can consider itself absolute, permitted to bypass the dignity and the rights of other individuals or their social groupings"* (Pope Francis 2015) (Italics mine). This injunction is of particular moral relevance in the pharmaceutical patents and access to medicines debate.

4.4 Should the language of international human rights and morality be incorporated into the access to medicines debate?

Promoting universal healthcare coverage, including affordable and regular access to essential medicines, is one of the pressing moral concerns of the twenty-first century. I have already mentioned the rising global calls to hold multinational pharmaceutical manufacturers jointly responsible, with governments, for the provision of medicines and treatments to all who need them. Proceeding along this line of reasoning raises a number of ethical and legal questions. Among them are: (1) whether global drug-manufacturers have or ought to have legal duties under international human rights law to ensure the realization of the right-to-health, (2) whether the WTO's TRIPS adopted in 1995 unfairly benefits multinational pharmaceutical manufacturers at the expense of the poor – especially those in developing countries (Cameron 2005, Geffen

2010, Hestermeyer 2012, Forman and Kohler 2012) and (3) whether it would be morally and/or legally justifiable to limit the exercise of pharmaceutical patents in developing countries?

Several legal scholars argue that multinational pharmaceutical manufacturers should have joint right-to-health obligations with governments because of the commodity they produce. Medicines, it is said, are not a luxury but an essential product with the potential to save life. They should therefore, be equitably and regularly available to all those who need them. It is, however, claimed that the 1994 TRIPS created a "powerful legal protection for pharmaceutical patents", making it easier for drug companies "to charge monopoly pricing" for medicines throughout the world. (Forman and Kohler 2012)

Legal scholar Thomas Pogge argues that drug manufacturers have or ought to have legal duties in respect of providing access to essential medicines. He relies on Article 25 of the 1948 Universal Declaration Human Rights for this assertion. It states that, "the right-to-health is a fundamental right because health is an important precondition for the realization of most other human rights" (Pogge 2011: 1) Gostin makes a similar argument. He believes that the WHO provision that guarantees the "enjoyment of the highest attainable standard of health is *one of the fundamental rights of every human being...*" (Gostin 2014: 20) (Emphasis added). He also maintains that this WHO provision "is the most important health-related international legal obligation". Based on the afore-going, Gostin proposes that international law instruments should be invoked to define the nature of the joint duties private businesses in the health sector have in assisting states with right-to-health obligations. He explains that the UN CESCR frames the content of the right, broadly "requiring that acceptable and good health goods, services and facilities be available and accessible to everyone" (Gostin 2014: 20). It is important to note that General Comment 14 of the CESCR acknowledges that states are legal signatories to the

Covenant and it expressly states that "…*all members of societies, including the private business sector, have responsibilities for the realization of the right-to-health*" (Forman and Kohler 2012: 7) (Emphasis added). This implies that the multinational pharmaceutical industry has shared duties because "access to medicines forms an indispensable part of the right to the highest attainable standard of health" (Forman and Kohler 2012: 27).

Explaining the peculiar duties owed by multinational drug manufacturers, legal scholar Patricia Illingworth (in Forman and Kohler, 2012: 79) highlights that, these drug-making companies are not purely commercial enterprises. She argues that they are "morally special" because of the essential products they produce and sell. She continues, arguing that multinational drug manufacturers have ethical duties to the public similar to those that physicians and other health professionals have. Health academics Forman and Kohler (2012: 10) support her by stating that a new "ethical paradigm on collective responsibilities to resolve access and innovation deficiencies in the developing world" – between states and other actors in the health sector is crystalizing. This paradigm is also starting to take root within the pharmaceutical industry. (Forman and Kohler, 2012: 10)

Unsurprisingly, the multinational pharmaceutical manufacturers and their academic supporters are reticent to embrace these claimed international human rights law joint-obligations. They prefer self-imposed ethical duties – which they discharge via voluntary drug donation programmes and other carefully selected access to medicines collaborative schemes. Most of the world's largest drug-makers argue that they are private for-profit entities without legally binding public health duties. CL Clemente, the former Pfizer executive senior vice president in South Africa, summarised this rationale succinctly in April 2001 when he stated, 'We are not the Red Cross. We are a for-profit company.' (Cameron 2005: 184) A similar assertion was made on

behalf of British pharmaceutical giant GSK, in a letter which "explicitly reject(ed)" Paul Hunt's, the former UN special rapporteur on health, claim that "pharmaceutical companies have right-to-health responsibilities that exceed those dictated by the ethics and law implicit in shareholder primacy" (Forman and Kohler 2012: 77). In its missive to Hunt, GSK referred to pharmaceutical patents as "family jewels", prompting Hunt to retort;

> The image was revealing. In one sense the image is legitimate – patents are immensely valuable. *In another sense, the image reflects a profound misunderstanding of the role of a company that develops a life-saving medicine…such a company has performed a critically important social, medical, public health and right-to-health function.* While the company's 'reward' is a grant of a limited monopoly over the medicine, enabling it to enhance shareholder value and invest in further research and development, *the company also has a right-to-health responsibility to take all reasonable steps to make the life-saving medicine as accessible as possible, as soon as possible, to all those in need.* For a limited period, the company holds the patent for society – but the patent must be worked, so far as possible, for the benefit of all those who need it. (Illingworth 2012: 77). (Emphasis added)

Hunt's articulation of the multinational pharmaceutical industry's legal and moral obligations – in respect of the right-to-health, is firm, clear and unambiguous.

Asher Alkoby (in Forman and Kohler, 2012: 46) writes that "most of the scholarly work on the responsibilities of corporations for human rights attempts to measure corporate activities against an international normative framework for the protection of human rights." Unlike Hunt, Alkoby thinks that there are currently no expressly binding provisions in international law that hold corporations to joint-responsibilities with states, for the right-to-health. By contrast, she argues

that, the normative international law framework relied on by academics involved with the access to medicines debate tends to oscillate "between descriptive (pointing to existing norms, conventions, or principles, and measuring corporate compliance with them) and the prescriptive (such as an argument for the right-to-health as a global moral imperative)" (Alkoby: 46).

