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To Whom It May Concern:

The three examiners' reports for the thesis *Pharmaceutical Security in South Africa: Law and Medical Geopolitics* have been received and digested. Discussions have occurred between my supervisor, Professor Pirie, and myself as to how to best address these suggestions. An exhaustive process of amendment and review has been conducted to ensure that all the examiners opinions have been carefully considered. A number of amendments have been made.

The most significant change, requested by two of the three examiners, was a greater explanation of the research methodology. In response, a short explanation has been inserted in the introduction and a longer methodology in an Appendix, including a list of the interviewees. By choosing to place the methodology in an appendix the flow of the thesis has not been compromised, whilst greater scientific rigour has been added.

One of the examiners requested a single research question be presented. After consideration, it was decided that whilst a single question is not present, the introduction does provide the reader with a clear sense of the objectives of the research and what questions it seeks to answer.

Other suggestions were small additions and amendments concerned with clarification and phraseology. These have all been acted upon.

It is hoped that these amendments are to the satisfaction of the Board and add to the quality of the thesis.

Yours faithfully,

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Pharmaceutical Security in South Africa: Law and Medical Geopolitics



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Declaration

I declare that **Pharmaceutical Security in South Africa: Law and Medical Geopolitics** is my own work and that all the sources used or quoted have been indicated and acknowledged through complete references.

Thomas Gater

September 2008



Abstract

The study focuses on the political and economic geographies of pharmaceutical delivery. In 1997 the South African government passed the Medicines and Related Substances Control Amendment Act, sparking outrage from both the local and international pharmaceutical industry, and resulting in court action in 2001. The industry believed that South Africa was in breach of its obligations under international intellectual property law. Those fighting for pharmaceutical security hoped the court case would be a 'landmark' in the global campaign for equitable access to medicines. This investigation seeks to analyse the domestic and international legacy of the court action. The inquiry takes its significance from the high prevalence rates of treatable diseases and the need for pharmaceutical security in South Africa and its neighbouring African countries. The absence of a sustainable international medicines delivery system is a global political, economic and moral failure. A solution is required that balances the positive productive forces of the market with a philosophy of justice and equity.

Keywords:

- Africa
- Geopolitics
- Health
- Inequity
- International Political Economy
- Law
- Medical Geography
- Pharmaceutical security
- South Africa



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Finally, I am hugely grateful to Professor Gordon Pirie for his support and guidance throughout my time in Cape Town. Coming to South Africa from the UK was made a great deal easier thanks to his enthusiasm and willingness to help me both before and after moving over. Academically I owe a great deal to Gordon, his patient and constructive feedback and encouragement have allowed me not only to adapt to the requirements of academic writing but also to enjoy it. Thank you.

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List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANC	African National Congress
ARV	Anti-retroviral (drugs)
AU	African Union
CEO	Chief Executive Officer
COSATU	Congress of South African Trade Unions
DBSA	Development Bank of South Africa
DoH	Department of Health (South Africa)
DTI	Department of Trade and Industry (South Africa)
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
HAART	Highly Active Anti-retroviral Therapy
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
ILO	International Labour Organization
IMF	International Monetary Fund
IMSA	Innovative Medicines South Africa
IPE	International Political Economy
MNC	Multinational Company
NGO	Non-governmental Organisation
PhRMA	Pharmaceutical Research and Manufacturers of America
PIASA	Pharmaceutical Industry Association of South Africa
PMA	Pharmaceutical Manufacturers Association (of South Africa)
R&D	Research and Development
SACU	Southern African Customs Union
SADC	Southern African Development Community
TAC	Treatment Action Campaign
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Programme
UNFPA	United Nations Fund for Population Activities
UNICEF	United Nations International Children's Fund
USTR	United States Trade Representative
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Introduction

South Africa is a country in transition. Enhancing equity and upgrading service delivery are key concerns of the post-apartheid government. One of the core areas in need of development is South Africa's health system. Establishing an equitable healthcare structure depends on numerous factors, one of which is access to safe, effective and affordable medicines. Achieving pharmaceutical security in South Africa has the potential to greatly improve the population's health, particularly in the face of the HIV/AIDS epidemic.

In a world shaped by the forces of globalisation the medicines delivery system is a truly international network. Research and development, manufacture and regulation, distribution and prescription span the globe. Decisions made at the headquarters of multinational pharmaceutical companies based in Europe or the United States are inseparable from the health of patients in South Africa. The medicines production network operates at multiple scales and transcends national borders.

In 2001 the South African government was taken to court by the multinational pharmaceutical industry. The case centred on a piece of legislation that attempted, through various mechanisms, to enhance access to medicines in South Africa. The pharmaceutical industry regarded these mechanisms as unconstitutional and in breach of South Africa's obligations under international trade law. Only two months into the legal case, however, the pharmaceutical manufacturers dropped their action against the government in response to considerable pressure from civil society, governments and multilateral organisations. The legacy of the court case is analysed in this study.

The 2001 court action was a micro-space in which business and governance collided, where government policy and law met with global economic forces. International medicines delivery is a highly complex system. The South African court action provides an opportunity to focus diverse and multidimensional factors into one critical unit. Confining the study to a temporally and spatially specific moment enables broad universal themes to be analysed effectively.

An assumption of this study is that the realms of business and governance are inseparable. The one is unable to act without the other. The provision of social goods, such as medicines, is tied into an integrated international political economy. Liberal

thinking may be too quick to dismiss the potential contribution of big business to social welfare. Many activists speak of the pharmaceutical industry in the same breath as tobacco or arms manufacturers. There is a tendency to dichotomise issues and actors into 'good' or 'bad'; however, the global pharmaceutical delivery system is far more complex than this. Is it realistic to demand the provision of medicines for all, whilst simultaneously undermining the very industry that produces those medicines? One of the purposes of the research is to investigate whether a more balanced approach, inclusive and supportive of all stakeholders, would benefit pharmaceutical security.

The research investigates the degree to which the legacy of the court case goes beyond the borders of South Africa. The resistance the pharmaceutical industry faced was of global proportions, but did it have global consequences? Systems and networks consist of webs of power and influence; did the actions in South Africa in 2001 alter the dynamic within the pharmaceutical web? The geopolitical fabric of the international pharmaceutical economy is analysed to see whether South Africa's position in the global and continental geography of therapeutic drug provision was affected.

The pharmaceutical delivery system stands at the intersection of a diverse range of disciplines. Medicine, Economics, Human Rights, Ethics, Politics and Law constitute the complexity of therapeutic drug provision. Geography also has the potential to contribute to addressing issues of pharmaceutical security. The discipline uniquely bridges the social sciences, whilst remaining faithful to concepts of scale, territory and space. Understanding the causes of differences and inequalities between places and social groups underlies many of the recent developments in Human Geography.

Adopting a geographical approach allows a thorough critique of current global medicines provision. An integrated approach is adopted that encourages simultaneous recognition of processes operating at the local as well as the transnational level, allowing for the conceptual mapping of the pharmaceutical delivery system. Such an approach is necessary in order to identify the numerous barriers to access that exist along the pharmaceutical production network and to examine the influence the 2001 court action has had on these obstacles.

The thesis research here attempts to marry the market-based assumptions of Economic Geography with the structural preoccupations in Political Geography. The

investigation also recognises that medicine provision, whilst ruled by economic and political forces, is a matter of life and death. As such, an effort is made to introduce concepts of equity and justice to the political and economic spheres of pharmaceutical delivery. Profits and principles may not be mutually exclusive. Achieving pharmaceutical security in South Africa and elsewhere may well depend on finding the right balance between economic, political and ethical standards.

The research was predominantly a 'desktop' study, with the vast majority of data obtained from secondary sources. The literature used comes from a wide variety of sources. Throughout the literature search, analysis and interpretation, there was an attempt to provide a representative sample of views. The literature comes from academic books and journals from a range of disciplines, including Geography, Politics, Economics, Public Health, Biomedicine and Philosophy. Pharmaceutical industry publications as well as government and civil society material were also consulted extensively. In addition, institutions such as the World Bank and World Health Organisation have produced significant volumes of literature that have been cited extensively throughout the research.¹

¹ A Methodology, including details of the primary data collection and a list of interview subjects can be found in Appendix A & B.

Chapter One: Health Inequity and the Body Politic

The persistence of avoidable deaths from treatable illnesses in the developing world indicates a failure in the global health care system. An individual's health is no longer just a concern for regional health services or the nation state; health is intimately tied to processes operating at the global level. As such, Medical Geography has the potential to greatly contribute to the analysis and understanding of local, regional and supranational determinants of health. A nation's degree of pharmaceutical security is a crucial aspect of a functioning healthcare system.

Pharmaceutical security and the injustice of health inequity.

Health inequalities exist. Inequality is an inevitable part of living in a diverse world. Inequity in health, however, is especially troubling. Inequity implies that the differentials between the haves and have-nots are avoidable, and that it is within our power to reduce the gap. This study begins with the assumption that a lack of access to medicines is inequitable and by extension unethical. At the core of the investigation lies a belief that allowing millions of people to live in pharmaceutical insecurity is a moral failure of the political and economic system.

The global health establishment has the financial and technological resources to bring pharmaceutical security to all people. Yet in spite of this one third of the world's population and half of all people in Africa and Asia have no access to medicines (Orbinski, 2007; Forman 2007; Wijnberg, 2007).² It is estimated that improving access to existing medicines could save ten million lives each year, four million of them in Africa and South-East Asia (Hunt, 2007; Ruxin et. al., 2005). The right to life is the most basic of all rights (Yamin, 2003). Medicines can be indispensable to life. Viewing pharmaceutical security as a matter of fundamental human rights forces recognition that death due to preventable diseases is an injustice.

Just as in the case of food and famine, death from a lack of medicines is a socio-political failure. In the 1970s and 1980s famine was a serious worry for the

² Roughly 79% of the global population without access to medicines live in low-income countries. Only 0.3% of those living in high-income countries lack access to medicines. The figure is roughly 20% in middle-income countries (Leach et. al., 2005).

developing world, and numerous studies were conducted to examine the phenomenon. One piece of work became the seminal reference for all those that followed, Jean Drèze and Amartya Sen's *Hunger and Public Action* (1989).

The opening paragraph of this classic insists that,

No social or economic problem facing the world today is more urgent than that of hunger. While this distressing state of affairs is not new, its persistence in spite of the remarkable technological and productive advances of the twentieth century is nothing short of scandalous (Drèze & Sen 1989, p. 1).

What applied to food security twenty years ago translates equally well to pharmaceutical security in the twenty-first century. With over 50% of people lacking access to medicines in some areas of Africa, it may not be too extreme to assert that these regions are facing 'pharmaceutical famine'. Drèze and Sen proposed that famine was rarely due to crop failure; more often it was a social phenomenon caused by entitlement failure. Death from preventable diseases should also be considered a social phenomenon.

Pharmaceutical security has developed into a social phenomenon as the delivery of healthcare has become commodified. From a purely economic view, healthcare is a commodity like many others in the service sector (for example, hair cuts or car repairs). From that perspective, the creation of effective new medical treatments is an intellectual achievement like many others (for example, the creation of new music or software). From a moral standpoint, however, there is significant difference between poor people not being able to get their hair cut and poor people lacking access to life-saving medicines (Pogge, 2005). Pharmaceutical products directly affect the health of a nation. They are irreplaceable. Functional – if not optimal – substitutes can be found to address inadequacies in other components of treatment, for example different infrastructure or alternative health providers. In contrast, no amount of administrative creativity can provide comparably effective

substitutes for a treatment such as Antiretroviral therapy (Shadlen, 2007). If medicines are not available, in most cases treatment is impossible.³

Alongside the presence of skilled health professionals, medicines form the foundation of all healthcare systems. In the developing world a far higher proportion of national health budgets is spent on medicine procurement than in the developed world. In sub-Saharan Africa 74% of the average health expenditure is on medicines, whereas only 7.4% is spent in developed countries (Foreman, 2002). Consequently, developing country health systems are far more price sensitive than those in developed countries. Not only do high prices for pharmaceuticals directly impact upon health budgets, they may also discourage resource mobilization (Shadlen, 2007). High prices can serve as a disincentive to invest in the development of healthcare infrastructure, as a clinic is next to useless without a supply of medicines

Pharmaceutical equity is dependent upon both the availability and accessibility of medicines. Availability relates to whether a medicine exists, accessibility involves consideration of whether an existing medicine can be obtained by a doctor or patient. Production and supply precede access (Shadlen, 2007); activists and policy makers can only focus on the steps needed to acquire medicines if they exist. The existence of a medicine is dependent upon whether a developer, normally a pharmaceutical firm, has invested in research and development in a therapeutic area. Development priorities are driven by commercial value or return on investment, the problem facing the poor is that their illnesses are not as profitable as those found in the developed world, resulting in a severe research gap.

One of the central assumptions of this investigation is that some medicines are more valuable than others. Here, value does not reside in profits but in terms of therapeutic significance (impact on mortality and morbidity). Only 10% of the \$55 billion (R424 billion) annual global spending on health research is devoted to diseases or conditions that account for 90% of the global disease burden (Idris & Arai, 2006). Research into the “big three” infectious diseases (tuberculosis, HIV/AIDS and malaria) is relatively well funded, however there exists a group of neglected diseases that receive minimal research attention. There is a desperate need for new medicines to control the re-emergence of human African trypanosomiasis and to replace current

³ Western public health scholars are often too quick to dismiss herbal and traditional medicines. There is a growing body of evidence that suggests that the traditional medicines found in parts of Africa, Asia and Latin America can have a significant therapeutic value for some conditions.

treatments for chagas disease, whilst diseases such as dengue fever and ebola remain untreatable (Ford, 2006). Market mechanisms that control pharmaceutical research have failed patients suffering from these infectious diseases.⁴ The balance between commercial value and therapeutic or social value lies at the heart of the efforts to achieve pharmaceutical security.

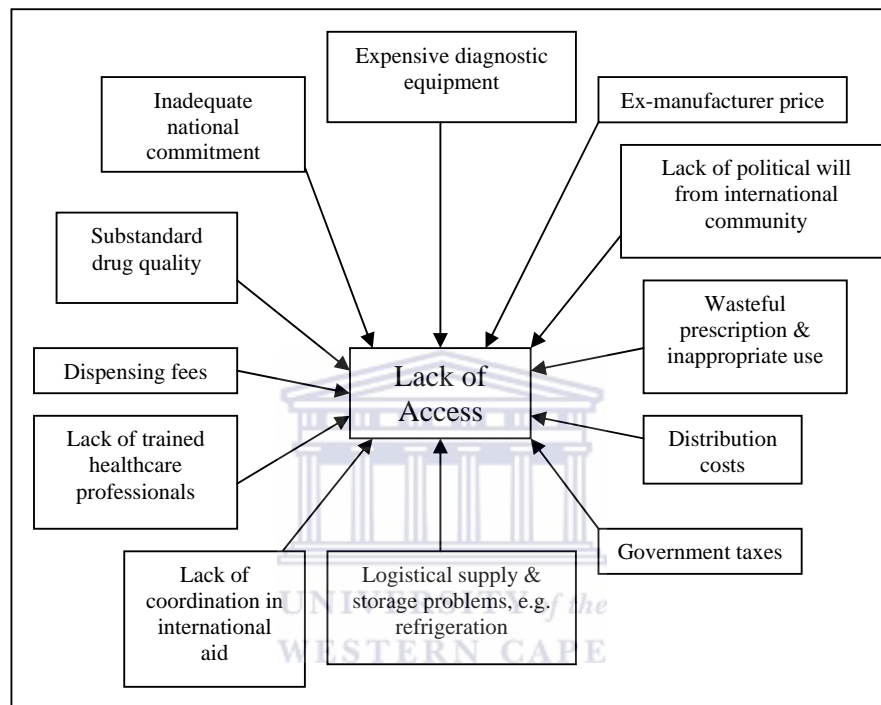


Figure 1.1 The multidimensional factors limiting drug access (Tetteh, 2008; t'Hoen, 2002; Shadlen, 2007; Leach et. al., 2005)

Many factors contribute to medicines inequity. This study focuses on the pharmaceutical industry and the ex-manufacturer price of medicines, but this is only one piece of a much greater puzzle. Whilst the pharmaceutical industry produces the medicines used to combat diseases, it is not responsible for distribution of treatments, diagnosis of illness, or prescription of a product. For example, the manufacturer's price represents only part of the cost to a consumer. The end price of a medicine includes government taxes, distributors' and retailers' margins. The WHO calculates that in developed countries, the manufacturer's price typically represents 50%-60% of

⁴ Market failure and research and development priorities will be considered in greater detail in Chapter Three.

the final consumer price, while in some developing countries up to 80% consists of import duties, taxes, distribution costs and dispensing fees (Foreman, 2002). The various dimensions of ‘access’ (Figure 1.1) emphasize the need for differentiated yet simultaneously operating access policies at the global, national and regional scale (Tetteh, 2008).

The multidimensional factors that shape a country, a region or an individual’s degree of pharmaceutical security require multi-disciplinary conceptual analysis. The following section argues that modern Medical Geography can provide the framework required for critical engagement with concerns over inequitable access to medicines.

The body politic: beyond biology

*Medicine is a social science, and politics nothing
but medicine on a grand scale –Rudolph Virchow
1848 (cited in Cooper et. al., 2007a, p. 29)*

All social organisms have an environment to which they relate. Despite the fact that the immediate cause of a disease may be a virus, the institutions and practices of society are largely responsible for creating the conditions within which disease-agents either flourish or die (Meade & Earickson, 2000; Gesler et. al., 1997). For many years Medical Geography failed to recognise the importance of the social, economic, political and cultural influences on an individual’s health. The sub-discipline has for too long been a tool of biomedicine.

Classical Medical Geography can be divided into two parts.⁵ First, spatial epidemiology engages the core principles of geographical thought – distance, direction, location and distribution – for the purpose of establishing a correlation between disease and physical environment (Litva & Eyles 1995; Eyles & Woods, 1983). Examples of such studies include those investigating malaria distribution in a country, measles diffusion in a region and suicide rates in a metropolitan area (Eyles & Woods 1983). Such studies take what Litva and Eyles (1995) call a “structural

⁵ For more detailed accounts see Eyles and Woods (1983), Gesler, Bird and Olieski (1997), Meade and Earickson (2000), Gatrell (2002), Curtis (2004), Litva and Eyles (1995), and Jones and Moon (1987).

functionalist” approach – this is a positivist exercise based on quantitative methods using concrete numerical data (Gesler et. al., 1997).

The second main part of classical Medical Geography is study of the spatial distribution of health services. Issues such as the impact of location on facility utilisation and analysis of spatial resource allocation policies are at the core of such an approach (Eyles & Woods, 1983). The health services that have been analysed have typically been limited to personnel and medical facilities rather than medicines. Studies also tend towards the regional or national scales and rarely deal with global structural patterns and processes.

Traditional divisions between the economic, social, political, cultural and environmental spheres have increasingly become irrelevant within Geography (Painter, 1995). This erosion of boundaries is also reflected in the sub-discipline of Medical Geography. It has become generally accepted that there is a need to go beyond the biological determinants of health. Medical Geographers are now aware of the need to situate health among the structural processes operating within society; and are inclined to look beyond the human body to the ‘body politic’ (Jones & Moon, 1987; Brown & Duncan, 2002; Gatrell, 2002).

Situating health within a socio-political framework complements principles of public health that emerged in the late 1970s following the International Conference on Primary Health Care at Alma Ata (1978). ‘The public health attitude’ forms the core of the majority of national health systems across the globe (Brown & Duncan, 2002). A crisis such as the HIV/AIDS epidemic has had wide ramifications for public health, destroying the boundaries separating such previously distant concerns as health, gender, sexuality, trade, property rights and human rights (Petchesky, 2003). In response, issues of access to medicines require a global framework for study and action. A nation-state’s health policies are not insulated from the outside world. On the contrary they are fundamentally integrated within global political and economic structures. Consequently, without wanting to put the study in an intellectual box, a largely structuralist approach will be adopted in this investigation.⁶

Structuralist analyses of medicine start with the assumption that health is embedded in the political economy. Essentially, structuralists focus on power and

⁶ Gatrell (2002) identifies five approaches to geographies of health and provides a detailed account of each of them. The five approaches are: positivist, social interactionist, structuralist, structurationist and post-structuralist.

domination and the way they are expressed across space through various structures, such as governments, multilateral organizations and multinational firms (Sprague & Woolman, 2006).⁷ The South African lawsuit, considered in subsequent chapters, exemplifies the kind of power politics that sit at the heart of structuralism. The framework provided by the structuralist political economy allows Medical Geographers to critically interrogate power politics and the influences it has on global pharmaceutical delivery.



⁷ For a more detailed account of the structuralist school see Gatrell (2002) and Johnston et. al. (2000).

Chapter Two: International Political Economy in Medical Geography

The intention throughout the work is to present an integrated theoretical/conceptual framework into which the research findings can fit. In the same way as an individual's health is inseparable from economic processes and political decisions, the theories that underpin these interactions cannot be forced into convenient intellectual boxes. A number of academic theories are presented in the forthcoming chapter, however, whilst they may originate from various subjects and sub-disciplines they all fit within and contribute to the architecture of a global pharmaceutical political economy.

A structurally determined international political economy (IPE) provides an appropriate conceptual framework for critically analysing the extent of and the reasons for health care inequity in its various guises. The IPE concept is well positioned within the social sciences to tackle the multidimensional complexities of the pharmaceutical delivery system. The interdisciplinary nature of IPE means that the flows of power, wealth and knowledge that characterise the global healthcare system can be analysed as a whole, rather than in isolation.

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Globalisation and health: Geopolitics as health diplomacy

The interdependence produced by globalisation has broken down the traditional ways of conceptualising the medical, economic, political and technological means to improve health.⁸ These formerly separate spheres have become linked across economic and political space.

At any location on the earth's surface there are both vertical and horizontal relationships. The vertical relationships link different elements in the same location, whereas the horizontal relationships link elements in separate locations (Johnston, 1983; Johnston et. al. 2000). In order for a government to craft health policy it must manage both the horizontal and vertical relationships. In the process of doing this it adopts mechanisms that spill into and out of every country.

⁸ The vast literature surrounding globalisation can mystify rather than clarify. This study will not attempt to wade through the many diverse accounts of the process of globalisation. Rather, the investigation is more concerned with its influence on how a geographer conceptualises health. Phillips (2005) provides a thorough and topical account of globalisation.

Despite claims by hyper-globalists that the nation-state is redundant, states remain core actors within global health diplomacy. It is the task of national governments to reorient their health and foreign policies in ways that align their national interests with the political, economic and epidemiological realities of a globalised world (Drager & Fidler, 2007). Such a task goes beyond classical diplomacy. Governments must now bargain with non-state as well as state bodies.

Constructing global health from state-centric perspectives bypasses one of the most significant developments in the global health governance structure, itself a “new political space”. There are numerous organisations occupying this space, which have seized opportunities to influence global healthcare delivery (Figure 2.1). Health activists and non-governmental organizations (NGOs), global philanthropists and the private sector have competed eagerly for resources and political attention and are engaged in constant flux between coalition and competition (Kickbusch, 2003). The capacity to influence health status and outcomes cannot be assured through national actions alone because of the intensification of cross-border and trans-border flows of people, goods, services, and ideas (Dodgson et. al., 2002). Ignoring these flows and organizations, particularly when dealing with issues of pharmaceutical delivery, would be to ignore powerful processes within global healthcare. A government seeking to maximize the welfare of its population must actively engage and form constructive relationships with these forces.

An age of medical geopolitics is emerging in which states are realising the global significance of health concerns such as HIV/AIDS, avian flu, and bio-terrorism. The recognition that health is a crucial determinant of development and security has pushed medical issues higher up the international agenda (Traulson & Almarsdottir, 2005; Loepky, 2004). After being consigned to ‘low politics’ for so many years, health is now regularly dominating talks at the United Nations and World Trade Organization. ‘Global health security’ was a significant theme at the session of the Executive Board of the WHO in January 2008. ‘Health security’ is equated to the activity required to minimize the impacts of acute public health crises that endanger populations living throughout different geographical regions (WHO, 2008a). Increasing access to medicines is an activity that certainly furthers health security.

Throughout the history of Geopolitics the discipline has always been associated with the analysis of global rivalries in world politics (Taylor, 1993), and the consequences these have for a population’s security. Constructing a specific

definition of geopolitics is notoriously difficult; the meaning of the concept has changed over time as structures of the world order have altered (O'Tuathail, 1998).

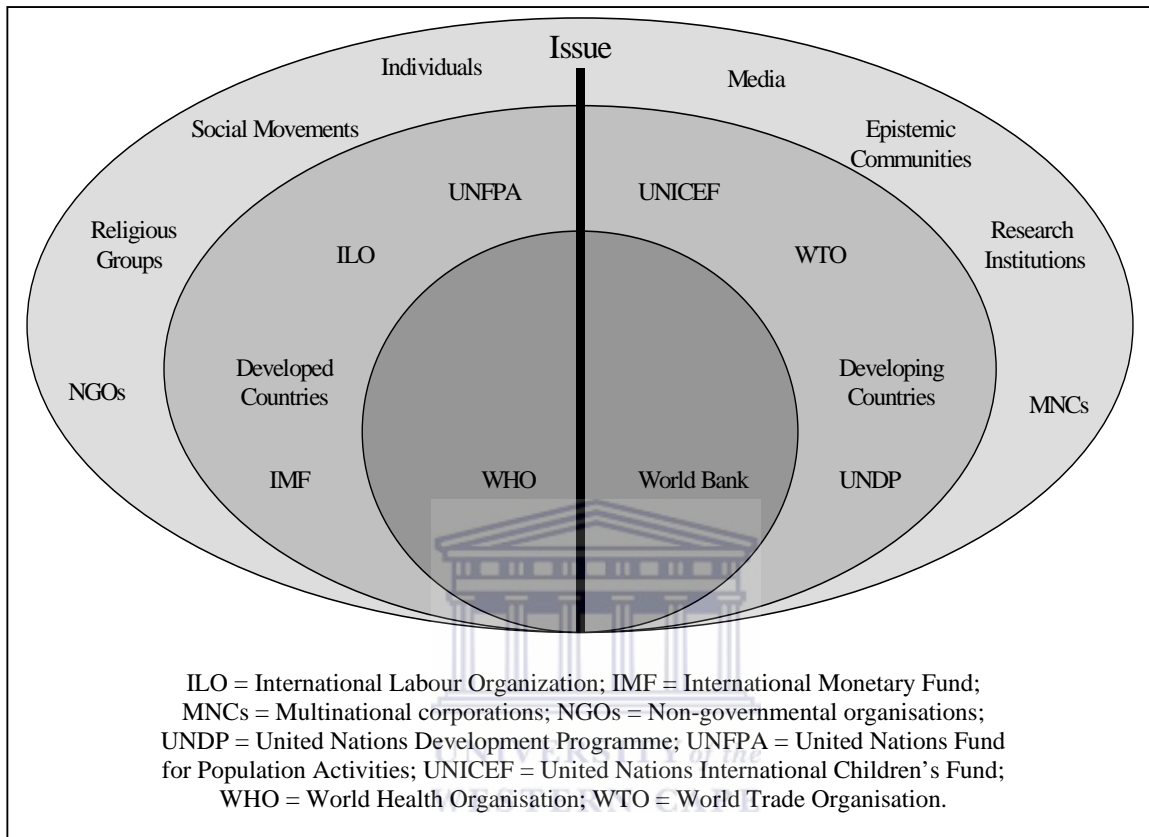


Figure 2.1 The Global Health Governance Structure. (Source: Dodgson et. al. 2002, p. 22.)

During the early years of Geopolitics in the late 19th and early 20th century it was understood as part of Western imperial knowledge dealing with the relationship between the fixed physical features of the earth and politics (Agnew & Corbridge, 1995). Following this the discipline became associated with the notorious Nazi foreign policy goal of *Lebensraum* (the pursuit of more 'living space' for the German nation). During the Cold War it was used to describe the global contest between the Soviet Union and the United States of America (O'Tuathail, 1998). In recent years the subject of Geopolitics has enjoyed a revival (but with little agreement as to its precise meaning and influence) as foreign policy makers, strategic analysts and academics have struggled to grasp and express the dynamics of the global political economy (Agnew & Corbridge, 1995; O'Tuathail, 1998).

Geopolitics tackles the 'big picture', offering a way of relating local and regional dynamics to global processes. Through a spatial approach it arranges actors, elements and locations into networks. After the end of the Cold War and the rapid globalisation of economics and politics, there has been a great effort to establish the boundaries of a 'new geopolitics'. Some commentators see a new political order dominated by geo-economic forces: where transnational flows of capital are changing the nature of states, and questioning the sovereignty and geopolitical structures that have previously dominated the planet (O'Tuathail, 1998). Since the end of the Cold War a number of international conferences and treaties on the environment, development, human rights, population and health have suggested that a new era of transnational cooperation has arrived (Dalby, 1998). Geopoliticians have a responsibility to interrogate such initiatives and analyse them critically.

Four main approaches to inquiry can be singled out within Geopolitics.⁹ First, traditional geopolitics is associated with imperial expansion and the geostrategic advantages of land power. Second, the power-relations perspective focuses on the hierarchical nature of the global order and issues of power equilibrium. Third, critical geopolitics focuses on the meanings and forms of representation that underpin geopolitical spaces. A fourth approach, political economy, encourages a wider and more nuanced consideration of geopolitics (Johnston et. al., 2000; Agnew & Corbridge, 1995). This last approach, adopted throughout the study, goes beyond preoccupation with the state.

Military security has traditionally been at the core of geopolitics, but there is increased recognition that other forms of security are becoming important. Relative economic power has begun to displace military force as a central feature of international relations. Technology, education and economic growth have become more important than conventional geopolitical attributes in determining success in the international system (Agnew & Corbridge, 1995). A state's or region's economic security has become a concern of 'new geopolitics'. Pharmaceutical security, as a vital component of a nation's health, is essential to the maintenance of economic and political stability.

The power of multinational corporations (MNCs) now dwarfs that of many states (Dalby, 1998). These firms can have a sizeable influence on a nation's

⁹ For a detailed account of the four approaches see Johnston et. al. (2000).

economic, and by extension, political security. Consequently, there are calls for Geopoliticians to move away from their preoccupation with the nation state towards a critical understanding of other power-wielding agents (Agnew & Corbridge, 1995). In this study Geopolitics is positioned as the analysis of divisions within global space through institutions such as states, firms, social movements and international organizations. This division results in the formation of distinct territories and spheres of political and economic influence through which the IPE is regulated. IPE is realised geographically through practices and ideas which are socially constructed rather than naturally occurring (Agnew & Corbridge, 1995). The ability of different localities and regions in the IPE to adapt to changing circumstances is not merely the result of natural resource endowments indeed, the processes of change and influence are far more subtle and dynamic than the traditional geopolitical framework recognises.

International Political Economy: the dynamics of power and wealth

The struggle over access to medicines is a case study of the fluidity and tenacity of global power structures (Petchesky, 2003) and the influence these structures can have on an individual's entitlement to health. International Political Economy (IPE) is the study of the interplay between power (politics) and wealth (economics) in the global arena. IPE allows for a twin focus on power and wealth motives at the micro-level and the political organization of international capitalism at the macro-level (Guzzini, 1998). The basic tenet of the political economy approach is that human experiences, including illness, arise from social relationships (Gesler et. al., 1997). It recognises that health is a social as well as a biological quality, embracing the concept of the 'body politic'.

Structuralism sees the political economy as necessarily conflictual (Frieden & Lake, 2000). Human existence is filled with elements of tension, and with boundaries where differing and sometimes conflicting interests or value systems collide (Balaam & Veseth, 2001). All production and consumption networks are subject to a multiplicity of geographically differentiated political, social and cultural influences. Political pressure groups and politicians have as much influence on economic outcomes as the laws of the marketplace (Dicken, 2003; Frieden & Lake, 2000). This

is particularly true for the pharmaceutical production network; due to the politically sensitive nature of pharmaceuticals the industry is one of the most highly regulated and publicly scrutinized. The pharmaceutical market is intimately integrated into national and supranational political processes.

As geographers began to focus on health inequalities it became clear that the way countries organised their healthcare systems had a major influence on the dimensions of healthcare inequalities (Meade & Earickson, 2000). As a result, since the early 1980s the political economy or structuralist approach has been championed by a small group of progressive Medical Geographers (Eyles & Woods, 1983; Jones & Moon, 1987; Gesler et. al., 1997).

The primary focus of political economy within Medical Geography has been the national economy's impacts on healthcare provision (Lee & Zwi, 2003; Gesler et. al., 1997). There has been little acknowledgement of the 'I' in IPE. The preoccupation with the national or regional determinants of illness risks neglecting the multi-scalar nature of global health. The permeability of national borders and the effect which international forces have on healthcare necessitates consideration of global processes by Medical Geographers. There are a multitude of national and local factors that determine access and use of healthcare (Figure 2.2). Such schematics are reproduced in a whole host of Medical Geography books, the majority of which, however, overlook the supranational elements of health inequity.

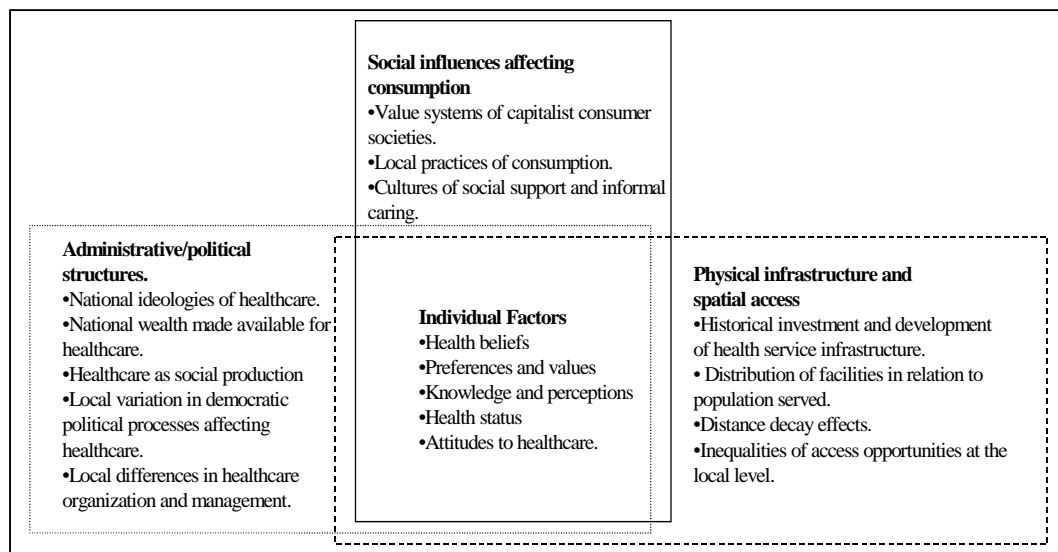


Figure. 2.2 A schematic model of healthcare access and use (Source: Curtis, 2004, p.115)

Qualitative changes in the dynamics between polity, market economy and civil society mean that geopolitical space is constantly shifting. As a consequence, health becomes patterned within society, with some groups achieving consistently better standards than others (Litva & Eyles, 1995). Such social injustice is the focus of conflict theorists working within Medical Geography, and provides a useful conceptual overlap with structuralism. Conflict theorists believe that social injustice stems from imbalance in the power dynamics of the political economy. They are concerned with how international governance is shaped by the interactions between subordinate and super-ordinate groups, and the conflicts that may arise from these interactions (Litva & Eyles, 1995; Ruggie, 1998). The South African court case of 2001 (detailed in Chapter Four) is a prime example of a conflict arising from such interactions.

Significantly, conflict theorists do not claim to be objective researchers. Research topics and the commitment to use their findings are all seen as reflecting the political and economic interests of the researcher. Medical Geographers informed by conflict theory seek to expose injustice (Litva & Eyles, 1995) and propose pragmatic solutions to inequity. Objectivity is impossible when dealing with an issue as important and emotive as pharmaceutical security. As such, the first assumption of this investigation was that inequitable access to medicines was an injustice and that it was symptomatic of global political and economic failure.

In order to understand the processes resulting in so many people lacking pharmaceutical security it is necessary to consider the political and economic aspects of medicine delivery. The relationship between the state and market is central to any investigation into inequitable access to medicines.

State-market relations: the diffusion of global power

Neither the state nor the market is primary within the global medicines delivery system. Since the study of IPE began, from the writings of John Stuart Mill to Karl Marx, there has been recognition that “pure markets” are a myth. Every market system is embedded in and affected by social and political realities (Prusak & Cohen, 1998). This is particularly true in the health sector. Governments play an important

role in the regulation of health consumables to prevent dangerous practices and to control costs (Bloom & McIntyre, 1998). Consequently, firms, such as those in the pharmaceutical industry, have little choice but to engage with states and to tailor their policies to the regulatory environment.

The relationship between capitalist corporate actors and the state is continually evolving. The IPE is a network of bargains between and among states and markets. This web of interdependence (Figure 2.3) determines the production, exchange and distribution of wealth and power across the global arena (Balaam & Veseth, 2001). As such, power is increasingly diffuse. The state is no longer the single mechanism through which security, production, credit and knowledge are distributed internationally (Guzzini, 1998; Cerny, 2000). In order to maximize their profits and compete with their rivals, corporate institutions have pushed hard to influence international trade negotiations (Loeppky, 2004). They have achieved this by operating at the interface between ‘wealth’ and ‘power’; the global firm has become a political as well as an economic force.

Keeping up with the shifting international economic environment has become a major challenge for domestic policy makers. Global economic rules increasingly penetrate state borders and can constrain domestic laws and regulations, emphasizing the permeability of the modern nation state and the polycentric nature of the global political economy (Lanoszka, 2003; Dicken, 2003). The degree of state autonomy is often debated when considering IPE. In the case of health, a number of international trade rules risk interfering with the ability of states to develop their own healthcare systems (Sinclair, 2006; Forman, 2007). The flow of medicines into and within resource poor countries is inextricably linked to wider systematic issues related to international and regional trade agreements (Ruxin et. al., 2005). The General Agreement on Trade in Services (GATS) and the Agreement on Trade Related Aspects of Intellectual Property Rights¹⁰ (TRIPS) are prime examples of such international laws.

Much of the world is shaped and understood in terms of law. Everyday concepts of authority, obligation, justice, and individuals’ relations to institutions such as the state are all structured in part, by legal norms, discourses and practices (Blomley et. al., 2001). Law has a geography. It has a place, scale and environment,

¹⁰ The following chapter analyses the consequences of TRIPS for equitable access to medicines.

and can be situated in a particular cultural, economic and political context. Human rights are pre-legal; they underlie a nation's legal system and whilst they should be independent from the state their realization is strongly associated with citizenship of a specific country (Verschraegen, 2006; O'Manique, 2007; Joseph, 2003). This investigation, therefore, goes beyond the narrow definition of law as rules. Instead, it considers law as the presence or absence of opportunities for states to protect the rights of its citizens through legislative means.

Legal mechanisms define the realm of the possible by establishing the boundaries of what is acceptable. A more interesting and useful exercise than the analysis of an individual law is examining the interests and capacity of actors to take advantage of the opportunities sanctioned by that law (Shadlen, 2007). By adopting this broad view of law it is possible to arrive at the realm of politics. In the face of market forces pushing for global unity in trade law, politics has increasingly become preoccupied with exploiting the opportunities presented by such legislation as TRIPS and GATS. The politicisation of economic decisions can be seen as most common for states at moments of active change (Goddard et. al., 1996). Thus, post-apartheid South Africa found itself, and still finds itself, in a transitional state.

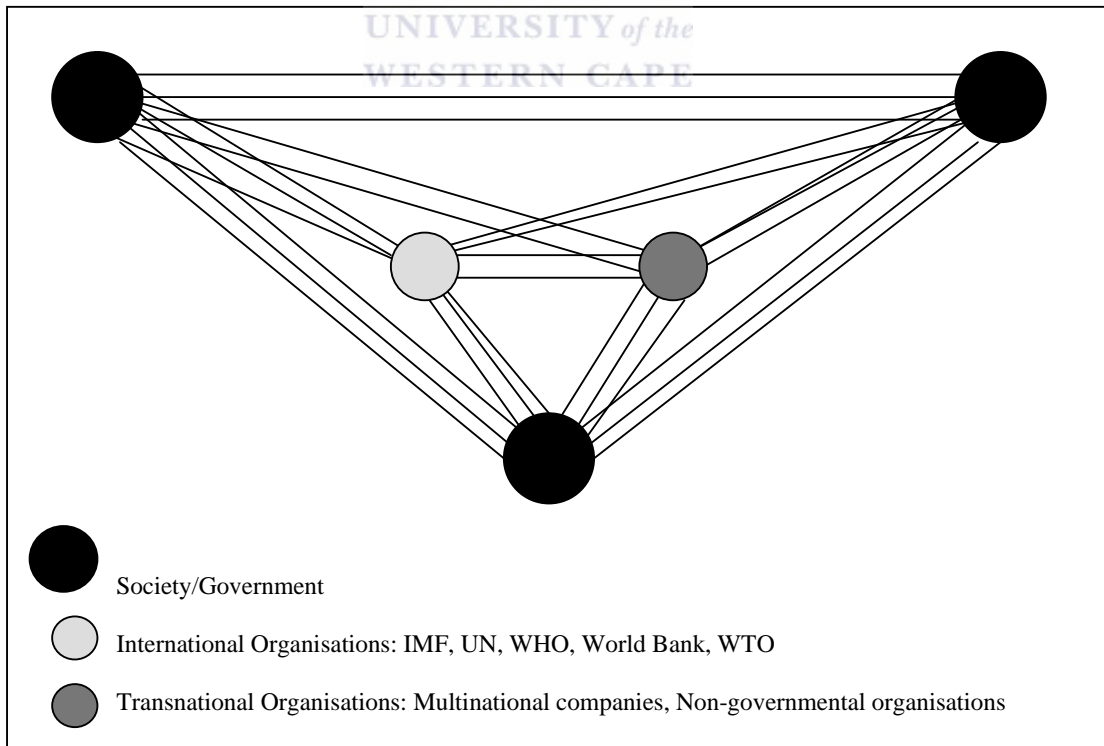


Figure 2.3 The web of interdependencies in the global political system (Source: Dicken, 2003, p.79)

The global pharmaceutical production network

Medicines are commodities. Conventionally, economic geographers study the production of commodities and their movement across space and time through linear models, such as the Global Commodity Chain and Global Value Chain.¹¹ The chains are meso-level concepts, above the micro-scale of the individual but below that of the macro-economy as a whole (Johnston et. al., 2000). Yet the medicines supply chain is highly variable, and positioned within a multi-scalar network of flows of material goods, power and knowledge. The chains ignore the multiple trajectories that exist within the medicines delivery system by over simplifying processes into linear flows. A linear model, therefore, proves problematic and hides the complexities that characterise the pharmaceutical delivery system

Approaching the delivery of medicines from a Global Production Network perspective captures the relational structures that characterise the system. The approach has its roots in the political economy, considering flows of both material and non-material goods across different organizational and geographic scales (Dicken, 2003, 2002). Using networks as a methodological and analytical tool enables the theorisation of a multi-scale institutional framework (Birch, 2007). Using the principles found in Global Production Network Theory it is possible to plot the activities, flows and relational structures that constitute the global medicines delivery system (Figure 2.4).