There are palpable tensions (legal and moral) between how multinational drug manufacturers interpret the IP protections and IP rights conferred by the legal system of patents versus how human rights and right-to-health campaigners conceive of them. As discussed in chapter two, jurist Edwin Cameron (2005) and his human rights colleagues stress that the system of patents is underpinned by the notion of public interest. By contrast, academic supporters of the industry like Joseph DiMasi, Ronald Hansen and Henry Grabowski place less emphasis on the centrality of the notion of public interest in their arguments for stringent pharmaceutical patent protections. Also, they shun the extension of international human rights law obligations to the drug-making sector. The industry's primary obligation, they claim, is to recoup the costs of bringing new drugs to market and to reinvest profits to fund more innovation. The cost of bringing a new drug to market is one of the biggest points of contention between the two sides in the essential medicines dialogue. Di Masi et al estimate that it costs about US$1.2 billion to bring a new drug to market (DiMasi et al. 2006). The figure is extrapolated from the US$802 million estimate - cited in a 2000 Tufts Center for the Study of Drug Development study authored by the team of health economists.

By contrast, legal academic Asher Alkoby (2012: 80) invokes deontological ethics to counter the notion of shareholder primary. He begins by granting that, "pharmaceutical companies and their shareholders are entitled to profits because of an implicit or explicit agreement between shareholders and pharmaceutical companies", but adds, "…surely, if an implication of this

agreement is that some people die unnecessarily while others line their pockets with corporate dividends, is unconscionable." He honours the "legal sanctity" of contracts by observing that, "…agreements are in general respected", and highlights that, "in the case of necessities the courts have been more flexible, as they should be, and have set aside signed contracts that impair the "right" to necessities". His last assertion about judicial attitudes has been borne out by the "pro social need" verdicts given by South Africa courts in the ARV treatment access cases mentioned in chapter 1.

4.5 Multinational drug manufacturers' patent enforcement in developing countries: A bitter moral pill

The multinational pharmaceutical manufacturers' litigation to prevent South Africa from adopting pro-health equity patent reforms in the late 1990s is well documented. However, the Republic is not the only developing nation to have been subjected to fierce legal challenges in defense of the industry's IP interests. The Union of India has endured similar legal battles. The Indian Patents Act of 1970 has undergone three key amendments – in 1999, 2002 and 2005 – in efforts to make the country's IP laws TRIPS compliant (Nair et al. 2014). After 2005, India saw a sharp increase in the number of suits related to "product patents". These culminated in the "Gleevec case", launched by Swiss drug manufacturer Norvatis in its territory in 1998. The matter is now regarded as the "mother of all product litigations cases in India" (Nair et al. 2014: 80). It is reported that the case caused great consternation among IP practitioners both in that country and internationally (Nair et al. 2014). It should be noted that drug company Roche, also from Switzerland, launched a patent infringement suit against Cipla, an Indian generic drug manufacturer, three years earlier. The multinational drug manufacturers lost both matters, leading to India becoming known as "the pharmacy of the developing world" (MSF Access

Campaign 2011) - a nickname that has unsurprisingly earned India the wrath of the multinational pharmaceutical industry - aided by the US government.

These actors have unleashed covert and overt campaigns to pressure India to abandon its pro-health equity interpretations of IP laws. Health equity non-profits Asia Pacific Network of People Living with HIV/AIDS (APN+) and Health Gap – Global Access Project issued a press statement on 25 September 2015, to coincide with the UNGA, which Pope Francis addressed on that day. In it the treatment access non-profits demanded that, "…the U.S. immediately stop pressure on India to change its pro-health patent and data protection laws". The statement further warned that "(the US' actions will) put the realization of health-related (sustainable development goals) out of reach for much of the world and directly contradict the goals and targets being set at the UN". The APN+ statement recalled that "(f)or millions of patients around the world, India is a life line for medicines". It further noted that, the "US pressure on India's generic manufacturing capacity has escalated alarmingly in the past few years, threatening the lives and health of millions in the developing world" (Health Gap - Global Access Project 2015).

Regrettably, the US abuses of power to frustrate patent reform in the public interest are legendary. It is reported that,

> After the passage of the TRIPS agreement, *the U.S. pressed many countries to give up their rights to use many of these pro-access policies…*Two particular cases stand out, pressure on South Africa to give up parallel importation and pressure on Brazil to give up compulsory licenses threatened to doom AIDS treatment programs and stoked international outrage and an access to medicines popular movement. The…2001 Doha Declaration on TRIPS and Public Health was passed *in direct response to U.S. pressure…*The agreement affirmed "the right of WTO

> members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibility [to promote access to medicines for all]. (American University Washington College of Law's Program on Information Justice and Intellectual Property, Global Access Project (Health Gap) and the European Community Advisory Board 2010) (Emphasis original).

In relation to South Africa, it is important to note that the US' sustained bullying is in flagrant disregard of its own good faith legislation - United States Executive Order 13155 signed on 12 May 2000.

It expressly declares that;

> (i)n administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country…(aimed to promote access to essential medicines).

At the time of writing, there were renewed pressures by the United States Trade Representative to have South Africa excluded from continued participation in AGOA. In her petition to the American Chamber of Commerce (AmCham), Anele Yawa of the TAC stated, "We know there's significant pressure on the South African government to abandon or to water down the proposed IP law reforms. We have seen very worrying delays in finalising the national IP policy, and we hope the South African government will not be moved to compromise the health of its citizens in order for U.S. pharmaceutical companies to continue to reap massive profits." (Section 27 website)

As his legal academic counterparts did earlier, Heinz Klug (2012) argues persuasively about how national and geo-political considerations, national economic interests, international trade

agreements and a desire to promote competition influenced the post democratic South African government's approach to public policy formulation.

He writes that,

> (d)espite (the new ruling party's) strong commitment to social change…the transformation of a number of institutions was significantly framed by the global environment in which the country found itself...as a result, impetus was given to different policies and competing political and economic factions, enabling particular institutions and rules to be embraced, created, reshaped, or simply forgone. (Klug, 2012: 297).

In my assessment, finalization of patent reforms to facilitate access to essential medicines, is arguably one of the key legal reforms that was foregone in exchange for South Africa's inclusion as a founding member of the WTO. A national policy decision whose adverse health effects (lack of equitable access to essential medicines) continues to plague the country twenty one years into democracy.