The drug supply chain is highly variable. Medicines can be procured through various mechanisms. Consequently, it is important to recognise that in order to bring down prices it is not sufficient to only target the pharmaceutical manufacturers. The drive to expand access to medicines must be placed within the context of a response to comprehensive healthcare systems development. Large numbers of health systems in the developing world are grossly under resourced. Activists, the state and the media often ignore the costs incurred and barriers faced further down the production network in favour of concentrating pressure on the multinational pharmaceutical industry. This strategy, however, could prove to be damaging to medicines access if it excludes the other factors in the equation.

¹¹ For an exhaustive account of these approaches see Gereffi and Korzeniewicz (1994), Johnston et. al. (2000) and Johnston et. al. (2002).

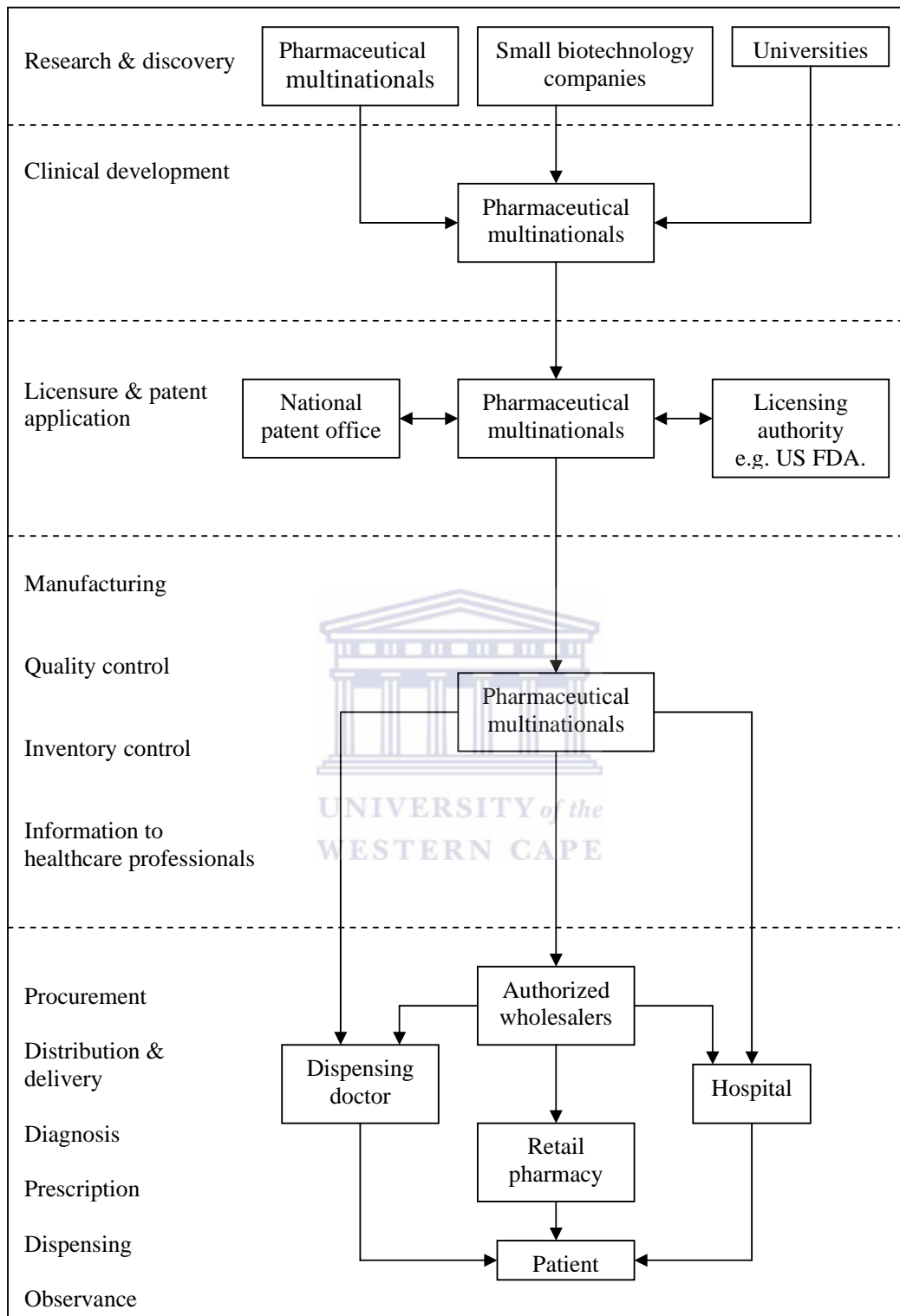


Figure 2.4 The Global Pharmaceutical Production Network. (Source: author compilation)

Pharmaceuticals as knowledge resources

Pharmaceuticals are knowledge resources. Their value lies in the scientific know-how required to produce them. (Lorenzen, 2005; Ernst & Kim, 2002). The entire structures of the pharmaceutical delivery system and the regulatory environment surrounding it are based on the assumption that technological know-how has a distinct geographical pattern, residing exclusively in the West.

Knowledge is a strategic resource. In the last thirty years developed countries have lost comparative advantage in manufacturing to emerging nations. In response to this, developed states have concentrated their efforts on promoting knowledge-driven economies, based on high value added activities such as R&D (Birch, 2007). In the new geopolitical landscape knowledge is power. Consequently, states and corporations do their best to protect it in the form of intellectual property rights.

Knowledge is dynamic, moved by a variety of market forces. As such innovation and techno-scientific change is constituted by space, place and scale (Birch, 2007; Prusak & Cohen, 1998). Initially the social sciences were slow to tackle ideas about the knowledge economy and post-industrial society (Birch, 2007; Brint, 2001). In more recent times, however, Geographers have embraced processes of knowledge production and distribution.

On the occasions that knowledge resources have been considered by Geographers, emphasis has fallen on the extent to which knowledge industries cluster spatially (Gertler & Levite, 2005). Geographers have considered regional concentrations of innovation around pools of talent. They question why certain metropolitan areas become hubs of the 'new economy' (Coenen et. al., 2004; Birch, 2007; Chiaroni & Chiesa, 2005; Bathelt et. al., 2004). Occasionally geographers reach beyond the local clusters of activity and examine the inter-regional and international connections within the knowledge economy, as well as the contribution of the knowledge-based sector to national development (Gertler & Levite, 2005; Cooke, 2006; Coriat et. al., 2003).¹² Geographers have yet to scrutinise the knowledge-based industries in terms of the accessibility of their products outside of the advanced economies. This study, relating to South Africa, attempts to break the mould, by

¹² For an excellent summary of geographical approaches to analysis of the knowledge economy, with particular focus on the biotechnology industry, see Birch (2007).

examining the use of and demand for a knowledge product rather than the enabling factors of its production.



Chapter Three: The Global Pharmaceutical Political Economy

The medicines delivery system is complex in terms of its scale, flows and the agents involved. The pharmaceutical industry is a global network largely underpinned by one force – intellectual property. The international intellectual property regime prescribed by the World Trade Organization is crucial to the pharmaceutical industry’s business model and it’s delivery of innovative medicines. The role of intellectual property is not without its critics, however, and dominates many debates over pharmaceutical security. The following section offers a brief introduction to the pharmaceutical industry and the structure of the medicines delivery system.

Profiting from pills: the multinational pharmaceutical industry

For many the pharmaceutical industry exhibits the characteristics of a multinational oligopolistic industry. It is associated with barriers to entry and a lack of competition leading to high prices, high profits and sub-optimal delivery of products to patients (McIntyre, 1999). Taking a new product through the various national regulatory systems is a lengthy and costly process. Only the large multinational pharmaceutical companies have the necessary resources to operate throughout the innovation cycle. Small and medium sized enterprises face entry barriers, leaving the multinationals in an almost unassailable position. Consequently, ‘Big Pharma’ drives the global research and development (R&D) agenda as well as controlling the vast majority of the manufacturing and production capabilities.

The pharmaceutical industry can be divided into four distinct sectors: non-prescription, pirate, generic, and research-based (Bale, 1998). The research-based pharmaceutical industry is the primary focus of this study. Multinational companies, which are able to invest vast amounts of money in innovation, dominate this sector, but some research also stems from small biotechnology companies as well as from universities and public laboratories. Generic manufacturers produce and sell products that are unbranded or branded products that are ‘off patent’. Generic companies are reliant upon the R&D conducted by the research-based pharmaceutical companies,

but because they only have to cover their manufacturing costs they can market products at lower prices than their brand name equivalents.

Monopoly pricing is a serious concern. As drugs are often a necessity, a patient's demand for a product is almost perfectly price inelastic: a price increase will not chase many customers out of the market, conversely a price decrease will not attract more customers into the market (McIntyre, 1999). Pharmaceutical products are disease specific, so the pharmaceutical market consists of a large number of therapeutic sub-markets. Companies often choose to specialise in a particular therapeutic area and dominate that sub-market. This seemingly monopolistic structure troubles a number of commentators who believe that it leads to inflated prices in the face of almost total market exclusivity. These critics often ignore the fact that as a product matures commercially, new and improved substitutes enter the market and there is a shift towards perfect competition. In reality it is very unlikely that a product will have exclusivity for more than one or two years.

It is a common belief that there is no price competition in the pharmaceutical industry. In recent years, however, there has been recognition that price competition is growing due to increased generic availability and the growth of biotechnology. For example, the largest pharmaceutical company, Pfizer, has only a 9% global market share; this compares favourably to other industries such as electronics and software whose markets exhibit higher concentrations of power (McIntyre, 1999; Deloitte Consulting 2007). In light of the recent opening up of the pharmaceutical market the industry is emerging as a dynamic oligopoly with substantial competition.

When reading some of the literature produced by the media, civil society and even some academics, one could be forgiven for thinking that multinational pharmaceutical companies are responsible for the HIV/AIDS crisis, that they created tuberculosis or were deliberately spreading malaria. A number of commentators label the pharmaceutical industry, along with the arms industry and tobacco manufacturers, as 'killers' (Werner et. al., 1997; Reekie, 2000). These comments are ill considered and do little but damage constructive debates about medicine delivery. Multinational companies are highly visible targets, and campaigns against big industry mobilize significant support for non-governmental organizations. To compare the production of medicines to the manufacture of arms and cigarettes is an irresponsible exercise in finger pointing.

While many people regard pharmaceutical companies as villains, the reality is that global health would be a lot worse off without them (Resnik, 2001). A great deal of research, development and manufacturing would not be done without investment from the industry. At the beginning of the twentieth century Aspirin was the only widely available modern medicine (Resnik, 2001). A century later, previously deadly illnesses are treatable within days. In many ways the pharmaceutical industry is a victim of its own success. Society expects the development pipeline never to run dry. It expects newer and better medicines to appear constantly, and for them to be available cheaply so that everyone can access them.

No reliable publicly financed method has been found to match the sums the pharmaceutical industry invests for the significant number of diseases and conditions that are treated in modern medicine. Governments typically do not think that far ahead and academic institutions channel their resources to experimental science and do not have the resources or the industrial development expertise (Association of the British Pharmaceutical Industry, 2007).¹³ No public sector system could develop or sustain the scientific talent required to develop new medicines. In the face of few viable alternatives, there is little option but for academics, governments, global institutions and non-governmental organisations to engage constructively with the pharmaceutical industry on issues of medicine inequity.

The industry has never denied that it is motivated by profit. The caveat is that there is no contradiction between profit-seeking behaviour and delivering medications that satisfy healthcare needs (Resnik, 2001; Lexchin, 2006). The problem lies in the fact that there is not an equitable distribution of satisfied healthcare needs. Profits are greater in the developed world markets, therefore research and development is centred upon those markets. The balance between the return for industry and the return for society is a contentious one.¹⁴ One pharmaceutical executive puts the matter as follows:

¹³ Sixty minute face-to-face interview with Mr M Worrall, Public Affairs Executive at the Association of the British Pharmaceutical Industry. June 2006. Transcription checked by interviewee and retained by author. For more information see Appendix B.

¹⁴ The industry attempts to pacify criticism and increase its contribution to society through Corporate Social Responsibility (CSR). The pharmaceutical industry does more than most industries in terms of CSR. It trains health personnel, donates medicines, conducts delivery programmes with partner organisations, and performs research into neglected diseases with the help of organisations such as the Bill and Melinda Gates Foundation. In 2005 the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) conducted a *Health Partnership Survey* to measure the

*We have people who put money in AstraZeneca...if they are pension funds to provide their investors with pensions. Whatever they are investing in us, they are investing in a for-profit model. If we were not making a profit we would be doing a disservice to them, to ourselves, and to patients.*¹⁵

The pharmaceutical industry's *modus operandi* is to provide its shareholders with a return on their investment. Above all else, the pharmaceutical industry strives to protect its business model. The methods that it uses to do this are often heavy-handed and ungainly, and consequently attract criticism from many quarters. Within the international political economy approach, the power of multinationals is often analysed. One view is that multinational firms are the primary “movers and shapers” of the global economy and as such wield almost unparalleled influence over states and supranational institutions (Dicken, 2003, 2002). The relationship between states and corporations can be simultaneously cooperative and competing, supportive and conflictual.

The main connections between countries have become the internal markets of multinational companies (Figure 3.1). Accordingly, developed states (where the multinationals are most often based) look to apply pressure on a country such as South Africa in an effort to protect their market. Such power dynamics follow Antonio Gramsci's theory of hegemony in which dominant groups in society attempt to impose their ideas about how a society should be run (Gesler et. al., 1997). One of the most explicit expressions of this hegemony is found in corporate lobbying activity.

industry's total contribution to the Millennium Development Goals. It found that in the period 2000 to 2005, the industry provided health interventions to help up to 539 million people, to a value of US\$ 4.4 billion (IFPMA 2007). The survey methodology and data were validated by the esteemed London School of Economics and Political Science. In 2007 the IFPMA produced a document entitled *Partnerships to Build Healthier Societies in the Developing World*. It gives details of 135 medicines delivery and R&D partnerships, as well as smaller activities and emergency relief efforts conducted by the pharmaceutical industry. The programmes cover diseases such as HIV/AIDS, malaria and tuberculosis; tropical diseases (sleeping sickness, chagas disease, lymphatic filariasis, leprosy and schistosomiasis); vaccine initiatives; child and maternal health interventions; as well as chronic diseases such as diabetes, breast cancer, asthma, epilepsy and haemophilia (IFPMA 2007).

¹⁵ Ninety minute face-to-face interview with Mr C Major, Head of Public Affairs, AstraZeneca Plc. July 2006. Transcription checked by interviewee and retained by author. For more information see Appendix B.

The corporation's legally defined mandate is to pressure, relentlessly and without exception its own self interest, regardless of the often harmful consequences it might cause to others (Bakan, 2004, p. 8).

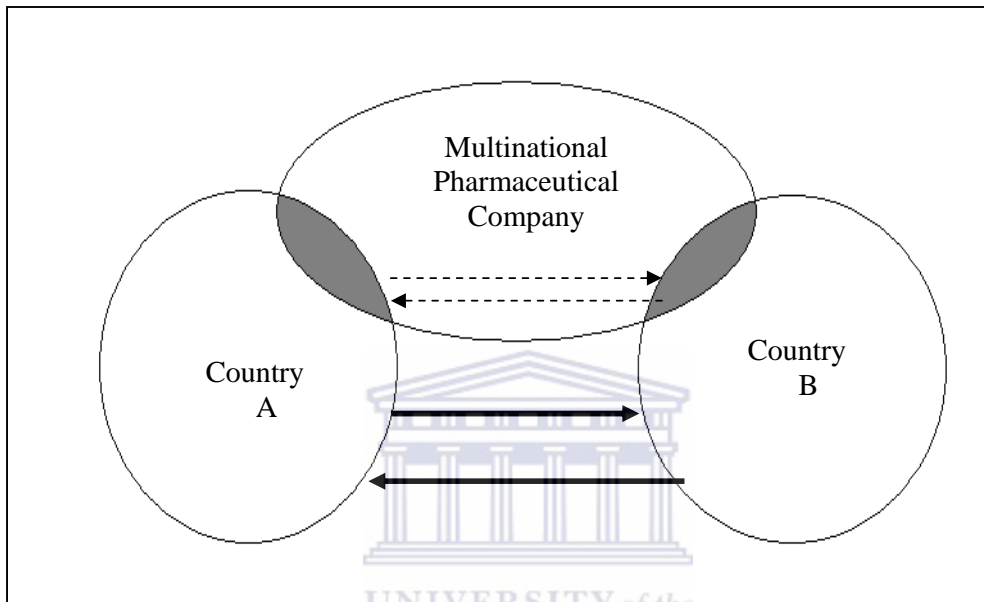


Figure 3.1 Countries linked through the 'internal markets' of multinational firms. (Source: Adapted from Dicken, 2003, p. 243)

In order to profit from the medicines it produces, the pharmaceutical industry relies on a finely balanced system of rights, obligations and protection. Intellectual property lies at the core of this system.

Pharmaceutical industry associations, such as The Pharmaceutical Research and Manufacturers of America (PhRMA), are among the world's most politically influential and well financed industrial lobbies (Lanoszka, 2003). The pharmaceutical industry spent over US\$1 billion (R7.7 billion) lobbying in the United States in 2004. Pfizer alone spent US\$66 million (R508.5 million) (Eagleton, 2006). A firm focus of pharmaceutical lobbying activity is intellectual property. The role of corporate lobbying at WTO negotiations cannot be underestimated. Often trade representatives from the United States and the European Union sound little different from

pharmaceutical executives pushing for stronger intellectual property regimes across the world regardless of a country's level of development (Vaver & Basheer, 2006).¹⁶

Intellectual property lies at the heart of the conflict between the pharmaceutical industry, civil society and governments over the provision of medicines. Whereas the industry sees intellectual property as integral to the continued production of innovative medicines, and therefore beneficial to global health, others are convinced that it is one of the biggest barriers to global pharmaceutical security.

The 'Grand Bargain': intellectual property and innovation

Intellectual property is the foundation of the pharmaceutical industry's business model. The protection of intellectual property is seen as the single most important factor when deciding what therapeutic area to invest in and in which countries to produce. Simultaneously, the global pharmaceutical intellectual property regime provides the focus for the majority of academic, activist and government criticism of the industry. Myths and misconceptions about intellectual property laws dominate the debate due to its highly complex and legalistic nature. The literature on intellectual property is vast and is challenging reading for those from a non-legal background: the following section gives no more than an outline of patent law.

The value of a medicine lies not in the pill a patient takes but in the knowledge that lies behind the production of the pill. Initial research and development of a new chemical entity is associated with very high fixed costs, but the marginal cost of manufacturing each unit is low and almost constant (Cleary, 2001). Knowledge is easily copied making it difficult for the inventor to protect it. In the absence of legal protection a firm would have little choice but to hide its discoveries from competitors and thus deny society the benefits of scientific advances. Ensuring disclosure of scientific breakthroughs, whilst still guaranteeing a return on the knowledge maker's investment is seen as the optimal model for encouraging innovation. In a conventional free market system without intellectual property protection, the innovator would bear the full cost of its failures but would be unable to profit from its successes because

¹⁶ Fifty minute telephone interview with Dr M Kamal-Yanni, Health Policy Adviser, Oxfam International, June 2006. Transcription checked by interviewee and retained by author. For more information see Appendix B.

competitors would be able to ride freely on its efforts (Pogge, 2005). Intellectual property laws correct such market failure.

Research and development costs for a specific drug are hard to obtain. Costs are incurred over long periods of time for R&D that does not necessarily lead to the planned innovation or a successful product (Williams, 2007). Additionally, R&D spending and returns are not completely segregated by medicine; a company's overall R&D effort represents a give and take between several drugs (Cahoy, 2008). Despite such difficulties a number of studies have been conducted attempting to establish an average figure for the industry's expenditure on R&D. A recent survey, conducted by Tufts University, sets the cost to deliver a single medicine at an average of \$1.2 billion in 2006 (Deloitte Consulting, 2007). Previous studies set the figure slightly lower (DiMasi et. al., 2003; Forman, 2007). Even allowing for overstatement and methodological difficulties it is safe to say that R&D costs in the pharmaceutical sector are considerable.