4.6 Conclusion

Gostin (2014) argues that the international law health governance system needs to be overhauled to remediate current global health inequities. He and others strong recommend that the new paradigm must be based on the principles of justice. Access to essential medicines is one of the pressing global health issues. Many health equity activists claim that rich countries and multinational pharmaceutical manufacturers must be held to joint responsibilities, with poor states, to provide access to the highest attainable standard of health for all. They unreservedly grant that multinational pharmaceutical manufacturers and their shareholders are entitled to profits but unequivocally maintain that the current pharmaceutical patents framework needs to be

reformed to provide greater equity in access to essential medicines. As Pope Francis of the Holy Sea pointed out, international laws and global commitments are helpful, but government leaders need to be cautious not to fall into a "declarationist normalism" – a false sense that the adoption of legal instruments is sufficient to remedy global health and disparities. True distributive justice requires deliberate, constant and measurable interventions. Global leaders have to work together so they can "(i)n time, … be in a position to bestow on (the world) the greatest possible gift—a more human face", as Steve Biko (1987) enjoined us.

CHAPTER 5: IS IT POSSIBLE TO NURTURE A WIN-WIN GLOBAL PHARMACEUTICAL INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES PARADIGM?

5.1 Introduction

Patient groups, civil society treatment access campaigners, and market analysts agree that delays in the finalization of the Department of Health's National Health Insurance (NHI) and the Department of Trade and industry's IP policy reforms are beginning to have adverse effects on South Africa's progress towards attaining national health equity (BMI Research 2015, FTPL 2015b). The BMI Research report details the state of the health industry in South Africa and gives a comprehensive analysis of the nation's economic and policy frameworks. In its summary BMI Research notes that, "(d)elays in implementing South Africa's national health insurance scheme and intellectual property reform will negatively impact patients' access to medical treatments in the short term" (BMI Research 2015: 4). By contrast, treatment campaigners and patient groups argue that the effects are immediate, with long-term consequences like preventable deaths, disabilities and immense human suffering for people without access to essential treatments. In October 2015, the Fix the Patent Laws Campaign "… called on the Department of Trade and Industry to end years of pharmaceutical company price gouging and broken promises for patent law reform and produce a final intellectual property policy." (2015b)

The delays in IP law reforms and the release of the NHI white paper have deepened skepticism about whether South Africa can afford to offer universal health coverage. The NHI draft policy document acknowledges that, "(t)he *South African health system is inequitable, with the privileged few having disproportionate access to health services. There is recognition that this system is neither rational nor fair.*" (National Department of Health, 2011) (Emphasis added). The government's failure to finalize IP law reforms fundamentally undermines the South African

state's ability to discharge its mandatory international, regional and Constitutional law right-to-health obligations. A 2003 United Nations Development Programme report recognized access to affordable medicines as one of the key components of health equity. It highlighted that, "(d)rug prices are a critical determinant of access to health care", noting that, "(p)atented drugs are substantially more expensive than generic versions" (cited by Forman and Kohler, 2012: 154).

Insistence on stringent enforcement of pharmaceutical patent protections by multinational drug manufacturers and delays in public health policy reform by President Mbeki's government obstructed the provision of potentially life-saving ARVs to millions of poor citizens, in the 1990s. More than 330,000 people are reported to have died prematurely between 2000 and 2005 because they lacked access to essential treatments. In addition, 35,000 babies were infected with the HI-virus in utero (Roeder 2007).

This chapter will briefly outline the time-line of the South African IP reform process. Firstly, a short synopsis of the structure of the South African pharmaceutical sector will be provided. Secondly, a narration of the business and social justice case for why pro-public interest IP law reforms are necessary will be advanced. Finally, I offer some thoughts on how South Africa might begin to substantively balance IP protections and facilitate access to essential medicines.

5.2 The IP law reform process in South Africa

In 1997 Dr. Nkosazana Zuma, then Health Minister, stated publicly that "…both the shortage of prescription drugs in the public sector and the exceptionally high prices in the private sector are the result of the pricing strategies adopted by multinational pharmaceutical companies who held patents in South Africa on most antiretroviral drugs" (Fisher and Rigamonti 2005: 4). Zuma's statements caused the Pharmaceutical Manufacturers Association of South Africa (PMA) to file a complaint with the nation's Public Protector (a neutral ombudsman with limited investigative

and no sanctioning powers), in June 1997. The formal complaint alleged that "offensive media remarks" made by certain officials from the Department of Health created "a perception in the minds of the general public that medicines in South Africa are unreasonably expensive and moreover that the blame for such expensive medicines lies with the manufacturing and primary importing companies" (Fisher and Rigamonti 2005: 5).

The PMA asserted that its "rates for the South African government are lower than those offered by international aid organizations and any shortages in the public sector are due to the rampant theft of pharmaceuticals." Secondly, "…the pharmaceutical companies denied that lowering drug prices would solve the access problems." It argued that "South Africa did not have an adequate infrastructure for the distribution of drugs pointing to India as an example of a country where access was and is an issue despite the availability of generic versions of AIDS drugs." (Fisher and Rigamonti 2005: 4) Undeterred by the PMA's public defenses and its complaint to the Public Protector, the South African government set in motion measures to amend Section 15C of its Medicines and Related Substances Control Act, 1997.

The TAC was displeased with the PMA's complaint to the Public Protector and the subsequent filing of the Pharmaceutical Manufacturers Association of South Africa and Another case. It developed arguments to publicly repudiate the drug entities' denials that lowering drug prices would solve the medicines access problem in South Africa. The multinational drug industry dropped its legal proceedings against the country in September 2001 – after massive global protests. This move was widely interpreted as a victory for treatment access activists and it was claimed that global moral outrage had stopped the powerful multinational pharmaceutical industry's attempts to bully a developing nation not to reform its IP laws in the public interest. (Fisher and Rigamonti, 2005)

Key stakeholders in the access to medicines arena concluded a number of landmark agreements, (after the withdrawal of the PMA case) leading to significant price drops for patented ARV drugs which were, until then, exclusively sold in the country by multinational drug-makers. In addition, four voluntary licences were issued in 2003 after the TAC filed a complaint with the Competition Commission for relief against the excessive medicine prices charged by patented drug manufacturers BI and GSK. The licences allowed for the local manufacture of generic ARV drugs by South African drug companies. One of the four companies was Aspen Pharmacare – now the largest generic drug manufacturer in the country (TAC, 2003b).

The TAC filed a new complaint with the Competition Commission in 2007 against "MSD (the South African subsidiary of multinational drug company Merck) for unlawfully refusing to grant licenses to allow for generic production of and affordable access to generic efavirenz" (TAC, 2008). A few other notable IP protection cases were filed by the multinational industry operating in South Africa, in the intervening years. Regrettably, none of them proceeded to trial and therefore the drug makers' insistence on stringent patent protections in the Republic has not been vindicated in a court of law. Litigation would have publicly tested the correctness of the industry's claims that stringent IP protections spur new drug innovations as argued by Di Masi and his colleagues (2006). The controversy on the cost of new drug development will be discussed later.

In terms of the public policy framework, the DTI has the lead mandate for the nation's IP law reform process. Its stated vision is to grow the country's economy in a manner that facilitates global competiveness and leads to inclusive economic growth and equity-based social development (DTI website).

The DTI's vision and mission statements have explicit restorative justice intentions as pronounced in the preamble of the nation's 1996 Constitution. Over the years, the DTI has taken measures to ease the isolationist economic outlook of the former South African apartheid government, which was barred from world trade, through sanctions and embargoes (Klug 2012).

In June 2009 the DTI took pro-active steps to overhaul the national IP framework to comply with international trade regimes and to adopt a public interest based pharmaceutical patent framework (FTPL, 2015). Three months later it announced that it intended to submit the draft IP policy to Cabinet in September to request approval for the document to be circulated for public comment (FTPL, 2015a). A month thereafter, the DTI Minister assured treatment access activists led by the TAC that:

> "(t)he Government is developing an Intellectual Property Policy (IP Policy) which will also address access to medicines and public health issues… (In addition) the IP Policy will establish a framework for legislative reform across all areas of IP Policy to ensure a consistent approach that contributes positively to the economic and social interests of South Africa" (FTPL 2015a).

Davies added,

> **"**(t)he Policy will provide clarity as to which sections of the Patents Act 57 of 1978 and the Medicines Control and Related Substances Act 101 of 1965 require amendment to ensure that the flexibilities relating to access to medicines and health are incorporated into national legislation" (FTPL, 2015a).

In May 2011 grassroots patient organisations, the TAC and MSF, launched the FTPL Campaign. The launch coincided with the 10th anniversary of the Doha Declaration on TRIPS and Public Health. The FTPL campaign was formed to add momentum to the DTI's IP law reform process.

A few months later, in May 2012, a treatment access delegation from MSF met with Minister Davies to obtain an update on where the legislative reform process was. The Minister assured the delegation that the draft policy would be released for public comment in June or July 2012. The draft policy was not publicly circulated as promised but the treatment campaigners obtained a leaked copy of the draft document which they allege had marked-up "comments from the multinational pharmaceutical industry associations" and the two local pharmaceutical associations (FTPL 2015b). The treatment activists claim that a DTI spokesperson told them that the IP policy would be tabled before Parliament on 5 December 2012 and that it would be finalized in March/April 2013 (FTPL 2015b). However, the draft policy was only circulated for public comment in September 2013, despite a slew of unmet undertakings made by senior DTI office-bearers between May 2012 and August 2013. Public comments on the circulated document closed in October 2013. It is reported that the DTI received a hundred responses from academics, the pharmaceutical manufacturing sector – both, local and multinational, as well as from civil society organisations like Section 27. On 29 October 2015, the FTPL Campaign addressed a letter to Minister Davies highlighting that it has been two years since the close of public comments on the draft IP policy and that no substantive law reform progress had been made. The letter further reiterated that the DTI had made and broken many of its own promises about when the reforms will be enacted into law (FTPL 2015b).

The access campaigners enquired about when the final policy would be sent to Cabinet for consideration. Minister Davies responded on the same date in a letter addressed to TAC General Secretary Ms Anele Yawa. He stated that, "(r)egrettably, the wide range of issues covered by Intellectual Property rights and the number of stakeholders, including yourselves, consulted and the various issued raised, has meant delays beyond our initial expectations."

Davies further stated that,

> considerable progress has been made and we are confident that the IP Policy will be ready for consideration by Cabinet in the first quarter of next year" (FTPL, 2015c). He also highlighted the importance of Paragraph 6 of the Doha Declaration which effected a permanent amendment of how "TRIPS flexibilities" should be interpreted. Davies asserted that "the first step in ensuring that those flexibilities are fully implemented is for the amendment to the TRIPS Agreement to be ratified by Cabinet (FTPL, 2015c).

Paragraph 6 of the Doha Ministerial Declaration on TRIPS and Public Health was adopted in 2005 (WTO website). It is curious that South Africa, a country in urgent need of pro public health equity mechanisms to bolster its ability to provide access to medicines has not ratified this vital piece of legislation 10 years since its introduction. Once again, the DTI has missed its deadline – the first quarter of 2016 has passed and the draft IP Policy had not been circulated to Parliament as at 6 June 2016.

The afore-going discussion attempted to show the social tensions caused by government's tardiness in finalizing IP law reforms. It highlighted the DTI's totally unconvincing official reasons for the slow progress. I shall now turn to probe how multinational pharmaceutical manufacturers view their ethical responsibilities.

I start this part of the discussion with a question; should for-profit businesses, especially multinational entities, be concerned with running their entities ethically and justly? In his commentary on the Volkwagen carbon emissions cheating scandal bioethics academic Peter Singer (2015) stated, '(i)f you used the term "business ethics" in the 1970s, when the field was just starting to develop, a common response was: "Isn't that an oxymoron?" Singer continues, "(t)hat quip would often be followed by a recitation of Milton Friedman's famous dictum that

corporate executives' only social responsibility is to make as much money for shareholders as is legally possible."

Singer (2015) is correct that the business sector's thinking on ethics has evolved somewhat over the past years. Large corporations routinely announce that they are committed to ethical conduct in their vision and mission statements. And that they care for all key stakeholders including the communities within which they operate. These assertions create an impression that the business *zeitgeist* is turning from shareholder primary to key stakeholders' primacy. However, the language of corporate social responsibility often does not, in my opinion, go far enough to embrace the notion of balancing business and human rights (to promote social equity) as envisioned by Paul Hunt, the former UN Special Rapporteur on the Right-to-health (Business and Human Rights Resource Centre website).