One of the reasons R&D is so costly in the pharmaceutical sector is that most new drug candidates fail to reach market (Figure 3.2).¹⁷ Pre-clinical and clinical testing phases generally take more than a decade to complete. Typically, fewer than 1% of compounds examined in the pre-clinical period make it to human testing, and only 22% of the compounds entering clinical trials survive the development process and gain regulatory approval from bodies such as the United States' Food and Drug Administration, the FDA (Grabowski, 2002).

The worth of intellectual property rights is not in a particular idea or technology but in the ability of the right holder to prevent the exploitation of that idea by a competitor. Such privileges are termed 'negative rights', as they give the owner not only the right to own or sell ideas but also to regulate the use and exclude others (Correa, 2007; Satardien, 2006). Intellectual property rights not only protect but also create scarcity of knowledge.

¹⁷ Failure can result from toxicity, manufacturing difficulties, inconvenient dosing characteristics, and inadequate efficacy (Grabowski, 2002).

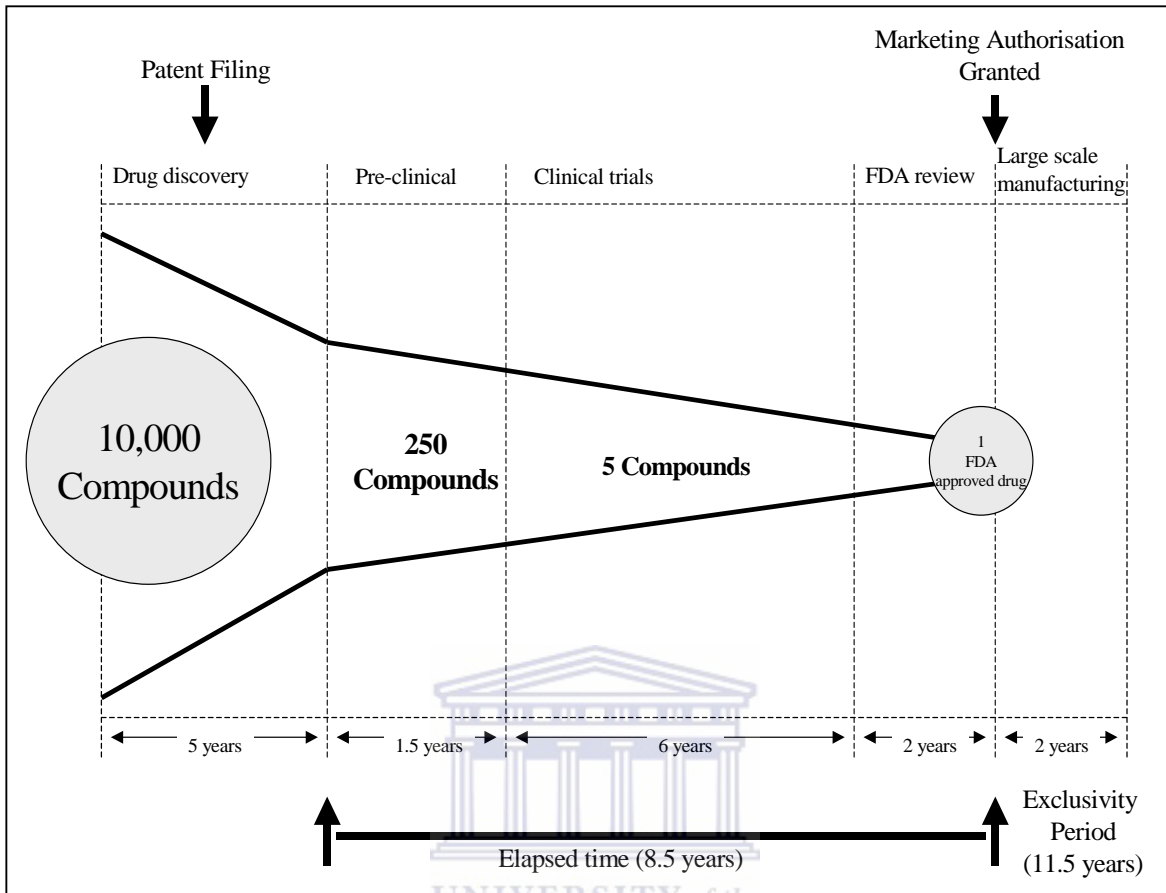


Figure 3.2. The risks involved and the time taken in pharmaceutical research and development. Note the protracted proportion of patent life that can be spent on drug testing and approval – half the patent duration in this example. (Source: adapted from Ringer, 2007, slide 8).

With rights, however, come obligations. Intellectual property rights bind knowledge makers into a social contract with society, a “Grand Bargain” (Koski, 2005, p. 393). The intention is to create a system that is mutually beneficial for producers and users, conducive to social and economic welfare. The pharmaceutical industry is guaranteed profits in return for it producing new medicines that benefit society.

Neoliberal economic philosophy holds that property rights are fundamental to a functioning market system, establishing a direct link between effort and reward, thus

stimulating innovation.¹⁸ The structuralist perspective, however, links intellectual property rights with dependency theory, holding the view that they increase the dependence of the world periphery on the core (Balaam & Veseth, 2001). Many developing country governments as well as civil society organisations subscribe to the structuralist view, believing that intellectual property is a component of a policy of technological protectionism intended at consolidating an international division of labour (Lanoszka, 2003).

The protection of intellectual property has in recent years moved from a defensive to an offensive corporate strategy. Patents have become corporate assets, reflecting a company's market competitiveness (United Nations, 2007; United Nations Commission on Human Rights, 2001). This is particularly true in the pharmaceutical industry, where shareholder value is directly linked to the depth and strength of a firm's product pipeline.

A central pillar of the new International Political Economy is a global intellectual property regime. The WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement is the specific legislative expression of intellectual property law to which all Member states must conform.



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¹⁸ For a country such as South Africa a strong domestic intellectual property regime is seen as a necessary condition for Foreign Direct Investment (FDI) and technology transfer. Protection of a multinational firm's intellectual property is an important precondition for investors in any country. For industrialised countries, assuring intellectual property is particularly important because their competitive edge lies in research and development in high technology fields (Cleary, 2001).

Trade Related Aspects of Intellectual Property Rights (TRIPS)¹⁹

The TRIPS Agreement is the embodiment of the tension between the right to life and essential medicines on the one hand and profit maximization and incentives for drug discovery by pharmaceutical corporations on the other (Aginam, 2007, p. 150).

The WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) firmly occupies the ground between the right to health and the right to wealth. Arguably no piece of global trade legislation influences the welfare of a nation's population in the same way as TRIPS. The Agreement exemplifies the structuralist paradigm of an individual's health being intimately situated within the international political economy.²⁰

As a consequence of its significance for medicines delivery, TRIPS has become the focus for global pharmaceutical activism. Intellectual property was previously an abstract issue left to academics, lawyers and economists. Since the signing of TRIPS, however, engagement with intellectual property has increased exponentially. Non-governmental organisations, such as *Médicins sans Frontières* and Oxfam, have run popular campaigns centred on pharmaceutical patents, and coverage regularly appears in the mass media detailing progress within intellectual property. The matter of intellectual property in relation to affordable medicines has dogged the

¹⁹ This section only attempts to give an outline of the most pertinent aspects of TRIPS in terms of pharmaceutical security. The following texts provide more detailed accounts of the legislation: Satardien (2006) gives a clear and concise account of TRIPS and the 30th August Decision. Cleary (2001) looks at TRIPS from an economist's view and also deals with its specific impacts on South Africa. Drahos and Braithwaite (2002) provide an exhaustive description of TRIPS whilst looking at the pharmaceutical industry's engagement with the legislation. James Love (2001a) offers procedural details and opportunities for governments to exploit within the global intellectual property regime. Cohen et. al. (2006) help position TRIPS within the wider debates over access to medicines. Cahoy (2008) produces one of the most digestible texts on the subject, and deliberately distances himself from some of the more legalistic approaches. For the most comprehensive explanation, Carlos Correa (2007) has produced an account detailing all the aspects of TRIPS and its impact on access to medicines.

²⁰ Upon scrutiny there are potential links between human rights and the TRIPS Agreement. TRIPS recognizes the balance between rights and obligations of technology holders whilst holding the wider objective of promoting social and economic welfare – however, this is not the same as saying that TRIPS takes a human rights approach (United Nations Commission on Human Rights, 2001).

WTO since its inception (McBeth, 2006) and it does not appear as if it is likely to go away in the immediate future.

The TRIPS Agreement is one of twenty-eight accords that make up the Final Act of the Uruguay Round of Multilateral Trade Negotiations that began in 1986 (Drahos & Braithwaite, 2002), ending in the formation of the WTO, the institution that embodies the neo-liberal economic dogma dominating the current international political economy. TRIPS is one of the WTO's founding Agreements and, as such, intellectual property occupies a central position within the organization.

The TRIPS Agreement was tied into the whole WTO package. Accordingly acceptance of TRIPS can be seen as a *quid pro quo* where by developing countries were offered benefits such as reductions in agricultural subsidies (Drahos & Baithwaite, 2002; Cleary, 2001). The reality is that most developing countries had little choice but to sign. The choice was all or nothing - sign all twenty-eight agreements or be excluded from the WTO. Consequently the developing countries' bargaining position was weak. A country such as South Africa – in the process of emerging from apartheid and the economic isolation that was associated with it – had barely begun to find its feet in the post-Cold War international political economy.

The terms of TRIPS and many of the other twenty-eight WTO Agreements were virtually dictated by the wealthy nations. The room for policy manoeuvre is narrow, and neo-liberal free market doctrine dominates (Loeppky, 2004). In this age of 'transparency', 'democracy' and the 'participatory ethic', African countries were not present during much of the Critical Uruguay Round of negotiations. Indeed,

It is doubtful if, before signing the document, and signing away the fates of their countries many African governments were able to find time even to read the document, let alone analyse the implications...for their countries... Countries such as the US, Britain and France insist on democracy and transparency in Africa. But the international organisations on which they sit and take decisions – such as...the WTO – are the most undemocratic, non-transparent and authoritarian institutions of global governance. (Tandon, 1999, p. 84)

In recent years there has been recognition of the exceptional nature of the TRIPS Agreement in terms of its potential influence on global health. The WTO, the World Intellectual Property Organisation (WIPO) and the WHO have established consultative mechanisms that are intended to increase participation, such as the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The need for a more democratic structure became essential as the gravity of the HIV/AIDS pandemic became apparent. The most explicit recognition of the TRIPS Agreement's responsibility towards health was made on the 14th November 2001 at the WTO's Ministerial Conference, meeting in Doha, Qatar. Signatories conceded that,

the TRIPS Agreement does not and should not prevent members from taking direct measures to protect public health. Accordingly...we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and in particular, to promote medicines for all (Vawda, 2003, p. 680).

The Doha Declaration was a historic moment for public health and for those fighting for equitable access to medicines. The Declaration was official recognition that economic policies can potentially have health impacts and that health takes priority over intellectual property rights.²¹ The Doha Declaration can be interpreted as acknowledgment that domestic action is not sufficient to ensure a populations health (Drager & Sunderland, 2007). It lends further weight to the structuralist assertion of health being intimately tied to the international political economy via the 'body politic'.

The TRIPS Agreement globalises the set of intellectual property principles it contains. Prior to TRIPS, states were free to decide what level of protection they would give to cover whatever forms of technology they believed were important for their development needs. Measures to protect pharmaceuticals could be taken where

²¹ Japan, Canada, the United States, Switzerland and Australia all opposed the Declaration on intellectual property, due in part, to lobbying activities from the pharmaceutical industry (Vawda, 2003).

national development, technological and health requirements suggested such action was beneficial (United Nations Commission on Human Rights, 2001; Drahos & Braithwaite, 2002). TRIPS has greatly eroded the degree of autonomy a state holds over its domestic intellectual property regime.

A principle of non-discrimination sits at the core of the WTO, according to which any trade barrier is applied equally to all members independent of their level of development (Correa, 2007, 2001; Senona, 2005). The TRIPS Agreement can be seen as an expression of global hegemony. The knowledge producing core countries exerted their geo-economic supremacy over peripheral nations in order to shape flows of wealth in the international political economy.

The Agreement exemplifies the classic one-size-fits-all policy. The principles enshrined within TRIPS are intended to apply in equal measure to DVDs and life-saving pharmaceuticals. TRIPS grants a twenty year patent to an invention if it is new, involves an innovative step and is capable of industrial application (Mugambe, 2002). In practice, however, the holder of a patent does not have twenty full years in which to exercise their exclusive right because a significant proportion of the patent life is exhausted while the patentee seeks to obtain regulatory approval, see figure 3.2 (Epstein, 2006). Patents prevent third parties from making, using, selling or importing a patented product without the owners consent (Sinha & Condon, 2005), a negative right.

Evidence indicates that local innovation in the majority of the developing world is not supported by a strong intellectual property regime (Correa, 2007). A country can only take advantage of patent protection if it has money to invest and the capacity to develop scientific knowledge. A country such as South Africa finds it hard to attract research and development investment, not because it has weak intellectual property (South Africa has very strong intellectual property provision relative to other middle-income countries), but because of other factors such as a weak chemical industry and a limited number of suitably skilled workers. Intellectual property is not the all-or-nothing solution it is held to be by its most vocal supporters. Other elements of industrial and workforce development are also important.

Whilst TRIPS is binding for all WTO Members, the Agreement recognises the difficulty of implementing such a strong regime for low-income countries. As such it set different deadlines for implementation dependent on a Member's stage of development. Developed countries had until 1996 to comply, most developing

countries had until 2000, with some allowed an extension to 2005, while there are at least 30 Least Developed Countries that have until 2016 to pass the legislation (Foreman, 2002; Abbott & Reichman, 2007). Such variations in implementation complicate analyses of the Agreement. What is clear, however, is that with the passage of time more and more medicines will be on patent in a greater number of countries. Consequently, concerns over intellectual property and pharmaceutical security are unlikely to deteriorate.

TRIPS flexibilities: recognition of health needs

Enshrined within the original TRIPS Agreement are a limited number of flexibilities that governments can use in order to ensure a patent is not abused and that welfare-damaging practices are kept to a minimum. TRIPS allows countries to create in their domestic patent law systems for permitting production or import of generic products as long as they adhere to the minimum standards established by the Agreement (Cleary, 2001; Love, 2001). However, there is a difference between what TRIPS allows and what countries actually do. Considering the extent of pharmaceutical inequity surprisingly few countries have taken advantage of the permitted flexibilities. TRIPS is a complicated and fairly ambiguous document,²² accordingly countries may not feel confident in exercising the rights they have. This situation is exacerbated by external pressure from other states (see Box 3.1).

The most controversial and widely publicised flexibility within TRIPS is the compulsory license. Compulsory licenses are nothing new, they have been part of patent law for years. Canada regularly issued compulsory licenses from 1969 until the late 1980s (Love, 2001). One result was that in 1982 the prices of licensed drugs were 47% lower than in the United States of America (Commission on Intellectual Property Rights, 2002). There is a need in certain therapeutic areas to switch from a low volume - high margin approach to a high volume - low margin approach, to ensure sustainable supplies (Abbott & Reichman, 2007). A compulsory license is a mechanism that, by allowing the generic production of a specific drug, can shift production to the high volume model. Article 31 of TRIPS states that

²² Forty-minute telephone interview with Ms V Ehrich, Chief Operating Officer of the Pharmaceutical Industry Association of South Africa (PIASA). 5th May 2008. Transcription checked by interviewee and retained by author. For more information see Appendix B.

A government may issue a compulsory license authorizing the government or a third party to produce generic drugs without the authorization of the patent holder when negotiations fail to obtain authorization on reasonable commercial terms (WTO, 1994; Article 31).

Box 3.1: Demanding a higher standard: Section 301 and TRIPS plus

The United States government disapproves of the TRIPS flexibilities. The United States Trade Representative (USTR) produces an annual Section 301 Report listing those countries, which it believes are threatening the economic interests of the United States (Drahos & Braithwaite, 2002). An unfavourable finding in the Section 301 Report can lead to the withdrawal of trade benefits or the imposition of duties on a country's goods. Countries named in reports issued by the pharmaceutical industry are often remarkably similar to those found in the final Section 301 Report.

Thailand was elevated to the priority watch list in 2007 after it issued compulsory licenses on three pharmaceutical products (Rimmington & Weissman, 2008). The Thai private sector is understandably afraid of losing tariff privileges from the United States if compulsory licenses are issued. About 20% of Thai exports to the United States, worth about US\$4 billion are under the United States' low tariff generalised system of preferences programme. On the other hand the government committee looking into compulsory licensing stated that Thailand would save up to US\$250 million (R1.9 billion) over five years by using generic drugs. The potential economic losses are greater than the money saved by purchasing generics (The Nation, 2008). The threat of economic sanctions forces governments to put a monetary value on an individual's life.

After Doha, the US and the European Union entered into a series of Free Trade Agreements (FTAs) with developing countries that imposed intellectual property requirements beyond those demanded in TRIPS, limiting exclusions from or exceptions to patents, these measures have been called 'TRIPS plus' provisions. The United States has concluded FTA negotiations with Chile, Singapore, Morocco, Panama, Peru and South Korea, all the agreements include 'TRIPS plus' provisions (Lee, 2007). Peru assessed the potential impact of an FTA with the US and found that the agreement would exclude approximately 800,000 people from having access to medicines (Cohen et. al., 2006). Until recently SACU (representing South Africa, Botswana, Lesotho, Namibia and Swaziland) were in negotiations with the US, but the negotiations deadlocked.

The flexibilities within TRIPS are intended to ensure that exclusive ownership of knowledge does not become detrimental to a population's welfare. Whether TRIPS will permit developing countries to take advantage of its flexibilities will depend on the willingness of individual nations to resist political pressure from the developed world.

Before a compulsory license is granted, the proposed user must try unsuccessfully for a reasonable amount of time to secure a license on realistic terms. This requirement is, however, subject to a waiver if there is a ‘national emergency’ or a ‘circumstance of extreme urgency’ (Chien, 2003; WTO, 1994). Unfortunately the TRIPS Agreement does not define what constitutes a reasonable amount of time, realistic terms, extreme urgency or an emergency. Hence disagreements emerge and uncertainty prevails.

The economic foundation of intellectual property means that an incursion on a patent can be measured in terms of monetary loss. As the loss can be given a value it is possible to compensate a patent owner for the reduction of their rights (Cahoy, 2008). The TRIPS Agreement states that the patent holder must be offered a royalty fee when a compulsory license is issued. There is no standard figure for the royalty fee and the level of remuneration is left to national policy, a condition that leads to further uncertainty.

Before the 1st January 2005, a WTO member nation had the option of issuing a compulsory license and importing from the big generic medicines producing countries such as India and Brazil. After India and Brazil became TRIPS compliant they could no longer produce and export cheap generic versions of patented medicines (Correa, 2007). If a country were to issue a compulsory license it would have to have sufficient pharmaceutical manufacturing capacity to produce its own generic versions. More than 90% of the developing country members of the WTO lack a functional pharmaceutical sector, the threat of a compulsory license is hollow without one (Tandon, 1999). This concern was raised by a number of middle and low-income countries at the WTO, and in 2001 at the WTO’s Ministerial Conference in Doha, the TRIPS Council was directed by the Members to develop an “expeditious” solution to the compulsory license challenge (Bourgeois & Burns, 2002).

On the 30th August 2003 a solution was announced. The agreement allowed any member country to export pharmaceutical products under compulsory license to a country facing a health emergency (Haffejee, 2003; McBeth, 2006).²³ Supporters of

²³ On the 6th December 2005, WTO Members made the August 2003 Decision permanent (Lee, 2007)

the Decision hailed it as proof that the trading system could take into account humanitarian and development concerns.²⁴

The TRIPS Agreement does allow countries room to manoeuvre in a way that can enhance access to medicines. If used correctly and to its full potential, TRIPS could form part of the solution to increasing equitable access to medicines. However, the Agreement remains largely unworkable due to its ambiguity. TRIPS lacks both a floor and a ceiling (Cahoy, 2008). There are few limitations on which countries can 'break' patents in order to control costs or the conditions that are necessary in order for a country to do so. Additionally, the flexibilities that do exist are overly complex and cumbersome, immediately excluding the nations that need to use them the most.

The significance of patents for pharmaceutical security

The debate concerning intellectual property in relation to pharmaceutical products has become greatly polarised. Disputes are dominated by two extremist views. On the one hand there are references in some media, civil society and academic material to patents killing and to the HIV/AIDS crisis being a "western legal holocaust" (Mannan & Story, 2006; Basheer, 2007). On the other hand, there are the one-sided views that extol the wonders of the patent system. Such views promise a country such as Eritrea rapid innovation and industrial success if it only introduced an intellectual property regime on a par with the United States (Basheer, 2007). Informed examination is necessary for a subject as complex and multi-faceted as pharmaceutical patent law. As with any matter, extremism is unhelpful for furthering dialogue and can ultimately be dangerous. A middle path is required.

The belief that patents have little or no influence on access to medicines is based on the argument that patents are the least significant factor influencing the

²⁴ Although the 2003 Decision expanded the scope of flexibilities the numerous conditions (including pre-shipment and labelling requirements to prevent re-exportation) continue to raise questions about its utility. Only Canada and Norway have effected legislative changes in their patent laws to accommodate the August 30th Decision (Aginam, 2007; Elliot, 2006). The Decision was finally put to the test by Rwanda when it officially notified the TRIPS Council, on the 17th July 2007, that it intended to import 260,000 packs of fixed-dose triple combination HIV therapy TriAvir from Apotex Inc., a Canadian firm (The South Centre, 2007) Whilst the process is ongoing serious misgivings about the system have been voiced. Apotex has stated that it would not consider entering the Canadian programme again unless the process was simplified (Gandhi, 2008), whilst MSF who were a driving force behind the Rwandan application, believe that the process is prohibitively complex (Médicins sans Frontières, 2006).

availability of medicines. The argument follows that whilst prices, largely dictated by the market exclusivity afforded by patents, can clearly be a barrier to access, other elements, such as healthcare infrastructure and R&D capacity for neglected diseases, play a more significant role (Bourgeois & Burns, 2002). Those who deny that patents increase pharmaceutical inequity regularly cite one study from a suite of several analysing the incidence of patents filed for pharmaceutical products in the developing world, particularly Africa (Attaran, 2004; Attaran & Gillespie-White, 2001). A 2004 study found that patenting is rare. In 65 low and middle-income countries, where 4 billion people live, only 17 products out of 319 on the essential drugs list were patented.²⁵ The overall patent incidence of 1.4% was concentrated mainly in the larger markets. The typical developing country is likely to have many fewer essential medicines under patent or pending application than the 17 it could theoretically have, as pharmaceutical companies usually do not seek patents in developing countries. Of the cases where companies could have obtained patents for essential medicines, they did so only 31% of the time (Attaran, 2004).

Evidently, patents are not barriers to access in the majority of cases. Patents do not explain why effective and safe drugs that have been in the public domain for years do not reach the millions in poor countries who need them, thus lending weight to the argument that other factors such as infrastructure have a greater influence on access (Bourgeois & Burns, 2002). The frequency of patenting in a country is largely explained by market size. Statistical analysis demonstrates that the patent laws were used more frequently in developing countries with large populations, high per capita incomes, or high levels of income inequality (Attaran, 2004). South Africa is a significant anomaly in the incidence of medicine patenting.

In addition to being the country with the largest number of HIV positive people worldwide, South Africa is also the wealthiest African country and is best

²⁵ The WHO produces a new Essential Drugs List every two years. Essential medicines are the foundation for nearly all public health programmes (Pecoul et. al., 1999). The World Health Organisation (WHO) defines essential medicines as, "...those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance...Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts...at a price the individual and the community can afford"(WHO, 2008b). The concept of essential medicines was a major breakthrough in the history of medicine, pharmacy and public health. The Essential Drugs Lists have two main functions. First, they have a practical function helping health departments choose the appropriate treatment in an overcrowded pharmaceutical market. Second, drugs on the Essential Medicines List have a symbolic function. Their essential nature gives them an exceptional status (Chirac, 2003). If a drug is named on the Essential Drugs List it indicates that a country's health system cannot function satisfactorily without it.

equipped to produce and supply generic drugs to its neighbours (Selgelid & Sepers, 2006). Pharmaceutical production is a global system, in which forces of demand and the capacity to manufacture transgress territorial boundaries. If other countries have the ability to manufacture, such as India or Brazil, the ramifications of imposing patents in those countries go far beyond their borders. Patents have a wider geographical significance than can immediately be appreciated from a quantitative study of patent incidence. Pharmaceutical companies own all the key patents in all the markets where they perceive the threats of competition from generic manufacturers (Drahos & Braithwaite, 2002).²⁶ As a Geographer it is important to recognise the geo-strategic nature of patents.

Another exception found in the Attaran study of medicines patenting is HIV/AIDS treatments. It found that in South Africa, in 2004, thirteen out of fifteen anti-retroviral treatments were patented. Considering the extent of the HIV/AIDS epidemic in Africa, this is a significant anomaly. As ARVs are relatively new drugs the majority of the products are still subject to patent - most of the medicines on the Essential Drugs List are older products that are off patent. Patents are particularly significant for HIV/AIDS because the most effective form of treatment is made up of a combination of medicines. Consequently if one of the medicines that constitute a Triple-Combination Therapy is under patent it threatens accessibility to the whole treatment (Selgelid & Sepers, 2006; Attaran, 2004; Foreman, 2002).

Limiting the Attaran study to the WHO's Essential Drugs List is also problematic. Almost 99% of medicines on the list are off patent, yet up to 50% of people in Africa have no access to these medicines. One needs to, however, ask why most of these products are off patent? In order for a medicine to be included on the list it must be affordable. A balance must be struck between efficacy and financial realism. Accordingly, once a new drug is patented (and is therefore more expensive), the WHO will recommend an older, often, less effective generic medicine in that therapeutic area. Patents, therefore, act as an exclusion criterion (Chirac, 2003). The Essential Drug List would look very different if it was purely judged on therapeutic need. Although many of the older medicines that are off patent and on the list are very

²⁶ Forty-minute telephone interview with Mr J Berger, senior researcher and Head of Policy, Research and Communications, the AIDS Law Project. 20th May 2008. Transcription checked by interviewee and retained by author. For more information see Appendix B.

effective, the risk is that the list becomes merely a directory of old, second rate medicines.

Despite the criticism attached to intellectual property, some form of protection is necessary in order to ensure continued development of medicines. Without a well-structured system of patent protection, neither the research nor the generic pharmaceutical industry would be able to grow and prosper as the rate of new product introductions and patent expirations would decline significantly (Grabowski, 2002).²⁷ In many therapeutic areas the strong exclusive rights that encourage innovation also defeat efficient dissemination of the product (Epstein, 2006). The holy grail of patent policy is to obtain the ideal incentives for both initial innovation and post innovation distribution.

The easiest way to reduce prices is to introduce competition, most commonly from generic suppliers. Whilst there are alternatives that exist, TRIPS already has provisions that allow for this (such as compulsory licensing). The UN Special Rapporteur on the Right to Health stated recently that pharmaceutical companies “should respect the right of countries to use, to the full, the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights” (Hunt, 2007; p. 3). Pharmaceutical companies and developed states must allow the most vulnerable members of the global community to take advantage of TRIPS flexibilities without the threat of sanctions or legal action. The vast majority of legal and moral cultures respect private property. If someone takes property without permission, they are called a thief. Moral norms cover similar ground, but an exception might be made for a starving child taking a loaf of bread from a wealthy family – the need is great and the loss is small, so perhaps it is morally justified (Outterson, 2006). The same could be said for pharmaceuticals: the medical need is great and the impact of a compulsory license is small.

The pharmaceutical industry claim that the price of a drug reflects, among other things, the cost of R&D. Intellectual property ensures that, for a certain period of time, a branded pharmaceutical product is not undercut by a rival generic equivalent. Critics of the industry, however, claim that prices simply reflect what the market will bear. Thus, for example, when Pentamidine a cheap treatment developed

²⁷ Forty-five minute telephone interview with Mrs V Beaumont, Executive Director of Innovative Medicines South Africa, 5th May 2008. Transcription checked by interviewee and retained by author. For more information see Appendix B.

for sleeping sickness was found to be effective in treating AIDS related pneumonia the price increased by 500% and it evaporated from the market in poor African and South-East Asian countries (Cooper et. al., 2007b). No additional research had been done, however the market demand exploded as its new use was discovered. The following section details the influence of market forces on pharmaceutical inequity.

The market rules: pay or die

The poor have no consumer power, so the market has failed them. I'm tired of the logic that says: 'He who can't pay dies'.

Dr James Oribinski, President of MSF, 2000 (quoted in Vachani & Smith, 2004, p. 117)

The patent system works in developing world markets where profits are guaranteed to be high. In such markets price is less of a barrier. Public health systems have considerable budgets for pharmaceutical spending and private patients have substantial purchasing power. The market is almost perfectly price inelastic.

Over 86% of the global drug market lies in North America, Europe and Japan. Africa accounts for between 1% and 2% of the global market; South Africa constitutes approximately 0.3% (Sprague & Woolman, 2006; Forman, 2007). Public spending on drugs is around \$239 (R1840) per head per annum in OECD countries. By contrast many developing countries spend less than \$20 (R154) per head per annum on all health programmes, and less than \$10 (R77) per head per annum in some sub-Saharan Africa states (Trouiller et. al., 2002). It is self-evident where a company driven by shareholder value is going to concentrate its research.

There is a well-known problem about public goods in economic theory: market mechanisms are not good at generating them because individuals find it hard to make a profit from their production (Drahos & Braithwaite, 2002). The problem is return on investment. Multinational pharmaceutical companies are largely unwilling to pursue a line of research unless the potential outcome is a product with annual sales of approximately \$1 billion (Grabowski, 2002; Commission on Intellectual Property Rights, 2002). Whilst this model is regrettable, pharmaceutical companies are not charities; however socially desirable it may be, one cannot ask them to forgo their

profits. No amount of intellectual property protection is going to make poor individuals in Africa a lucrative target for the pharmaceutical industry.

Intellectual property rights alone do not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (WHO Intergovernmental Working Group, 2008). Patents guarantee a certain length of market exclusivity, however if few individuals in that market can pay in the first place, this period of exclusivity is worthless. Arguments that revolve around patents are insignificant in the case of diseases that exclusively affect the very poorest individuals. The value of a patent is determined as much, and perhaps more, by the size and profitability of the patient market than the novelty of a patent holder's invention (Love, 2004). Other incentives must be found.²⁸

Many therapeutic areas are being neglected because the patients are poor. 'Treatments' for premature baldness, social shyness and erectile dysfunction garner significantly more R&D investment than medicines for many infectious diseases. The '10/90 gap' is a phrase often used to describe the situation. It illustrates the current global R&D distortion, in which only 10% of R&D spending is directed at the health problems that cause 90% of the global disease burden (t'Hoen, 2006). The R&D environment is risk averse and the patent system provides inadequate rewards for the more risky first-in-class products (Love, 2004). This results in a steady stream of pharmaceutical products concentrated within the same therapeutic areas, each offering only slight incremental improvements.

One study decisively illustrates the neglect of diseases of the poor. Between 1975 and 2004, 1556 new chemical entities were marketed. Out of this number only 21 were found to target neglected diseases. This small number accounts for only 1% of all pharmaceutical development over the past thirty years (Trouiller et. al., 2002; Chirac & Torrele, 2006).²⁹ Out of the 1393 products registered between 1975 and 1999, drugs for cardiovascular and central nervous system diseases accounted for

²⁸ The May 2008 meeting of the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property discussed possible alternative mechanisms. Including previously suggested schemes such as prize fund initiatives, the purchase of product patents, open source molecule libraries, international R&D treaties and advanced purchasing commitments (Kremer & Glennester, 2004; Love et. al., 2007; Love, 2006; Cohen et. al., 2006; Dentico & Ford, 2005; Barder et. al., 2005; DiMasi & Grabowski, 2004; WHO Intergovernmental Working Group, 2008; Grabowski, 2004).

²⁹ Neglected diseases are defined here as tropical diseases such as leprosy, African sleeping sickness, onchocerciasis, trachoma, buruli ulcer, leishmaniasis, chagas disease, guinea worm, lymphatic filariasis and schistosomiasis. The study also included malaria and tuberculosis, which together accounted for 11 of the 21 new chemical entities marketed (Chirac & Torrele, 2006; Trouiller et. al., 2002).

28% of the new chemical entities; 68.7% of the 1393 registered products presented little or no therapeutic gain compared with what was already available (Trouiller et al., 2002).

For diseases prevalent in both developed and developing countries (cardiovascular disease, central nervous system disease and cancer) innovation is assured. Developing countries are seeing an increase in the prevalence of chronic diseases. Issues of pharmaceutical security should be less problematic in these therapeutic areas as the pharmaceutical industry can be certain of considerable levels of profit in the developed world markets and thus are likely to be willing to provide price reductions or licenses for generic production in poor countries. The diseases that are neglected are those with exclusive demand from the developing world.

There is a distinct danger that patients in developing nations will become 'therapeutic orphans' if the pharmaceutical industry lacks suitable incentives (285 Resnik, 2001). A fundamental premise of global pharmaceutical delivery must be that not all products are of equal value. Whilst premature balding or social shyness are unfortunate for an individual they are not threats to personal health. By contrast, neglected tropical diseases can devastate whole populations. A system must be found that can make tropical diseases, as well as malaria and tuberculosis, as lucrative for the pharmaceutical industry as those pseudo-medical conditions found in wealthy markets. Anything less is not merely a failure of the market but a moral and political failure.

Chapter Four: The Law and Medical Geopolitics

Achieving healthcare equity in South Africa has been one of the main focuses of the post-apartheid government. The government inherited a health system that functioned only for a small minority of the population. As such the government's priority has been to redress the imbalances that had become ingrained in the health system. This has had to be done in the face of the HIV/AIDS epidemic that has swept through Southern Africa. Improving access to medicines is a key mechanism through which the government can make an impact on health in South Africa.

The South African health challenge

South Africa faces a vast number of ongoing health problems, the most pernicious being HIV/AIDS. Whilst the pharmaceutical policies adopted by South Africa impact upon the access and availability of all medicines, they have largely been guided by the recognition by activists and, latterly, government that a medicines delivery system must be established that is capable of halting the advance of HIV/AIDS. The emergence of the South African HIV/AIDS crisis was perhaps the most significant catalyst for global pharmaceutical activism (Smith & Duncan, 2005). The 2001 South African court case provided the first opportunity for government, domestic civil society and global activists to unite in order to express their belief in the connection between corporate greed and pharmaceutical delivery.

The HIV/AIDS problem has grown steadily in stature in the last twenty years. In 1990 when Nelson Mandela was released, HIV prevalence among pregnant women in South Africa was estimated to be 0.7%, by 2005 it had risen to 30.2% (Hassim et. al., 2007). In 2001, at the time when the government was fighting for its right to implement the Medicines and Related Substances Control Amendment Act, 30% of all deaths in South Africa were due to HIV/AIDS (Grimwood et. al., 2006).³⁰ According to recent figures released by the Development Bank of Southern Africa (DBSA) 7.6 million South Africans are HIV positive – 2.2 million more than the

³⁰ The distribution of deaths from HIV/AIDS is not uniform across South Africa; there are considerable geographical disparities. In the year 2000, 8.4% of deaths in the Western Cape were attributable to HIV/AIDS, whereas 41.5% of deaths were HIV/AIDS related in KwaZulu-Natal (Grimwood et. al., 2006).

South African Department of Health figures for 2007. Of these, about 6.1 million are the economically active people between the ages of 20 and 64 (Momberg, 2008).³¹ In the year 2000, the International Labour Organization estimated that due to AIDS South Africa would lose 24.9% of its workforce by 2020 (Barnard, 2002).³² For a country in a period of transition the loss of a quarter of one's workforce to a single disease is potentially devastating. After an agonisingly slow start the government has been forced to tackle the scourge of HIV/AIDS head on.

Health policy in the apartheid era, like all government action, served the dominant objective of maintaining economic and political supremacy for the minority white population. Its purpose was to maintain a difference in the quality of life of different population groups and so promote voter support for the National Party (McIntyre & Gilson, 2002). With the end of apartheid in South Africa, democratic considerations such as fairness, equitability, accountability and transparency entered into government (Sprague & Woolman, 2006). It is important to recognise that after only fourteen years of a newly democratic South Africa, many of the processes aimed at redressing the ills of apartheid are still ongoing.

As political transition approached, a progressive health movement developed, comprising health activists, academics and returning exiles. A purposeful effort was made to prepare the liberation movement for its future role as government. In 1993 the ANC established its own Drug Policy Commission to debate pharmaceutical policy issues (Gray et. al., 2002). The National Health Plan for South Africa, produced by the ANC in 1994 clearly acknowledges, "every person has the right to achieve optimal health" (African National Congress, 1994, p. 9). The South African Constitution contains one of the few legally enforceable constitutional rights to health care in the world (Sprague & Woolman, 2006; Hassim et. al., 2007; Hogerzeil, 2006). Section 27 of the Constitution seeks to redress the past by making a fundamental

³¹ A number of commentators believe that the DBSA statistics are more reliable than the government figures because they were collected from clinics, local municipalities, development planners, morgues and funeral homes, rather than being based on estimates. The figures are updated annually, and are used by the bank to determine funding for municipal projects (Momberg, 2008). However, it matters little whether one uses the government statistics of 5.4 million or the DBSA statistics of 7.6 million, for both indicate a health crisis.

³² HIV/AIDS is often not itself a killer, but it lowers the immune system of a sufferer to such an extent that other infections, such as pneumonia or tuberculosis, cannot be fought. Predominantly as a result of HIV, South Africa is one of the WHO's 22 high burden tuberculosis countries. In Africa 34% of adults newly diagnosed with tuberculosis were also infected with HIV in 2004; in South Africa this figure was 55.3% (Grimwood et. al., 2006). Figures for HIV/AIDS related deaths are often underestimated as the cause of death is attributed to another condition.

break with a healthcare system that had been saturated with immeasurable inequities, where the lottery of race, geographical location and income were the primary determinants of the quality of health care services received by an individual. Section 27 confers not only a negative right, under which the state or individuals should not adversely interfere with an individual's right to secure healthcare services. More significantly, it confers a positive right to receive healthcare from the state (Ngwena, 2000).

Box 4.1: Section 27 of the Constitution of the Republic of South Africa.

1. Everyone has the right to have access to
 - a. health care services, including reproductive health care;
 - b. sufficient food and water; and
 - c. social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
3. No one may be refused emergency medical treatment.

(Republic of South Africa, 1996a)

Addressing a history of health inequity

Since 1994 the South African government has introduced many new health related policies: free primary health care services for all; free health care services for children younger than six years, pregnant women and disabled people; a patients' rights charter and other initiatives (Singh et. al., 2007). With increased health care entitlements, coverage, and clinic construction, access to medicines became all the more important (Bond, 1999). Whilst constitutional obligation guided policy reform within the health sector, much of the drive behind new initiatives came from the indomitable Health Minister Dr Nkosazana Dlamini Zuma. During her tenure (1994 – 1999) she was more radical than her ministerial counterparts in seeking social justice and redistribution. She enthusiastically challenged powerful health sector interests, such as tobacco companies, urban doctors and health insurers (Bond, 1999). The pharmaceutical industry could not escape Dr Zuma's gaze.

Table 4.1 Time line of events leading up to the 2001 court case in South Africa
(Source: adapted from Gray et al 2002)

1996	<p>January – Formal Working Group established to draft legislation. February – Launch of the National Drugs Policy.</p> <p>July – Regulations published for comment.</p> <p>November – Public hearings on regulations, withdrawn in face of opposition. Draft of Amendment Act completed</p>
1997	<p>May – Amendment Bill tabled (Act 30 of 1997) June – Public hearing on Bill. Bill withdrawn. July – Rewriting of Bill. August – Amendment Bill re-tabled (Act 72 of 1997) September – Public hearings. December – Bill passed by Parliament as Act 90 of 1997</p>
1998	<p>February – PMA institute court action.</p> <p>May – South Africa placed on the USTR Special 301 Watch List</p> <p>October – Responding affidavit by Department of Health.</p>
1999	<p>No visible progress</p>
2000	<p>May – United States TRIPS plus policy reversed for sub-Saharan Africa.</p> <p>July – PMA replying affidavit submitted to court.</p>
2001	<p>January – Court date set.</p> <p>March – Court case begins. Short postponement. April – PMA and Department of Health settle out of court.</p>

In 1996 the South African government launched the National Drug Policy, strongly resembling a WHO template. Albeit vague and generic in parts, the National Drug Policy was comprehensive and clearly signalled the Department of Health's principles and intentions (Gray et. al., 2002). The policy had a number of specific objectives: firstly it sought to ensure the availability and accessibility of essential drugs to all citizens; and secondly to ensure the safety, efficacy and quality of those drugs. The policy also enshrined specific economic objectives including lowering the cost of drugs and establishing complimentary partnerships between government and private providers (Republic of South Africa, 1996c).

The election of the African National Congress (ANC) to government presented a significant window of opportunity in which to implement reforms. Governments that replace discredited regimes feel compelled to deliver immediately on their election promises. There is not only an assumption that something has to be done but that everything can be done. As such there is a danger that government policies are seen as good because they are based on the correct principles, rather than being technically well developed or because they accommodate a broad coalition of interests. The Department of Health has been criticised in some quarters for flawed and rushed reforms. By adopting a centralised and uncompromising approach the likelihood of conflict increased, and also contributed to repeated technical errors making the pharmaceutical policy vulnerable to legal attack (Gray et. al., 2002).