Many businesses still operate within the libertarian theory of justice. Philosopher Robert Nozick, a leading libertarian philosopher emphasizes that justice is attained "*if and only if* (government) *protects citizens' liberty and property rights*" (Beauchamp and Childress 2013) (Emphasis added). Nozick argues for a theory of justice anchored on only three core principles of property rights, namely justice in acquisition, justice in transfer and justice in rectification" (Beauchamp and Childress 2013). His framing of the theory of justice is eagerly embraced by supporters of stringent pharmaceutical patent rights, health economist Joseph DiMasi and his colleagues at the Tufts Centre for the Study of Drug Development among them.

The Tufts team has written extensively in defense of the multinational pharmaceutical industry's property rights. Like Nozick, they emphatically support the argument that governments should not be expected or encouraged to "redistribute wealth originally acquired by persons in the free market" (Beauchamp and Childress 2013: 255) Beauchamp and Childress summarise Nozick's

view as follows: "justice consists in the operation of just procedures, not in the production of just outcomes such as an equal distribution of health resources. *There are no welfare rights, and therefore no rights or justified claims to health care can be based on justice*" (Beauchamp and Childress 2013: 255). (Emphasis added). Left unchallenged, their shutting out of right-to-health claims rooted in distributive justice could have dire repercussions premised for destitute patients who cannot afford to purchase potentially life-saving treatments.

The global health community needs to frankly interrogate whether the terms, the "free market" and/or "free trade" aptly describe the global business environment. Does the so-called "free market" offer equal opportunities for all who wish to participate in it? More importantly, health equity campaigners need to interrogate whether free-market and free-trade agreement principles operate purely on *"just procedures*" as claimed. If it is still claimed that they do, health equity advocates should then enquire into how the multinational drug industry ethically or legally justifies instances where it has been proven to have acted in bad faith? For instance, in February 2014, Pro Publica, a non-profit entity committed to journalism in the public interest, published a comprehensive list of all instances of unfair and unjust conduct by the mostly-rich-country-based drug manufacturing conglomerates. The article's summary notes that,

> (i)n the last few years pharmaceutical companies have agreed to pay over $13 billion to resolve U.S. Department of Justice allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the Food and Drug Administration (Groeger 2014).

I would like to recall Illingworth's (2012) argument that the global pharmaceutical industry is not purely a for-profit industry but a "moral hybrid" because of the nature of essential health products that it produces. It could be argued that multinational pharmaceutical manufacturers

have a legal duty of care like other healthcare professionals to act in the best interests of all persons who need access to essential treatments. Glaring breaches of trust and corporate governance regulations raise ethical and legal questions about how an industry responsible for promoting health can repeatedly be found guilty of willfully endangering the lives of vulnerable patients and unsuspecting publics. How can aggressive pursuit of commercial profits justifiably trump the legal duty to produce and market safe medicines and to create knowledge for the production and manufacture of potentially life-saving medicines, for all who need them? Are these ethical and legal duties of care to society not what was intended by the authors of the legal system of patents that the drug-makers readily lay claim to in defense of their IP rights?

5.3 Is it Possible to Nurture a Win-Win IP and Access-to-Essential-Medicines Paradigm in the Public Interest In South Africa and Beyond?

Winnie Byanyima, Oxfam Executive Director, observed in response to revelations of global income inequalities: "(e)xtreme inequality isn't just a moral wrong. We know that it hampers economic growth and it threatens the private sector's bottom line" (Oxfam Inequality Press Statement 2015). Other social justice activists (Business and Human Rights website, Cameron 2005, Forman and Kohler 2012, Klug 2012) have expressed similar sentiments and furnished reasons as to why the business community ought to urgently reassess its ethical and human rights responsibilities to help curb gross health and wealth disparities.

Granted, businesses need to make profits to be sustainable and to honour their shareholders' financial investments. Edwin Cameron maintains that upholding the rule of law necessitates that we unequivocally protect the legitimate property rights of business owners, including their IP rights (Cameron 2005). He writes, "*(t)here can be little question that companies that develop new drugs should be rewarded, and that they should be encouraged to innovate. They should*

also be compensated for the cost as well as the risk of their research and development" (Cameron 2005: 167). (Emphasis added)

I have identified two main barriers that, in my opinion, hamper substantive progress towards reaching a consensus to strike a balance between pharmaceutical IP rights protections and the equally important public interest of providing equitable access to medicines. The two deal breakers seem to be developing countries' ongoing dissatisfaction with the current WTO pharmaceutical IP regulatory system – the TRIPS Agreement, the secrecy of bilateral trade agreements. The US' protectionist international engagement policies have caused a lot of consternation among other countries. In addition, the trust equity deficit between developed and developing nations has led to the formation of new economic partnerships among African Union member countries and other developing regions of the Brazil, Russia, India, China and South Africa, or BRICS, trading bloc. By trust equity deficit I mean, the worsening lack of trust between developed and developing nations, as evidenced by the tensions surrounding the conclusion of the TTP and the latest signing of the AGOA bilateral trade agreements, both of which will be discussed in greater detail shortly.

The US and its Western trade partners need to understand that trade agreement secrecy or coercing developing nations to accede to stronger IP protections via TRIPS Plus provisions in bilateral trade agreements are not amenable to the notion of African traditional justice. Sandile Ngcobo, retired Chief Justice of South Africa explains that egalitarianism is at the core of African justice. "Open justice is the principle that the doors of all courts (and all key negotiations fora) in the nation be open to the public…This concept has been around for centuries. It is deeply rooted in the African tradition" (Ngcobo, 2010).

I now turn to evaluate non-Western countries' (especially African and Asian nations') misgivings about the WTO's *TRIPS* signed in Marrakesh, Morocco on 15 April 1994. At its inception, it was hoped that TRIPS would establish a "uniform, homogenous, one-size-fits-all" global IP regulatory system (Coombe in Calboli and Ragavan 2015: xvii). Calboli claims that drafters of the IP legal framework sought to walk a tightrope between harmonization and diversity.