The Medicines and Related Substances Control Act of 1965 was seen as the most effective vehicle for reforming the pharmaceutical delivery system in post-apartheid South Africa. An Amendment Bill was tabled in the National Assembly in May 1997, but it immediately met vociferous opposition and was withdrawn. A small working group came back with a new document but the redrafting was minimal. The Bill was passed by Parliament as the Medicines and Related Substances Amendment Act in December 1997.³³ In February 1998, the Pharmaceutical Manufacturers' Association of South Africa (PMA) and 41 co-applicants sought an interim interdict from the High Court in Pretoria preventing the President from bringing the Act into effect (see Table 4.1). The PMA CEO stated at the time that the association

³³ Thirty-five minute telephone interview with Mr A Gray, Senior Lecturer at the Department of Therapeutics and Medicines Management, Nelson R Mandela School of Medicines, University of KwaZulu-Natal. 17th June 2008. Transcription checked by interviewee and retained by author. For more information see Appendix B.

supported government aims of redistribution and justice but believed the law was poorly constructed (Sidley, 2001). The PMA was obliged to oppose any measure that could be harmful to intellectual property rights and thus had the potential to damage the basis on which the pharmaceutical industry operates.³⁴

The Amendment Act regulates and controls all medicinal substances in terms of possession, use, sale, manufacture, import, export, cultivation and collection (Constitutional Court of South Africa, 2000; Republic of South Africa, 1997). It was one particular section of the Act, however, that caused controversy. Section 15C was poorly worded and open to a range of interpretations.³⁵ The Section appeared to give the Minister of Health wide-ranging powers to introduce aggressive marketplace competition to lower the price of medicines:

The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may...prescribe the conditions on which any medicine which is identical in composition, meets the same equality of standard and intended to have the same proprietary name as that of another medicines already registered in the Republic...may be imported (Republic of South Africa, 1997, Section 15C).

The primary mechanism by which to introduce competition was the parallel importation of branded pharmaceuticals from other countries. Parallel trade takes advantage of the fact that pharmaceutical companies sometimes charge significantly lower prices in one country than the other (Mugambe, 2002).³⁶ Parallel importation is a pure expression of the free trade principle, but is largely opposed by the

³⁴ Ehrich interview, 5th May 2008 (detailed footnote p 37) and Berger interview, 20th May 2008 (detailed footnote p. 42).

³⁵ Gray interview, 17th June 2008 (detailed footnote p. 51).

³⁶ Contrary to popular conception, parallel importation does not involve buying from generic suppliers. It is simply shopping around for the best price a company charges for a branded drug internationally (Love, 2001b). Parallel trade is common practice in the European Union.

pharmaceutical industry as it diminishes their control over price regulation within different countries.

Another key mechanism for increasing pharmaceutical security for South African patients is generic substitution of brand name medicines. Generic substitution requires pharmacists to prescribe a cheaper generic version of a medicine, if one exists, when presented with a patient's prescription (Mugambe, 2002; South African Department of Health, 1996).³⁷ Unsurprisingly the favouring of generic versions over their brand name counterparts is opposed by the multinational pharmaceutical industry.

Box 4.2 Brazil: Political will in a hostile environment?

Brazil provides an example of how a middle-income country can exploit its existing industrial and intellectual capacity, as well as its legal framework, to ensure availability of affordable generic medicines. Brazilian success is a product of a favourable legal system coupled with a progressive social policy, not dissimilar to that in South Africa.

In 1996 the Brazilian government guaranteed all HIV/AIDS patients access to treatment and care (Chaves, 2007). By the end of 2001 the occurrence of HIV-related opportunistic infections was reduced by 60%-80%; mortality rates were reduced by 50%; in-patient hospitalisations plunged to 14% of the pre-HAART figures, consequently the state saved some \$1.1 billion (R8.5 billion) from 1997 to 2001 (Sprague & Woolman, 2006). After the Brazilian government began producing AIDS drugs generically, the prices of equivalent branded drugs dropped by 79% between 1996 and 2000. In contrast, the prices of drugs with no generic competition dropped by only 9% over the same period (Pecoul, 2001).

The Brazilian success was due to its assertive use of the threat of compulsory licenses made credible by the presence of domestic production facilities, the majority of which received public funding. Brazil was able to negotiate price reductions or voluntary licenses with multinational firms as an alternative to issuing a compulsory license (Grace, 2004; Abbott, 2007; Sprague & Woolman, 2006).

There is much to be learnt from Brazil, but South Africa is unable to adopt such wholesale reforms. Brazil lacked any meaningful patent system for pharmaceuticals prior to 1996, however South Africa has a long established intellectual property regime (Grace, 2004). In addition the number of AIDS patients in South Africa dwarfs that in Brazil. South Africa would need considerably more facilities, at far greater expense, to produce ARVs for all who need them (Hanefield, 2002).

³⁷ This does not apply to medicines under patent unless a compulsory license has been granted for a generic version.

The most debated issue surrounding the Amendment Act and one that became central to the court case in 2001 was whether the Act allowed for compulsory licensing. During the late 1990s the possibilities for significant cost savings offered by TRIPS and compulsory licensing came to the forefront of the access to medicines debate. This, coupled with increased awareness of the extent of the HIV/AIDS crisis and the development of triple combination highly active antiretroviral therapy (HAART), created renewed optimism for advocates of pharmaceutical security. The hope was that South Africa could follow the example set by Brazil, another middle-income country, in its supply of medicines to those individuals infected with HIV/AIDS (Box 4.2). This optimism only served to distort the original aims of the Amendment Act.

Box 4.3 The PMA objections to the Amendment Act:

1. It enabled and authorised the Minister of Health to unilaterally determine the prescribed conditions for the supply of more affordable medicines, without setting out guidelines limiting the powers granted and depriving companies of their property.
2. Section 15C enabled the Minister of Health to determine the extent to which patent rights would extend irrespective of the provisions of the South African Patents Act.
3. Patent rights could be appropriated without any provision for compensation.
4. In contradiction of TRIPS, Section 15C discriminated against the pharmaceutical industry.

(Satardien, 2006)

When the Act was introduced the South African government was not pursuing a strategy of issuing compulsory licenses on patents. Instead it saw the act as a modest effort to introduce United States-style cost savings through the wider use of generic drugs and European-style use of parallel imports of cheaper branded drugs (Love, 2001b). In responding to the PMA lawsuit in 1998 the South African government stated that they had no intention of using Section 15C to issue compulsory licenses. A curious situation developed in which the government, in order to 'win' the lawsuit, abandoned any hope of using the Act to issue a compulsory license. Effectively the government was arguing a narrow interpretation of the Amendment Act. Conversely, the pharmaceutical industry based its case on a broad interpretation, whereby they

believed that compulsory licenses could be issued (Love, 2001b; Cleary, 2001).³⁸ The controversy over the provision (or not) of compulsory licenses and opposition to the powers given to the Minister formed the basis of the PMA court case (see Box 4.3).

The politics of the moral high ground

Pharmaceutical manufacturers were not alone in their criticism of South Africa. They were backed by a number of Western governments, including Switzerland, France, Germany and most notably the United States. The involvement of the United States was a classic instance of states being linked through the ‘internal markets’ of multinationals. In line with theories of hegemony within the international political economy, the lead up to the 2001 court action clearly demonstrates an attempt to subordinate South Africa’s needs in order to benefit the geo-economic aspirations of the United States.

As a result of considerable lobbying from the pharmaceutical industry, the United States applied pressure on the South African government. This included putting South Africa on the US Trade Representatives Special 301 Watch List in May 1998 (See Box 3.1, Chapter Three). It cited South Africa’s inadequate intellectual property protection as the reason despite the fact that all the reforms in the Amendment Act were TRIPS compliant. An official in the United States Patent and Trademarks Office stated “We acknowledge that our position is more restrictive than the TRIPS agreement but we see TRIPS as a minimum standard of protection” (Bond, 1999, p. 775). This statement openly acknowledges that the United States believed in ‘TRIPS plus’ standards of intellectual property and, more importantly, its actions demonstrated that it expected others to follow suit.

In June 1998 the White House announced that four items, for which South Africa had requested preferential tariff treatment under the Generalized System of Preferences program, would be held in abeyance pending adequate progress on intellectual property rights in South Africa (Bond, 1999; Lanoszka, 2003). The international community, quite rightly, interpreted such moves as macroeconomic

³⁸ A number of domestic complexities muddied the waters. South Africa had compulsory licensing provision in its existing patent law. The Minister of Health was at odds with Minister of Trade who was reluctant to issue a compulsory license under the old patent law, as it offered the possibility of litigation. Additionally President Thabo Mbeki’s dissident theories about HIV/AIDS made it difficult for officials to discuss initiatives that would make ARVs affordable (Love, 2001b).

bribery and were quick to condemn them. By ignoring existing WTO rules in TRIPS permitting parallel imports and compulsory licensing, as well as identical provisions practised in various areas of US commerce, they sent the message ‘do as we say not as we do’ (Bond, 1999). Whilst such practices are common within the geopolitical power plays of the global economy, the South African case incited global outrage. The United States, along with the multinational pharmaceutical industry, seriously underestimated the opposition they would face.

By the late 1990s the global activist and academic community had drawn a connection between pharmaceutical security and trade policy, particularly intellectual property.³⁹ The South African Amendment Act provided the first opportunity for these concerns to be voiced. A dry trade issue between two countries that may have previously slipped under the radar of non-governmental organisations was now being explicitly linked to the supply of life saving medicines. By mid-1999 the issue had become about HIV/AIDS.

The HIV/AIDS epidemic provided a unique environment.⁴⁰ Up until the mid-1990s when HAART became available in industrialised nations, AIDS was as much a death sentence for a white middle-class gay man in London as it was for a black working-class women in Cape Town. The HIV/AIDS epidemic established a commonality of experience never seen before, it ignored traditional socio-economic barriers such as race, gender, income and sexuality (Schneider, 2002). It transcended distance and location; people in the North and South suffered from HIV/AIDS and were equally helpless.⁴¹

The court case provided the political moment to focus a global campaign (Barnard, 2002). Intellectual property rights activists (such as Consumer Project on Technology) teamed up with organisations such as *Médicins sans Frontières* (MSF) and Health Action International (HAI) as well as South Africa’s Treatment Action Campaign (TAC), to deliver their message via the vehicle of HIV/AIDS (McIntyre et al., 2004).⁴² The years of hostility between the South African government and

³⁹ Berger interview, 20th May 2008, (detailed footnote p. 42).

⁴⁰ Gray interview, 17th June 2008, (detailed footnote p. 51).

⁴¹ The International AIDS Conference was held in Durban, South Africa in June 2000. Access to treatment featured very strongly – Berger interview, 20th May 2008.

⁴² Ehrlich interview, 5th May 2008 (detailed footnote p. 37).

HIV/AIDS organisations were forgotten for the sake of defeating the powerful multinationals. A coalition formed around a moral consensus: what had previously been a trade issue quickly became politics of the moral high ground (Friedman & Mottiar, 2004).

That the most powerful country in the world would spar with the most promising emerging democracy in Africa over access to life-saving AIDS medicines was a public relations nightmare for the Clinton administration in the United States (Bond, 1999). The case changed from one about a law affecting trade in pharmaceuticals, to one of denying AIDS patients life and more dramatically, putting Mandela in the dock once again. Nelson Mandela, the great freedom fighter, was speaking on behalf of all Non-Aligned Movement countries against corporate greed and American neo-imperialism.⁴³ The campaign surrounding the court action snowballed, taking on greater significance and symbolism than many expected.

The United States dropped its stand in 1999. This had much to do with demonstrations during the Gore election campaign in which he was confronted at election rallies by demonstrators accusing him of killing babies in Africa, and with placards reading “Gore’s Greed Kills” (t’Hoen, 2002; Petchesky, 2003). In May 2000, the United States ‘TRIPS-plus’ policy was relinquished for sub-Saharan African countries (McIntyre et. al., 2004). This was a small victory for the activist community and governments striving for pharmaceutical security. It signalled future unwillingness on the part of the United States to so enthusiastically and unconditionally support the pharmaceutical industry.

The case finally came to court in March 2001. By this time, due to its vigorous campaigning, the TAC was submitted as *amicus curiae* (friend of the court). The admission of the TAC to the proceedings served to lend not only greater publicity to the case but was also seen as a legal acknowledgement of the consequences of the court case for HIV positive people (Figure 4.1). The TAC also threatened to give evidence that would lay open to public scrutiny details of pharmaceutical firm R&D costs for AIDS drugs, as well as other aspects of the manufacturers’ advertising and marketing policies and expenditures (Barnard, 2002).

Shortly after the trial began it became clear that Section 15C of the Medicines Act was modelled on a draft legal text prepared by the World Intellectual Property

⁴³ South Africa took the 3 year leadership of the Non-Aligned Movement in September 1998

Organisation (WIPO) Committee of Experts. Given WIPO's involvement, and their role in TRIPS enforcement, it was impossible for the pharmaceutical industry to argue that the Amendment Act violated TRIPS (Sprague & Woolman, 2006; t'Hoen, 2002). The case was settled out of court, barely a month after it began. It was hailed as a great victory for the South African government and the activist community.



Figures 4.1 Images from Treatment Action Campaign protests, Pretoria 2001.

(Source: TAC, www.tac.org.za/photos.html)

The lawsuit ultimately set no legal precedent. It did however alter the balance of power within the global pharmaceutical political economy. Developing countries saw that they could stand up and win against the multinational pharmaceutical industry as long as they remained TRIPS compliant. The activist community saw how

effective legal mechanisms could be. In South Africa the Treatment Action Campaign along with the AIDS Law Project continues to use the court system successfully to gain rights for HIV/AIDS patients, in an approach dubbed “social litigation” (Jones, 2005). Pressuring a company through the courts, rather than through traditional forms of protest, has proved fruitful for a number of civil society organisations across the globe.

The multinational pharmaceutical firms recognized that they had little to gain from their aggressive enforcement of publicly unpopular legal positions (Sprague & Woolman, 2006). The prospect of 39 companies, whose combined profits far-outweighed the GDP of South Africa, moving to block access to affordable medicines, particularly in relation to HIV/AIDS, did immeasurable damage to corporate reputations (Joseph, 2003). The pharmaceutical industry has had to work hard to regain the trust of governments and the World Health Organization following its humiliation in South Africa. It has done this largely through developing a less aggressive stance towards intellectual property in certain therapeutic areas and geographical regions and also through increased Corporate Social Responsibility projects. The legacy of the 2001 court case is multi-faceted and disputed in many quarters. The court case certainly had an impact on the global pharmaceutical political economy. The following chapter attempts to identify some of these consequences and discusses the sense in which the 2001 court case was only a partial ‘victory’.

Chapter Five: The changing geopolitical landscape of pharmaceuticals.

The South African court action of 2001 was a test case for governments, industry and activists. The power dynamic within the pharmaceutical geopolitical landscape shifted, only very slightly, away from the traditional centres of power. Although the case set no legal precedent it undoubtedly gave the global access to medicines campaign the confidence to challenge the major forces within the international pharmaceutical political economy. Issues of morality, rights and justice collided with law, politics and economics in one spatially and temporally confined moment. What had previously been a campaign that was confined to the liberal fringe was now part of global 'high politics'.

The power of law



The 2001 court action demonstrated the potential that judicial and legislative mechanisms hold for advancing pharmaceutical security. Whilst the medicines delivery system is a truly global operation it is still subject to laws. Regulation of the global pharmaceutical industry is geographically constituted. Whilst the flows and processes that make up the pharmaceutical international political economy are transnational in nature, corporations operate in specific locations across the globe. These nodes of activity are subject to law. The South African case showed that multinational companies are not above the law and that the nation state has not yet been sidelined within the international political economy.

Just as multinational pharmaceutical firms are subject to obligations brought about by law so are governments. The condition of a government having power over a territory is that it upholds the rights of its citizens. In the case of South Africa, these rights are enshrined within the Constitution. The duties a government is expected to fulfil present activists with opportunities to call an administration to account, if necessary through the courts. The global pharmaceutical political economy is subject to laws, rights and obligations at every level. In the last seven years these obligations

have been grasped by a great number of organisations to enforce justice in pharmaceutical provision.

South Africa has seen a number of instances in which access to medicines has been enforced through the judicial process. One such instance occurred when a coalition of South African non-governmental organisations, led by the AIDS Law Project, brought a complaint against the pharmaceutical multinationals GlaxoSmithKline and Boehringer Ingelheim. In this case the South African Competition Act was used, asserting that the firms were pricing three medicines excessively, arguing that a right to life should be put before profiteering. The Competition Commission investigated and found that there was sufficient evidence of excessive pricing, denial of access to an essential facility and engaging in an exclusionary act to warrant referral to the Competition Tribunal for adjudication. After this finding both companies settled the case in December 2003 (Williams, 2007; Singh et. al., 2007). According to the settlement, GlaxoSmithKline and Boehringer Ingelheim were willing to provide the three drugs to generic manufacturers, Aspen Pharmacare and Thembalami Pharmaceuticals, for production within South Africa and for export to forty-seven African countries for a royalty of no more than 5% of net sales (Sprague & Woolman, 2006).⁴⁴ Here, a judicial ruling significantly enhanced pharmaceutical provision for those infected with HIV/AIDS.

South African civil society has also successfully used a rights-based argument to force the Department of Health to change its treatment policy.⁴⁵ One of the most notable examples occurred in December 2001 when the Treatment Action Campaign won a lawsuit against the South African Minister of Health, Manto Tshabalala-Msimang, and nine provincial Health Ministers. The case forced the government to provide Nevirapine through the public health sector for the prevention of mother-to-child transmission of HIV. The government previously stated that they had no evidence of its safety or efficacy despite numerous studies showing that it could cut

⁴⁴ Additionally, in early 2008, four South African pharmaceutical manufacturers were found by the Competition Commission to be colluding in fixing bids for the supply of medicines through the South African tender system.

⁴⁵ One of the great successes of South African civil society during and following the court case is how it has turned the matter of intellectual property into a populist issue. Many of the tactics it used were reminiscent of the struggle against apartheid. For example, the Treatment Action Campaign started a civil disobedience campaign on March 20th 2003. Hundreds of activists presented themselves for arrest and demanded the arrest of the Health Minister and the Minister for Trade and Industry (Achmat, 2004).

transmission rates by up to 50% (Beresford, 2001a; Schneider, 2002; Singh et. al., 2007). A government is the steward of a nation's health and, as such, it has a duty to do everything within its available resources to provide treatment for its citizens. The South African government has been shown that if it does not live up to its obligations then it no longer faces merely protests but binding and enforceable judicial reprimand.

The emergence of the global pharmaceutical justice campaign

The global social consciousness that developed around issues of pharmaceutical security in the lead up to the 2001 South African court case was reinforced by the 'victory' in Pretoria and has continued to gain strength. The court action had a pivotal role for global health activism. Rather than pursuing diffuse campaigns that concentrate on abstract global processes there has been greater effort to direct action towards single events, specific companies or particular pieces of legislation. Events in South Africa highlight how effective a temporally and spatially concentrated campaign can be. Whilst transnational processes were implied within the campaign conducted by civil society, South Africa provided a specific geographical point to which everyone could turn.

Since 2001, a number of similar cases have occurred. Civil society has largely followed the same model of simultaneous domestic and global action. In 2007, Swiss pharmaceutical company Novartis challenged the Section of the Indian Patent Act that denied an extension of its patent for a cancer treatment, Gleevec (Dickson, 2007). The Indian Patent Act aims to prevent a phenomenon commonly referred to as 'ever-greening', a process by which companies attempt to extend patent life for a treatment based on little or no improvement on the previous drug.⁴⁶ The patent application for Gleevec was rejected on the grounds that it lacked increased efficacy (Basheer, 2007). The case showed remarkable parallels with the South African court action in that it represented a challenge to government legislation based on a belief that India was contradicting its obligations under WTO law. In the end, following a global

⁴⁶ GlaxoSmithKline's important first line AIDS treatment, Combivir, is another example of an ever-greening product. In the summer of 2006 following massive protests in Bangalore and Bangkok, GlaxoSmithKline withdrew its patent applications in Thailand and India. Combivir was a fixed dose combination of two earlier discovered drugs and involved neither newness nor an inventive step. The principal new ingredient was silicone, an ineffective addition graphically illustrated by Indian demonstrators when they dumped sand in front of GlaxoSmithKline's offices (Oxfam 2007).

campaign, the Indian court rejected the Novartis case. The case was highly significant because the Indian generic industry is known as the ‘pharmacy of the world’. Had Novartis’ challenge to India’s Patent Act been upheld then it would have limited the number of generic medicines available to many countries striving for pharmaceutical security.



Figure 5.1 ‘Profit Pills’, the slogan of an Oxfam 2006 campaign. (Source: Oxfam, www.oxfam.org.uk).

In November 2006 and January 2007, Thailand issued compulsory licenses for two new AIDS treatments and a heart disease medicine. In January 2008 it issued an additional four compulsory licenses on cancer medications (Rimington & Weissman, 2008). The Thai action was seen as a breakthrough: it was the first time that a license had been issued on second-generation HIV/AIDS drugs which remain much more expensive than first-generation treatments in which generic competition is robust. It also signalled a refusal by the Thai government to limit compulsory licenses to AIDS medications. There is credible concern among the pharmaceutical industry and a number of WTO members that if licensing is used indiscriminately then it could seriously undermine the patent system. A senior official of the Pharmaceutical Industry Association of South Africa (PIASA) believes that the issuing of compulsory

licenses in countries such as Thailand and Brazil is merely used as a mechanism to drive their local pharmaceutical manufacturing industry.⁴⁷ There is a risk that a ‘cry wolf’ situation could develop if TRIPS flexibilities are overused, and this could lead to an erosion of mechanisms available for genuine emergencies.

In response to Thailand’s issuing of licenses, the multinational firm, Abbott, withdrew applications to market seven new medicines in Thailand (Rimington & Weissman, 2008). An extensive campaign was launched by Oxfam and *Médicins sans Frontières*, as well as by Thai civil society that concentrated on putting pressure on Abbott and encouraging the Thai government to stand firm in the face of pressure from the United States and European Union. The latest indications are that the Thai government intends to continue producing the generic products under license.

The incidents in India and Thailand both illustrate how the global medicines access campaign questions the orthodoxy of the global pharmaceutical political economy. The challenge is most often directed at the intellectual property regime that lies at the heart of pharmaceutical delivery, binding national laws with the multinational production and supply of medicines.

The Doha Declaration of 2001 shows a direct causal link with the South African court action of the same year.⁴⁸ Due to the ‘victory’ and the publicity gained from the South African Amendment Act dispute, a developing country coalition entered the Doha negotiations with confidence. Successes in South Africa and Brazil gave a green light to developing countries to move aggressively on the matter of access to medicines (Petchesky, 2003). The Doha negotiations, an event that would not normally capture the imagination of the public, were placed in the glare of the media spotlight with the help of the international NGO movement. The increased public pressure was combined with the developing countries operating as one bloc, something rarely seen before or since, and proving to be a commanding force (t’Hoen 2002). As noted in Chapter Three, the Doha Declaration was a seminal moment for those seeking global pharmaceutical security: evidently the WTO recognised a hierarchy of values.

⁴⁷ Ehrlich interview, 5th May 2008 (detailed footnote p. 37).

⁴⁸ Berger interview, 20th May 2008 (detailed footnote p. 42).

Changing the pharmaceutical geopolitical order

Arguably, the Doha Declaration changed the landscape of the international pharmaceuticals political economy forever. The pharmaceutical IPE was driven solely by property rights and market forces, however following the South African case issues of morality and justice increased in significance. The real worry for the pharmaceutical industry was no longer South African law but the fact that the access to medicines campaign had triggered a much broader discussion about the links between patents, the price of drugs and the costs and risks of research (Drahos & Braithwaite, 2002; Lanoszka, 2003). The way in which intellectual property was enforced was also questioned. The geopolitical order of global health was challenged. The heavy-handed tactics of the United States Trade Representative (USTR) and other Western nations were seen as unacceptable in the sphere of health. The HIV/AIDS crisis lent significant weight to this argument, and Western governments were shamed into easing their pressures on nations affected by the devastating epidemic.

After the South African court action it became clear that industrialized countries that exercised trade restrictions to defend the interest of their multinational industries could no longer exert pressure without repercussions at home (t'Hoen, 2002). The global campaign surrounding access to medicines succeeded in bringing South African HIV/AIDS patients into the consciences of the American and European electorate. By making the issue one of global significance, all actors within the international political economy were tied into a web of morality and justice. Geographical remoteness and detachment no longer mattered. In addition to pressure at home, industrialized nations were alarmed at the global spread of HIV/AIDS and its repercussions for development and security across the world. Consequently, bodies such as the USTR have been forced to reconsider their previously unyielding position towards intellectual property overseas (Lanoszka, 2003). Multinational pharmaceutical firms have found themselves politically isolated, no longer able to count on the backing of Western governments.



Figure 5.2 Treatment Action Campaign Protest, Pretoria 2001. (Source: TAC, www.tac.org.za/photos.html)

The pharmaceutical industry has undoubtedly become less aggressive towards developing nations. This softening is a consequence of the absence of unconditional backing from industrialized nations, as well as a general recognition that firms must be seen to be taking a proactive role in promoting global health. Justice, morality and social responsibility have to take a central role within pharmaceutical business plans. To the industry's credit, the majority of companies have responded.

Corporations have the capacity to be moral agents. They make decisions that have important consequences for human beings (Resnik, 2001). There is growing recognition in the pharmaceutical sector that social responsibility makes good business sense. The damage done by conflicts, such as in South Africa, to a firm's public relations cannot be underestimated. In a commendably progressive statement on the occasion of Glaxo Wellcome and SmithKline Beecham's merger in 2001, the new CEO noted that,

The pharmaceutical industry today sells 80% of its products to 20% of the world's population. I don't want to be the CEO of a company that only caters to the rich...I want those medicines in the hands of many more people who need them (Smith & Duncan, 2005, p. 98).

The pharmaceutical industry's introduction of 'justice' into its lexicon is not, however, purely altruistic. A dynamic relationship within the pharmaceutical IPE exists between the pharmaceutical industry, activists and governments. This relationship is based on the power of those striving for pharmaceutical security to instigate legal proceedings, apply public pressure and issue licenses for generic production. Whilst wholesale changes to the system have not occurred, the mechanisms already in place ensure that enough incentives are present for the prices of pharmaceuticals to be reduced. In South Africa, the mere threat of a law providing for compulsory licenses and other pro-health mechanisms led to rapid and significant drops in the price of patented ARVs. At the beginning of 2001, a triple combination therapy cost approximately R3500 per month. By June 2001, the price of the same medicines had dropped to approximately R1000 per month (Mugambe, 2002). The number of donations of drugs also increased during and following the South African court case, although these often had conditions attached (Haffejee, 2003). One of the most significant developments in recent years, particularly in South Africa, has been the issuing of voluntary licenses by multinational firms.

The increase in voluntary licenses is a consequence of the willingness of organisations such as the AIDS Law Project to bring companies to account through the courts. Licenses are normally granted in order to avoid court action, thus the degree to which they are 'voluntary' is debateable.⁴⁹ They are issued by pharmaceutical firms for their branded medicines and allow a named generic manufacturer to produce the product. Voluntary licenses avoid legal battles by securing multinationals the patent protection they require whilst increasing the affordability of a patented medicine (Innovative Medicines South Africa, 2005). With

⁴⁹ Berger interview, 20th May 2008 (detailed footnote p. 42).

the increased efforts of the pharmaceutical industry, and the undoubted reduction in prices public criticism has started to move away from the pharmaceutical industry and intellectual property and towards government (in)action.

A number of commentators believe that intellectual property no longer takes centre stage and that the pharmaceutical industry is no longer the villain in the global debate over access to medicines (Barber, 2001b). New issues now are whether donors will supply the money to buy and effectively distribute ARVs as they become available at or below marginal cost of production. And if the money is there, what is the wisest way to spend it? Should there be an international agency to purchase and distribute the drugs? (Barber, 2001b). Persistent attacks on relatively enlightened companies such as GlaxoSmithKline and Merck may be seen as a tactic designed to achieve by threat what cannot be gained by calls for compassion and international solidarity. A danger, however, is that this could reinforce a global political culture of blame. Such a culture could needlessly harm pharmaceutical companies which are valuable national and international assets (Taylor, 2001). Nation states have the mechanisms available to them under international law to lower prices and they also must take responsibility for effective pharmaceutical procurement and distribution where prices are already affordable.

Too much emphasis is often put on the pharmaceutical industry to the exclusion of the state's responsibility to its citizens. For example, Oxfam has criticised Abbott pharmaceuticals for making their ARV, Kaletra, available at a discounted price of \$2,200 (R16, 921) per year in Guatemala where the gross national income per capita is \$2,400 (R18, 497) (Oxfam 2007). The discount clearly still leaves a significant number of people without access to medicines, but to what extent is a company expected to cut its prices? If a firm reduces its drug price, attempting to increase access, but the citizens of a country are still too poor to afford it, when does it become the state's responsibility to improve the economic situation of its citizens or a donor's responsibility to purchase the treatment for the country? A pharmaceutical firm is not a charity and whilst they have responsibilities these must be balanced with making a profit for their shareholders.

“Snatching defeat from the jaws of victory”

It would be wonderful, of course, if South Africa’s decimation by AIDS could genuinely be blamed on greedy firms that might be brought to heel with a couple of paragraphs of legislation. Government would be spared so many agonising choices...

(Barber, 2001a, p. 2)

The South African government basked in the glow of publicity created by its ‘victory’ over the PMA in the Pretoria High Court. South Africa was the darling of the global left and the figurehead of the Non-Aligned Nations: the government of the freedom struggle had stood firm against the neo-imperialist pressures of the United States and the amoral multinational pharmaceutical industry.

Partly as a result of the TAC campaign it was commonly believed that the ‘victory’ would mean that Section 15C would be used to access generic anti-retroviral therapy for South African AIDS patients. Unfortunately, before the last champagne bottle had been opened, the government warned against expecting it to provide ARVs. The government’s policy remained that ARVs were too expensive and it would continue to treat only the opportunistic infections caused by the virus (Baleta, 2001). The Congress of South African Trade Unions (COSATU) believed that this was an example of the government “snatching defeat from the jaws of victory” (COSATU 2001).

In the late 1990s and early 2000s The South African government took a view that contradicted accepted scientific orthodoxy concerning HIV/AIDS. The former Health Minister, Tshabalala-Msimang⁵⁰, has continually stated her belief in the toxicity of ARVs (Beresford, 2001b). On the other hand she considers garlic, olive oil, lemon and beetroot effective treatments for HIV/AIDS. The Minister of Finance, Trevor Manuel, is quoted as describing ARVs as akin to ‘western voodoo’ (Jones, 2005). President Thabo Mbeki repeatedly questioned the link between HIV and AIDS

⁵⁰Since the completion of the research and following the resignation of President Thabo Mbeki in September 2008 and the appointment of Kgalema Motlanthe as interim President a new Health Minister was appointed. Barbara Hogan, has already shown far greater commitment to achieving pharmaceutical security in South Africa. In fact, upon receiving news of her appointment the TAC held a champagne fuelled party outside her house!

during his time in office (Mbali, 2004). The UN Special Envoy for HIV/AIDS in Africa, speaking to the closing session of the XVI International AIDS Conference in Toronto, August 2006, observed that

South Africa...is the only country in Africa...where government is still obtuse, dilatory and negligent about rolling out treatment. It is the only country in Africa whose government continues to propound theories more worthy of a lunatic fringe than of a concerned and compassionate state (Satardien, 2006, p. 5).

The AIDS denialism that has characterised the South African administration is driven by a number of factors. First, the South African government appropriated the medical findings of certain dissident scientists, to the exclusion of more reliable and robust evidence (Mbali, 2004). Due to the lack of resources at the government's disposal and a largely inadequate health infrastructure, the government of 2001 found it difficult to even contemplate dealing with a crisis of such magnitude. The government has heard only what it wants to hear. By blaming HIV/AIDS exclusively on poverty, and furthering a belief that poverty alleviation is the only way to combat the virus (it is undoubtedly one way), the government was able to deny its obligation to provide ARVs.

Second, there was a strong belief in a Western conspiracy based on racial and sexual constructions of 'the African' (Mbali, 2004). Whilst there are some very real examples of racism in the history of HIV/AIDS, the government altogether rejected the Western biomedical paradigm relating to the virus. Apparent medical solutions to HIV/AIDS were rejected as Western medication of poverty and underdevelopment (Jones, 2005).

Third, during the lead up to the court action of 2001, both the United States and the pharmaceutical industry showed their opposition to the possibilities of compulsory licenses (Mbali, 2004). The government knew that if it issued a license of the scale needed to treat all those infected with AIDS in South Africa, the opposition from both the United States and the multinational pharmaceutical firms would be considerable. By denying the necessity of ARVs the government avoided any possibility of conflict.

One of the ironies of the South African court case is that although it brought global attention to intellectual property's connection with medicines delivery and highlighted the possibility of TRIPS flexibilities, it had no impact on South Africa's patent environment. The crucial piece of legislation for pharmaceutical intellectual property in South Africa remains the Patent Act of 1978, a relic of the apartheid era. The South African Patent Act goes beyond the requirements of TRIPS, making a compulsory license very difficult and costly to issue. Under the TRIPS agreement South Africa would only have to declare the HIV/AIDS crisis a national emergency and then issue a compulsory license to import generic ARVs (Barber, 2001a).⁵¹ The South African Patent Act makes it a far more challenging process. As one case shows, in March 2001 Cipla Ltd, an Indian generic manufacturer wrote to the South African Department of Trade and Industry asking for a compulsory license to sell up to eight AIDS drugs available at the time only from the patent holders. Cipla was to sell these treatments at approximately \$400 (R3,083) below the price offered by most multinationals. Unfortunately under the existing domestic patent law it would have been illegal to issue a license, to the detriment of health in South Africa (Mugambe, 2002).

A possibility for South Africa might be to reform its patent law so that it came in line with the minimum standards enshrined within the TRIPS Agreement. The struggle over the Amendment Act and the Novartis court case in India illustrate however, how difficult this would be. Any reform would surely come under considerable pressure from various quarters. Whilst the 2001 court action can be seen as a success in many ways, the reluctance of the South African government to step out of line concerning intellectual property must be considered a victory for the pharmaceutical industry.

As discussed in previous chapters, an individual's health is inseparable from the economic, political and social processes that surround him or her, the 'body politic'. The health policies followed by a government are inextricably tied to both domestic economic decision and macroeconomic phenomena. South Africa's economic development path has closely followed the neo-liberal doctrine advocated

⁵¹ In June 2008, the International Federation of the Red Cross and Red Crescent Societies called for HIV/AIDS to be deemed a global disaster. The Federation believes that the United Nations definition of a disaster should be applied to HIV/AIDS. The United Nations defines a disaster as "any serious disruption of the functioning of a society, causing widespread human, material or environmental losses which exceed the ability of a society to cope using only its own resources" (International Federation of Red Cross and Red Crescent Societies 2008, p. 3).

by Western governments and the WTO. At the time of the 2001 court case South Africa was regularly hailed as an exemplary observer of the Uruguay Treaty commitments, including TRIPS. As such the South African government did not want to engage in any activity that would call its 'model WTO citizen' status into question (McIntyre et. al., 2004). This has been reflected in its conservative pharmaceutical policy, particularly when considering intellectual property.

Following South Africa's emergence from apartheid the government adopted strict macroeconomic policies demanding fiscal restraint and liberalization of markets (Sanders & Chopra, 2006; South African Department of Finance, 1996; McIntyre & Gilson, 2002). These principles were enshrined within the policy document entitled Growth, Employment and Redistribution (GEAR). GEAR was an attempt to guide South Africa through its difficult transition period, yet, it has been accused of excluding the government's pro-equity principles in favour of an emphasis on efficiency. In an attempt to contain spending, basic social services were privatised and social spending (including on health) was reduced. The stagnation of overall expenditure has made achieving equity in the health sector extremely difficult (McIntyre & Gilson, 2002; Mbali, 2004; Sanders & Chopra, 2006; Republic of South Africa, 1996b). The government's reluctance to spend on ARVs can be positioned within this neoliberal rubric.

On the other hand, it could be argued that the government has operated to the best of its abilities within the constraints of a globalised economy. Defying the pharmaceutical industry's intellectual property rights would have very real consequences. For example the government would likely have faced trade sanctions, and been forced to increase taxes to pay for growing expenditure on medicines procurement, which would in turn discourage investment (McIntyre et. al., 2004; Cleary, 2001; Mbali, 2004). Such defiance was not an option for South Africa as it left apartheid behind and tried to establish itself within the international political economy.

Pharmaceutical security cannot be analysed in isolation. The provision of affordable medicines is part of a balance between numerous concerns at the macro and micro level of the political economy. For a country in transition, such as South Africa, the demand for equitable distribution of resources is vast, ranging from education to housing, employment to health. The South African government has made progress in the health sector since 1994 (although not as much as it could have), and

in recent years it has become more responsive towards pharmaceutical equity and the treatment of HIV/AIDS, yet challenges remain.

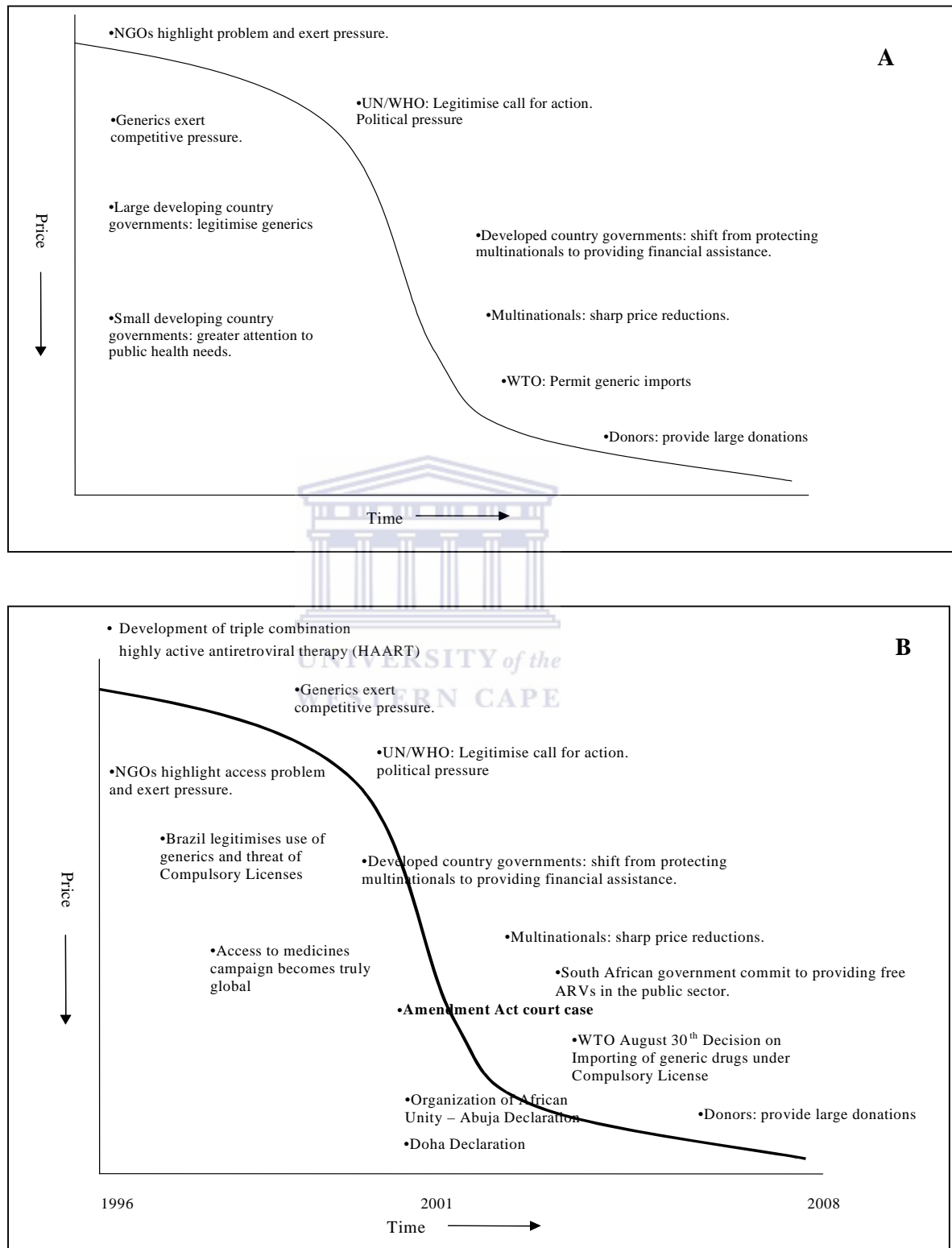


Figure 5.3 An idealised sequence towards pharmaceutical price reductions, globally (A) and in South Africa (B). (Source: based on Vachani & Smith, 2004).

Progress: pharmaceutical policy in South Africa

It took a further three years after the court case was dropped for the full package of reforms laid out in the Amendment Act to come into force on 2nd May 2004 – almost six and a half years after Nelson Mandela signed the Amendment Act of 1997 (Hassim et. al., 2007). Despite the delays and bureaucratic inefficiencies that pharmaceutical policy has had to endure in South Africa, progress has been made. The pharmaceutical production network consists of a vast number of stakeholders, all seeking to maximize their profits, an arrangement which can considerably distort medicine prices. One of the most significant developments since 2004 has been the founding of a pricing committee. It signals a recognition by the government that the affordability of a medicine is dependent upon eliminating excessive profits and perverse incentives throughout the production network, from factory to pharmacy.

Before the introduction of pricing regulations South Africa had one of the highest fees in the world for the distribution component of the pharmaceutical supply chain (Dumnett, 2002). Pharmacists were able to charge a dispensing fee based on a percentage of the Rand value of the medicines they sold, providing a perverse incentive for pharmacists to stock and sell the most expensive medicines (Kahn, 2003; McDonald, 2004). From 2004 the pricing regulations established a flat rate dispensing fee for pharmacists, eliminating their percentage cut and increasing price transparency (Dumnett, 2002; Tshabalala-Msimang, 2005).⁵² The government has been accused of concentrating too much attention on the end of the production network to the exclusion of the ex-manufacturer price, which may be considered more influential to the affordability and availability of medicines (Williams, 2007).⁵³ The pricing regulations do, however, extend to ex-manufacturer pricing. A single exit price was established for each medication and price lists have been made available to the public (Kahn, 2003; McDonald, 2004; Tshabalala-Msimang, 2005). The primary mechanism, nevertheless, is market based and driven by retailer demand. Since it is no longer as profitable to sell higher-priced drugs, the hope is that the market should shift towards cheaper generic pharmaceuticals.