TRIPS opponents charge that it offers inequitable IP rights protections "to the advantage of the US and those favoring certainty in commerce, and to the detriment of other countries, particularly those considered to be less developed" (Coombe in Calboli and Ragavan 2015) Put differently, it is argued that TRIPS prioritizes the pecuniary interests and legal rights of multinational pharmaceutical manufacturers at the expense of destitute patients in need of affordable access to essential treatments (Cameron 2005, Geffen 2010, TAC and Forman and Kohler 2012). The Doha Declaration on the TRIPS Agreement and Public Health was signed in Doha on November 14, 2001 and was adopted to entrench pro-public health guarantees – known as TRIPS flexibilities, into the original TRIPS Agreement (Cameron 2005, Geffen 2010, TAC, MSF Access Campaign, and KEI). Cameron (2005: 167) notes that the Declaration, "…affirmed that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all."

Allegations that the US government vociferously defends American pharmaceutical IP rights have been proven. In his commentary on the global health impacts of the leaked text of TTP, legal academic and health analyst Dean Baker (2015) writes,

"(a)fter five years of secret negotiations directed and controlled by pharmaceutical lobbyists and drug-company-dominated trade advisory groups the official text of the Trans Pacific Partnership negotiated by the Obama administration has been released"

He adds that the TTP text

> "confirms critics' worst fears – pharmaceutical behemoths like Pfizer, Bristol-Myers Squibb, Merck, Glaxo-Smith Kline, and Abbot Laboratories have gained expanded monopoly protections and greatly enhanced enforcement rights. Patients, both domestically and abroad, will suffer delayed access to more affordable medicines and biologics. In the U.S., resulting price increases will lead to even more rationing and burgeoning out-of-pocket payments. In low- and middle-income TPP partners, excessive prices that neither patients nor governments can afford can and will result in death" (Baker).

Some US Congress leaders have lobbied President Barack Obama on behalf of the sector since the beginning of formal TTP negotiations. In their letter to him dated 27 July 2011, the group of ten US lawmakers wrote,

> "Critical to increasing U.S. companies' ability to export and contribute to U.S. GDP growth is ensuring that our government does all it can to help provide a level playing field for U.S. companies globally and advocates for intellectual property rights that provide certainty for America's innovative companies in the biosciences and other sectors…As you know, the U.S. has a knowledge-based economy that is the envy of the world, and much of our dominance can be traced to deliberate policies to foster growth in this sector of the economy. The United States Trade Representative should ensure that the TPP agreement respects strong intellectual property standards for all sectors,

especially the intellectual property intensive sectors critical to the success of the American economy…" (US Members of Congress Letter, 2011).

Perhaps, the American leaders' perception that their nation's "knowledge-based economy is the envy of the world" provides some explanations for the US multinational pharmaceutical drug-makers' boisterous and underhanded attempts to derail pro-public interest patent law reforms in South Africa and other jurisdictions. However, there seems to be light at the end of the health equity tunnel. A group of more than 50 congressional lawmakers recently addressed a letter to President Barack Obama's administration. In their missive dated 11 January 2016, the politicians asked the US government to develop guidelines that would require drug-makers to license their patents to others in a bid to end "price gouging" (Silverman 2016). The Congressional members also requested the National Institute of Health (NIH) to utilize its "march-in rights" powers to accelerate the provision of medicines to those currently unable to access and purchase them (Silverman 2016). The march-in rights mechanism is a US Federal provision that allows a government agency that funds private research to override a patent as well as "to require a (government funded) drug-maker to license its patent to another party in order to alleviate health and safety needs which are not being reasonably satisfied". They can also be utilised when it is thought that the benefits of a drug are not available on "reasonable terms" (Silverman 2016). Events from around the world show that the issue of pharmaceutical patents (high medicine prices) has become a vexing legal and ethical issue. Providing affordable and regular access to medicines for all who need them has become a priority issue for increasing numbers of politicians in the United States. This is in sharp contrast to the social attitudes of the 2011 pre-TTP Congressional lobbyists who acted primarily in the pecuniary interests of multinational pharmaceutical manufacturers.

The stance of the fifty legislators is bold and uncharacteristic. Granted their efforts are intended primarily for the benefit of US citizens who need access to exorbitantly expensive drugs like hepatitis treatments Solvadi and Harvoni, which retail for US$94,000 for a 12-week treatment. An 18-month long US Senate Finance Committee investigation led by Members Ron Wyden and Chuck Grassley found that Gilead's, the manufacturer of both drugs, pricing strategy was revenue driven (Wyden website, 2015). Their report also revealed that Medicare (the US' public insurance scheme) spent more on the drug in the first half of 2015 than it did in all of 2014. These frank revelations are helpful for the global treatment access debate. It is no longer possible for US institutions of power to lift the corporate veil without their revelations being swiftly picked up and disseminated to the rest of the world via the various social media platforms. Unlike in the 1990s and early 2000s, social justice campaigners are able to organize and register their moral outrage against perceived corporate or government overreach. This has significantly reshaped and tilted global power structures – forcing companies like Gilead and industry moguls like Martin Shrekli to swiftly reconsider their essential drug pricing strategies. Shrekli, the former Chief Executive Officer of Turing Pharmaceutical, gained global notoriety after he hiked the price of an old drug called Daraprim by 5,000% - from $13.50 to $750 per pill (Diamond 2015). In an interview 3 months after this controversial decision, Shkreli's only regret was, "I should have raised prices higher. That's my duty." He explained that, "(my) is job isn't making patients better" but rather "…making the most dollars. My shareholders expect me to make the most profit…That's the ugly, dirty truth" (Diamond 2015). During the interview Shkreli kept reasserting, "I'm going to maximize profits… That's what people [in healthcare] are afraid to say" (Diamond 2015).

One is left wondering whether staunch libertarians like Nozick would agree with his views on capitalism, profit maximization and shareholder primacy. Shkreli's statements have offered the broader public a rare glimpse into the purported "duties of a pharmaceutical executive". His brashness and avarice have profoundly worsened the trust equity deficit between the multinational pharmaceutical manufacturers and other key stakeholders in the global treatment access dialogue.

5.4 Conclusion

In this chapter, I have explored the broad framework of the right-to-health at international human rights law, in particular states' and other key stakeholders' duties to provide access to essential medicines to all who need them. I also discussed the history of South Africa's attempts to reform its IP law in the public interest, highlighting the DTI's failures to finalize the draft IP Policy and some of the external causes of delays – including vigorous opposition from multinational pharmaceutical manufacturers, onerous trade agreements imposed on developing nations by developed countries and ongoing disaffection with current global IP regulatory systems TRIPS. I would be remiss to blame South Africa's lack of IP law reform progress solely on external factors. I think Trade and Industry Minister Davies' explanations of why South Africa's IP law reform process had not progressed since September 2013 are disingenuous, politically expedient and show the DTI's dismal failure to execute its legislative mandate, to the detriment of millions of impoverished citizens who lack access to essential medicines. I conclude by arguing that, the ANC government has again - like it did with its disastrous handling of the HIV/AIDS pandemic during the Mbeki era, committed fundamental ethical and human rights law breaches by failing to discharge its peremptory section 27 Constitutional mandate to provide equitable access to healthcare to all South Africans. Remedying South Africa's appalling in-country health

disparities was one of the main restorative justice undertakings that the democratic government committed to when it took power on 27 April 1994. The ruling ANC ought to, after twenty-two years in power, show unflinching moral courage by finalizing the IP law reform process in the public interest - external pressures from the US government and other Western trade partners notwithstanding.

South African lawmakers ought to be encouraged by changing political and public sentiments in the global pharmaceutical patents and access to medicines dialogue. I think that it is ethically and legally significant that more than 50 US Congressional law-makers have formally challenged the adverse public health impacts of "pharmaceutical price gouging".

CHAPTER 6: CONCLUSION

The right to access to the highest attainable standard of health is a fundamental human right of every human being (WHO, 2015: Factsheet 323, African Charter) It has been argued that the right-to-health is an essential component of the right to life (Lee 2015). Nation states have international law duties to provide equitable access to healthcare to all their citizens. Access to essential medicines was stipulated as one of the primary elements of the right-to-health by the Declaration of Alma Ata in 1977 (Kar, Pradham, Mohanta 2010). Forman and Kohler estimate that about two-thirds of the world's population lack regular access to the medicines. The majority of those reside in Africa and Asia (Forman and Kohler, 2012). Pharmaceutical patents have been highlighted as a major barrier to drug access and affordability for the world's poor. Health equity academics and lawyers (Gostin 2014, Forman and Kohler 2012, Lee 2015) have relied on theories of distributive justice to argue that the multinational pharmaceutical industry ought to be held to joint international human rights law obligations with nation states, to provide regular and affordable access to medicines to all who need them.

However, multinational pharmaceutical manufacturers and their academic supporters have resisted all attempts to hold them to binding right-to-health obligations. They vociferously rely on the libertarian theory of justice to resist being legally bound to joint right-to-health obligations with states. Libertarianism prizes individual liberties over public utility and its proponents like philosopher Robert Nozick and former pharmaceutical industry executive Martin Shkreli argue, that the main concern of private business is to maximize profits for shareholders without interference from governments. In their view, the duty of a pharmaceutical company executive is to maximize profits for shareholders and not to "make

patients better", as callously explained by former Gilead Chief Executive Martin Shkreli (Diamond 2016).

The notion of right-to-health duties as a fundamental human right is undisputed. States' legal duties in respect of the right are expressly stipulated in provisions of international law instruments like the UN Constitution (1946), the Universal Declaration of Human Rights (1948) and the International Covenant on Economic and Cultural Rights (1966). However, no such binding stipulations exist for private companies – like multinational pharmaceutical manufacturers. For this reason, attempts to extend binding human rights obligations to corporates have not been successful, according to Alkoby (in Forman and Kohler, 2012:46), who notes that "most of the scholarly work on the responsibilities of corporations for human rights attempts to measure corporate activities against an international normative framework for the protection of human rights."

States have both positive and negative human rights duties in respect of the right-to-health. Positive duties enjoin them to take proactive steps to realize certain minimum core requirements. By contrast, negative duties debar them from acting in harmful ways that will impede equitable access. Their negative responsibilities include a duty to prevent third parties from acting in ways that harm individual or population health (Lee 2015). Based on the latter duty, I think nation states ought to be able to hold multinational drug manufacturers to binding right-to-health duties by preventing them from charging unconscionably high prices for essential medicines. The status quo of asking industry to assume moral responsibilities in relation to access to medicines – through their corporate social investment and voluntary drug donation schemes, is not enough. As Biko (1987), Gostin (2014), Forman and Kohler (2012), Pope Francis (2015), Pogge (2011) and others have argued, growing global wealth and health

disparities necessitate an urgent overhaul and radical transformation of the current world economic and political power structures. Western thought (which vigorously advances Western interests) has dominated global relationships for far too long and to the detriment of the majority of the world's population (Oxfam Inequality Press Release, 2015). This report extensively highlighted the adverse impacts of trade agreements on global health equity. It set out how non-Western individuals perceive the WTO's TRIPS Agreement which governs the current global pharmaceutical IP regulatory system. In my opinion, developing nations' dis-ease with Western-led trade agreements did not start with the TRIPS Agreement. US academics Jean Lanjouw and Iain Cockburn authored a robust appraisal of the adverse impacts of the General Agreement on Tariffs and Trade (GATT) on pharmaceutical patents and access to medicines in developing countries. They wrote in their 2001 systemic review of GATT, (2001: 265),

> As of the end of the 1980s, at least 40 developing countries (including the most populous) did not grant patents for pharmaceutical product innovations…Most of these also did not grant process patents. As a result of the intellectual property component of the GATT agreement, and US bilateral pressure since the mid-1980s, most countries have either implemented or are committed to implementing new legislation that allows for 20-year protection for all pharmaceutical innovations. That is, they are moving, in one step and together, from 0 to 20 years of protection.

More recently, economic development academic Joshua Meltzer (2016: 91) wrote a detailed review of the potential adverse impacts of the TTP and the Transatlantic Trade and Investment Partnership agreements on Africa's economic development. He noted that together the two agreements "will cover nearly 60 percent of global GDP". He predicts with concern that "(t)rade

rules established through these mega free trade agreements will become de facto global standards." Africa and other developing countries will be bound by the rules even though they are not a part of the negotiations of the current negotiations. These could lead to more tensions about the misaligned interests of developed and developing economies.

Lack of trust among key stakeholders is a salient feature of the global pharmaceutical patents and access to medicines landscape. Treatment access activists, pharmaceutical executives and public health policy-makers have not been able to reach meaningful consensus on how to balance patent rights and equitable access to medicines. The disagreements are evident in treatment access activist Rachel Kiddell-Monroe's (Kiddell-Monroe, 2015) assertion that the pharmaceutical industry has to date been able to fashion a dominant narrative about the need to protect their business rights that is believable to all. She laments that the access to medicines lobby has become too stuck on disproving the industry's version. Appealing to them that, "…we need to stop dancing the pharma foxtrot and start a citizen's samba, a dance that quickens the pace and out-dances the other. In this way we become the leaders and the pharmaceutical industry has to keep time with us, not the other way around". The "out-dance the other" strategy is problematic because it means one party gains the upper hand while another is subdued.

My recommendations are,

(a) the multinational pharmaceutical industry must desist with its dogged insistence on stringent global patent protections and refrain from charging unconscionably high prices on essential medicines,

(b) global access campaigners must to agree to legitimate legal protections of pharmaceutical patents in exchange for reasonable relaxation of current stringent patents on essential medicines,

(c) Governments throughout the world – both developed and developing countries, must stand together and ensure that TRIPS flexibilities are adhered to and that they are uniformly applied to honour the access to medicines public interest provisions granted by the Doha Declaration

(d) The African Union must develop a coherent regional pharmaceutical patent regulation system and clarify how the continent will cooperate to leverage TRIPS flexibilities to facilitate access to essential medicines for their citizens. Lack of regional legislative certainty impedes the right-to-health guarantees enshrined in Article 16 of the African Charter.

(e) the African Union must direct its member states to incorporate the access to medicines objectives of the African Union Model Law on Medical Product Regulation which was adopted during its Summit of Heads of State and Government that was convened in Addis Ababa, Ethiopia on 30 to 31 January 2016 (PharmaAfrica, 2016).

My conclusion is that governments throughout the world are increasingly under pressure to override pharmaceutical patents in the public interest - to facilitate regular and affordable access to medicines. For example, in the United Kingdom, a coalition of physicians, patient and advocacy groups called on the ruling party to override Roche's patent on the breast cancer drug Kadcyla (which retails at about $155,000) to allow the manufacture of a cheaper version (Silverman, 2016). I have discussed the US Congressional lawmakers' request urging the National Institute of Health to utilize its "march-in" rights, earlier (Silverman, 2016). Furthermore, two US access to medicines non-profits, KEI and the Union for Affordable Cancer Treatment, have subsequently filed another "march-in" request in respect of Astellas' prostate cancer drug Xtandi (which retails at about $130,000 per annum). The applicants have asked "the US government to exercise its rights under federal law to make the fruits of tax-payer-funded research more available on reasonable terms" (Silverman, 2016).

How the US government responds to its conflicting national duties in respect of its traditional allegiance to the powerful pharmaceutical industry lobby and the desperate public cries for affordable access to essential medicines, will set the stage for substantive reform of the global IP framework reform. The *zeitgeis*t has fundamentally changed. A delicate moral and legal balance is urgently required to meet growing global requests to push back against "profit gouging" by multinational drug manufacturers, on the one hand, and the United States government's tendency to aggressively protect US pharmaceutical patents in bilateral trade agreements with developing nations, on the other hand. The "march-in rights" requests filed in that country have gone a long way to debunk the multinational pharmaceutical industry's Washington-based lobbyists' claims that insistence on stringent IP protections globally is crucial because the rest of the world is envious of the US' successful knowledge-based economy. They have also assisted in disproving pro-pharmaceutical industry claims that "only rogue developing nations" like South Africa and India are intent on attacking the multinational sector's legitimate pharmaceutical patents.

South Africa must urgently finalise its IP laws reforms. It must do so bolstered in its resolve by the legal and moral opportunities created by recent international developments in the access debate. The human rights and right-to-health entitlements of millions of destitute South Africans cannot forever be held ransom to the tardiness of bureaucrats and politicians, and/or the unconscionable profit-making of multinational pharmaceutical manufacturers. Key stakeholders in the global access debate must abandon both the foxtrot and the samba – and join hands for a new dance that will ultimately lead to the provision of equitable access to medicines to all who need them.

Public policy-makers and pharmaceutical executives need to understand that socio-economic rights like the right-to-health in section 27 are not social services but the fundamental

constitutional entitlements of citizenship. Section 7(2) of the Bill of Rights expressly stipulates that "the state must respect, protect, promote and fulfil all rights in the Bill of Rights". The right-to-health is one of the fundamental human rights covered by this injunction. Drug manufacturers who oppose IP law reform fail to comprehend that the property rights they stake under section 25 of the Constitution cannot be severed from the restorative justice mission of the post democratic Republic. There is also a golden opportunity for the multinational pharmaceutical industry to correct its battered corporate image by voluntarily acceding to the human rights duties identified by former UN Special Rapporteur on the Right-to-health Paul Hunt in 2008 (Lee 2015). The pro health equity objectives contained in Hunt's report entitled 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Essential Medicines', offer a useful roadmap from which the sector can start good faith and legally binding discussions about how the unpopular TRIPS framework can be reconstructed to fairly balance pharmaceutical IP protections and the public interest.

In a promising development, the UN is taking the international law lead in the new pharmaceutical patents and human rights dance started by its former Special Rapporteur Paul Hunt. UN Secretary-General Ban Ki-moon convened a High-Level Panel on Access to Medicines in December 2015. He invited contributions to address the vexing "*policy incoherence between international human rights law, trade rules and public health objectives* regarding the innovation of and access to health technologies" (Global Commission on HIV and the Law website, 2015). (Emphasis added) A global access to medicines dialogue was subsequently held on 3 February 2016 at the UN's offices in New York, "*to explain some of the vision and urgency behind the setting up of the panel, which includes an expert committee of representatives of some 10 international organisations and others*. (The call also includes) an

open online call for contributed ideas…and (plans to host) two public hearings" (New, 2016). (Emphasis added) Finally, South Africa should follow the compelling legal example of the African Union which took the bold step to reform its regional approach to the pharmaceutical patents and access to medicines dialogue by adopting the African Union Model Law on Medical Product Regulation during the Summit of Heads States and Governments held in Addis Ababa, Ethiopia, from January 30-31 (PharmaAfrica, 2016).

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