⁵² The retail pharmacy industry vehemently opposed the reform, believing the dispensing fee to be too low. The pricing regulations were challenged but upheld in the Constitutional Court at the end of 2005. In 2006, the dispensing fee was once again challenged in the courts, but was upheld (Williams, 2007).

⁵³ Berger interview, 20th May 2008 (detailed footnote p. 42).

If a government makes a political commitment to buy medicines for a certain therapeutic area, it creates a market. Private companies will respond to this market. This is one of the most explicit examples of the link between politics and economics within the global pharmaceutical delivery system. Since the Millennium there has been a considerable increase in the volume of international donor funds for health (Vachani & Smith, 2004). This has coincided with greater commitment from African countries towards health, enshrined within the Abuja Declaration of 2001 in which countries pledged to allocate 15% of their national budgets to health care (African Union, 2001). The private sector will respond when a market is stimulated, whether this is through domestic or international commitment. Since the beginning of the century multinational pharmaceutical companies have cut prices considerably as they know they have a secure and extensive market, particularly for HIV/AIDS treatments.

On the 8th August 2003, the South African government finally made a commitment to provide ARVs for free in the public sector. The Operational Plan on Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, followed in November. The plan made an ambitious commitment to provide ARVs for over one million people by the 2007/2008 financial year (Hassan, 2005). Although in April 2008 the public sector was providing ARVs for only 478,000 people (South African Department of Health, 2008). Despite the failure to meet its target, this figure constitutes the highest number of people initiated on ARV treatment in any single country. The government has also succeeded in stimulating competition for its ARV tender. South Africa has the highest number of people infected with HIV/AIDS in the world, consequently when its government commits to providing treatment through the public sector, generic as well as brand name manufacturers respond.

In June 2008 the South African Department of Health awarded a tender worth R3.6 billion (US\$478 million) over two years for the procurement of antiretroviral drugs. The tender is spread over six suppliers but dominated by two South African firms, Aspen Pharmacare (with over half the total tender) and Adcock Ingram. The price of most items is lower than it was in the 2005 tender. The percentage decrease ranges from 20% to 71%. The government attributes the reduction to higher volumes, and increased generic entry leading to a more competitive climate (Republic of South Africa, 2008).

Increased generic entry has partly been stimulated by the generic substitution policy in the Amendment Act. With doctors and pharmacists prescribing the generic

version of products, generics now account for over half the pharmaceuticals consumed within South Africa.⁵⁴ The generic substitution policy, coupled with the Competition Act of 1998 has contributed greatly to increasing the affordability of medicines by encouraging generic competition.⁵⁵ Parallel importing, another much heralded mechanism for improving access to medicines, has never been used by the South African government despite the fact that it has legislative approval.⁵⁶

The generic substitution policy, competitive tendering process and donor commitments are all effective pull factors within the pharmaceutical production network. In order for the South Africa pharmaceutical industry to grow, however, it is necessary to deploy push and pull mechanisms simultaneously. The direct quantifiable economic benefit of the research based pharmaceutical sector to the South African economy was calculated at R10 billion for 2006. The potential for further growth is vast considering South Africa's strategic importance within a continent wracked by disease and desperate for a sustainable supply of medicines. As such the pharmaceutical industry has been deemed a lead sector in South Africa's Industrial Policy Action Plan (Republic of South Africa 2007a).⁵⁷ The National Industrial Policy Framework, of which the Industrial Policy Action Plan is a part, seeks to diversify the South African economy towards high value-added goods and services. Crucially, rather than the government financing a broad sector, it will concentrate its resources on supporting specific activities (Republic of South Africa, 2007a). The production of ARVs is seen as a specific strategic activity that the government will support, partly through the tender process but also through its Strategic Investment Programme (Republic of South Africa, 2007a, 2007b).⁵⁸

The Framework states that a coherent approach should be taken across government. For example, the Department of Trade and Industry (DTI) should work

⁵⁴ Gray interview, 17th June 2008 (detailed footnote p. 51) and Ehrich interview, 5th May 2008 (detailed footnote p. 37).

⁵⁵ Berger interview, 20th May 2008 (detailed footnote p. 42).

⁵⁶ Gray interview, 17th June 2008.

⁵⁷ Beaumont interview, 5th May 2008 (detailed footnote p. 43).

⁵⁸ The Strategic Investment Programme and the promise of a full scale national rollout of ARVs induced Aspen Pharmacare to invest R182 million in a manufacturing facility in Port Elizabeth capable of producing significant amounts of generic ARVs. Due to this investment, Aspen has secured a number of voluntary licenses from multinational firms (Sprague & Woolman, 2006).

closely with the Department of Health (DoH) in relation to pharmaceuticals, something that they have previously failed to do, much to the frustration of the pharmaceutical industry. The South African pharmaceutical industry indicates that the DTI has been very supportive of the industry due to the considerable foreign exchange that it brings into the country. The industry's relationship with the DoH, however, has been more challenging. The industry believes that a muddled arrangement of price regulations and an inefficient regulatory environment have made it increasingly difficult to operate in South Africa.⁵⁹ As with any industry, pharmaceutical firms require a predictable environment. Uncertainty is likely to result in less research and the registration of fewer medicines, ultimately harming patients.

A clear pharmaceutical policy that runs across government departments would greatly benefit the pharmaceutical industry in South Africa. Even without this, however, there are signs of growth. The total value of exports from the research based pharmaceutical sector was approximately R414 million in 2006, compared to R122 million in 2003, growth of approximately 240% (Deloitte Consulting, 2007). There are indications of a deliberate approach to building the country's manufacturing capacity in niche areas related to tuberculosis, malaria and HIV/AIDS. The target is to make South Africa a centre of excellence in these fields.

The majority of multinational pharmaceutical firms are present within South Africa due to its favourable market and location for onward expansion into Sub-Saharan Africa. Some firms have maintained their manufacturing facilities whilst others use South Africa as their distribution and management centre for Southern Africa (Deloitte Consulting, 2007). With appropriate government policies, such as tax relief, investment credits and technology transfer (Sprague & Woolman, 2006), the pharmaceutical industry in South Africa could gain a comparative advantage as a producer of low cost pharmaceuticals to the rest of the continent. The possibility of South Africa becoming Africa's pharmacy, and the benefits this might have, are discussed in the following chapter.

⁵⁹ Beaumont interview, 5th May 2008 (detailed footnote p. 43) and Ehrich interview, 5th May 2008 (detailed footnote p.37).

Chapter Six: Achieving Pharmaceutical Security in Africa

In the eyes of Nobel Prize winning economist Amartya Sen, freedom is development (Sen, 1999). Health is intrinsically tied to freedom and thus is a central pillar of development. A healthy individual is free to accomplish and contribute far more than a person who is unhealthy. Issues of freedom, justice and responsibility are inseparable from each other and as such must dominate any discussion of development and the international political economy.

Three of the United Nation's eight Millennium Development Goals are health oriented – reducing child mortality among children under five, reducing maternal mortality, and reversing the spread of communicable diseases, specifically HIV/AIDS, malaria and tuberculosis (Bradford, 2007). It is no coincidence that Africa, the continent most blighted by disease and ill health, is also the continent with the most significant development challenges. Improving the health of Africa's population is inseparable from increasing African economic growth and political stability. Achieving pharmaceutical security for Africa would greatly ease the burden on the continent.

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Africa's challenge

The African disease burden is crippling the continent. The devastating burden of HIV/AIDS and a multitude of other infectious diseases in Africa reinforce a geography of global inequality, whilst simultaneously shaping local development and governance initiatives (Jones, 2005). Disease prevalence within the region envelopes all other concerns, from education to industrial development. The omnipresence of largely preventable diseases necessitates pharmaceutical security in Africa.

Life expectancy in Africa stands at thirty-nine years, considerably lower than any other region (Orbinski, 2007). This is largely due to the prevalence of HIV/AIDS in the continent's southern region. A conservative projection holds that one in three fifteen year olds in the region will die of AIDS (Joseph, 2003). The number of shocking statistics relating to the African disease burden, and specifically HIV/AIDS, is heart rending. Whilst death is the most definitive consequence of illness and

disease, incapacity is also a significant issue. The malaria parasite, which in most cases is not life threatening, can seriously hamper a person's ability to work and contribute to a household. The Ugandan government estimates that the average Ugandan has six episodes of malaria each year. It estimates that workers suffering from malaria can be incapacitated for five to twenty days. A study in Apac, Kampala and Rukungiri Districts showed that malaria was responsible for 54%, 33% and 50% respectively of absenteeism from work per month (Ugandan Ministry of Health, 2008).

Despite high burdens of illness, it is estimated that 50% to 60% of the African populace lack access to essential medicines (Tetteh, 2008; WHO, 2007). In Sub-Saharan Africa it is estimated that only 28% of people with AIDS have access to ARVs (Forman, 2007; UK Department for International Development, 2008). Whilst this figure is disturbingly low, it is a vast improvement – in 2004 there were only one hundred thousand people on ARV therapy in Sub-Saharan Africa, but four years later there are over one million people (UK Department for International Development, 2008). A significant proportion of this increase is due to South Africa's commitment to public sector ARV supply. Estimates show that in Sub-Saharan Africa, ARVs combined with effective prevention strategies could save up to ten million lives over the next fifteen years (Forman, 2007). In order for Sub-Saharan Africa to meet the Millennium Development Goals, there must be greater commitment to provide ARVs to those who need them.

The signs, however, are not positive. Treatment for HIV/AIDS is relatively expensive and logistically problematic. In contrast, vaccine delivery is inexpensive and needs little follow up. Despite this, coverage with the six basic vaccines of childhood has stagnated in almost every region in the world since 1990 with Africa at a disturbingly low 50% to 60% take up rate (Labonte et. al., 2005). If fairly basic vaccine programmes are failing to be delivered, despite the fact that vaccines are readily available, then one must question whether resource intensive HIV/AIDS programmes can be sustained.

The problem of access to pharmaceuticals in Africa is similar to the problem of famine, addressed in Chapter One. In many cases pharmaceutical famine results not from a shortage of medicines, but from a government's failure to distribute drugs so that people can buy them (Drèze & Sen, 1989; Barnard, 2002). In some cases, as has already been shown, there is a lack of affordable pharmaceuticals at the ex-

manufacturer level (such as second-line ARVs and treatments for neglected diseases). In the majority of cases, however, particularly when one considers those drugs on the WHO's Essential Drugs List, medicines are readily available and accessible if adequate sums of money are committed to their procurement. The average health spend per person per year in the United Kingdom is £1,400 (R21,366), in Sub-Saharan Africa it is just £5 (R76.50), the WHO recommended minimum is £17 (R259.87) (UK Department for International Development, 2008). In such an environment very few pharmaceuticals, whether they are discounted or donated, can get to patients.

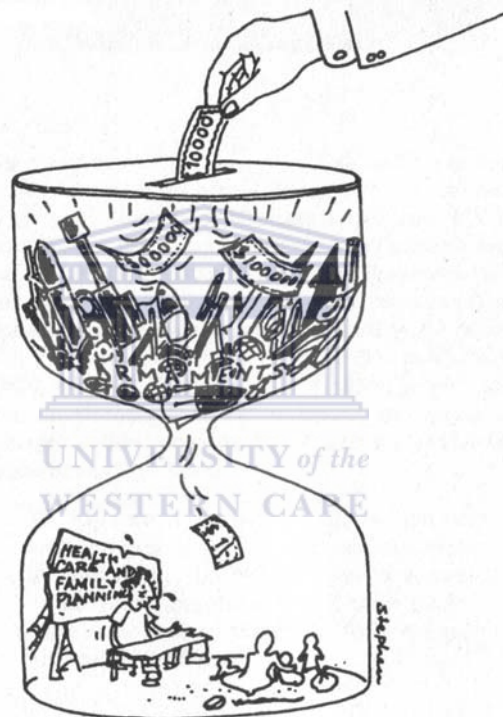


Figure 6.1 Cartoon representing the priorities of some African governments towards weapons rather than social services, including health (Werner et. al., 1997, p. 85)

African governments are frequently criticised for not allocating adequate resources to health. At the time of the 2001 court action the South African government came under fire from the Pharmaceutical Researchers and Manufacturers of America (PhRMA) and the United States government when it spent \$1.3 billion (R10 billion) on a submarine and fighter planes, yet only allocated \$3 million (R23 million) to AIDS treatment in the same year (Barber, 2001c). Western governments, however, should be cautious in their criticism. Africa spends almost \$15 billion (R116

billion) a year, four times what it spends on health and education, servicing the debts it owes to those states that are so quick to condemn them (Labonte et. al., 2005). Debt is part of the body politic. Macroeconomic processes, largely enforced by Western governments, are directly related to a government's capacity to provide pharmaceuticals for its citizens.

Unfortunately the meagre resources the average African government allocates to health are often lost through various leakages in the system. In Rwanda it is estimated that 27% of health spending is on administration costs (UK Department for International Development, 2008). Bureaucratic inefficiencies and dysfunctional institutions account for a considerable proportion of health care funds (Weissman, 2008). Such inefficiencies seriously limit the functioning of competent pharmaceutical procurement. In addition prices are inflated as the drug moves along the delivery system. By the time a medicine gets to a patient it often costs two to three times the ex-factory value (Health Action International, 2007).

Corruption and the theft of drugs from the production network is also a serious problem in many countries (Figure 6.2). A recent survey in Nigeria shows that twenty-eight public health centres received no drugs from the federal government over a two-year period. In 2007 the Director General of Nigeria's National Agency for Food and Drug Administration and Control disclosed that it was common for donated drugs to be stolen and resold in the open market. With incidents such as this in mind, the Global Fund to Fight AIDS, Tuberculosis and Malaria has considered suspending two grants to Nigeria totalling \$80 million (R616 million). The Fund has already terminated grants to Uganda and Chad due to mismanagement and corruption (Weissman, 2008). In Ghana a new breed of unregulated itinerant drug vendors has emerged as alternative health providers in the absence of other sources (Parry et. al., 2004). A thriving trade in black market medicines drives a 'pirate' drug industry selling counterfeit drugs which at best have no therapeutic benefits and at worst can be extremely harmful.

Furthermore, many African countries face a plethora of obstacles within their health care infrastructure. There are very few hospitals and clinics, and those that do exist may not have the necessary equipment, electricity or clean water. Communities are isolated as roads are of poor quality. There is a desperate lack of healthcare professionals, and those are concentrated in urban areas (Parry et. al., 2004; Sanders & Carver, 1985; Sanders & Chopra, 2003; Association of the British Pharmaceutical

Industry, 2007; Curtis, 2004; Ayodele, 2008).⁶⁰ As a consequence of so many diverse challenges, securing pharmaceutical security within Africa relies on more than just the benevolence of the pharmaceutical industry. Ensuring justice within medicine provision requires a concerted effort from all stakeholders within the global pharmaceutical political economy.

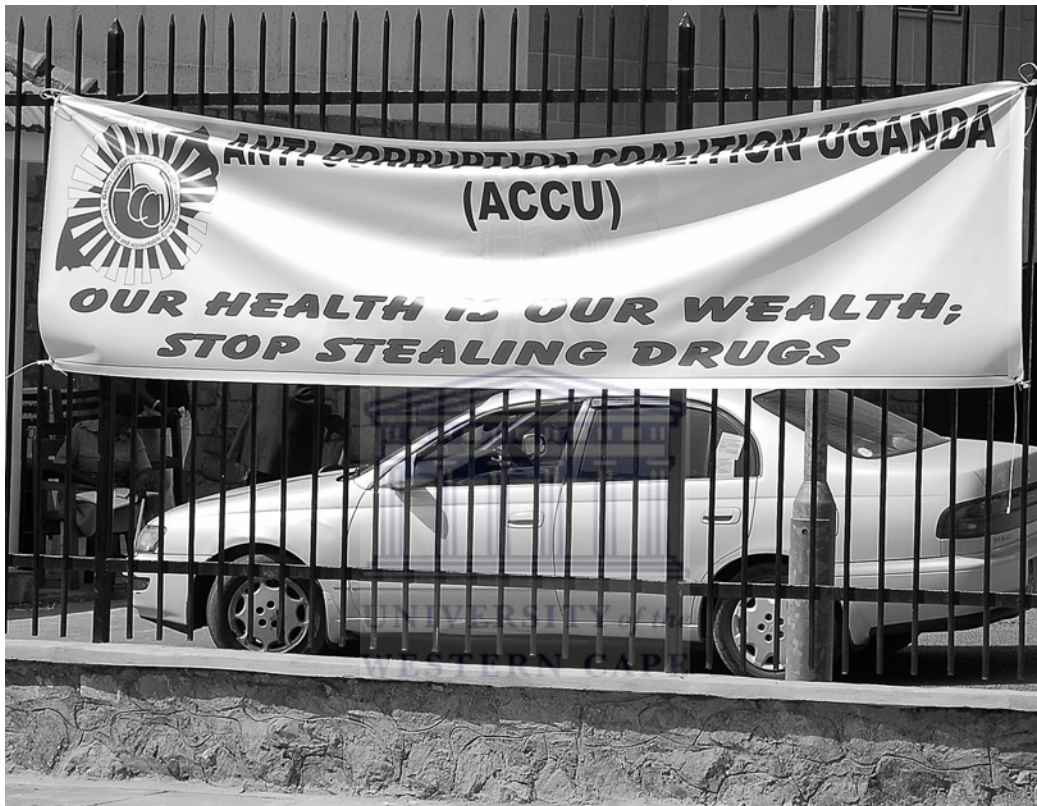


Figure 6.2 “Our Health is Our Wealth; Stop Stealing Drugs”. A sign produced by the Anti-Corruption Coalition of Uganda outside the Parliament building Kampala (Source: Author, November 2007).

The following section proposes three ‘solutions’ that could potentially enhance pharmaceutical security in Africa. The suggestions are certainly not exhaustive. Solving the problems of medicines access on the continent requires far greater investigation than this thesis can provide. The recommendations are based on the previous analyses of the pharmaceutical political economy, and as such operate at three different scales: the national, regional and global. Crucially, the three ‘solutions’ are self-supportive. It would be very difficult for one measure to fully function without the others, as such a coordinated approach is required.

⁶⁰ Worrall interview, June 2006 (detailed footnote p. 26).

Solution 1: Putting health higher on the African agenda

For many years African public health systems have been neglected. This neglect can be attributed to various factors, ranging from the imposition of Structural Adjustment Programmes to government mismanagement and investment in prestige projects. Thirty years ago the trend was highlighted of building ‘disease palaces’ (large hospitals) in urban centres. At the time the cost of financing one bed in the Parirenyatwa hospital in Harare, Zimbabwe, was equal to the cost of running a rural health centre. The capital involved in the construction of a new teaching hospital in Lusaka, Zambia, would have financed the building of 250 health centres, which could have catered for the entire population (Sanders & Carver, 1985). In recent years, however, focus has shifted towards effective healthcare spending, including sustainable pharmaceutical procurement. Sadly, in the case of access to medicines and health care in general, it has taken millions of deaths from AIDS before governments, as well as donors and the pharmaceutical industry, decided to take substantive action (Drahos & Braithwaite, 2002).

In April 2001, barely a month after the South African court case was settled, the African Union (AU) produced the Abuja Declaration in which it committed states to increasing their health care spending to 15% of their annual budgets. It also recognised that reversing the HIV/AIDS epidemic, tuberculosis and other infectious diseases should constitute the AU’s top priority for the first quarter of the century. The Declaration proclaims that AU member states “resolve to enact and utilize appropriate legislation and international trade regulations to ensure the availability of drugs” (African Union, 2001). This statement implies that countries are committed to use the flexibilities allowed for in TRIPS, such as compulsory licensing, parallel importing and generic substitution. Unfortunately, however, African countries have used few if any of these mechanisms. At the WTO General Council Meeting in May 2005, following the second extended deadline for a permanent amendment to the TRIPS Agreement being missed, the Swiss representative expressed his dismay that developing countries were haggling over the wording of a permanent amendment while the temporary system remained unused (McBeth, 2006).

Whilst the systems may not be perfect, there are still plenty of opportunities for a country of limited resources to use the TRIPS flexibilities to enhance pharmaceutical security. This is particularly true following the 2001 court action,

governments can be sure of support from a strong global activist movement, the WHO and WTO. It is also unlikely that the pharmaceutical industry would seek to challenge African governments if they introduced flexibilities, due to the minimal significance of the African market. It is in no one's interest for the public health measures in the TRIPS Agreement to lie dormant.

In 2007 the African Union Pharmaceutical Manufacturing Plan was produced. The plan argued for regional production of pharmaceuticals within Africa (African Union, 2007). There are however, a number of prerequisites for the development of a pharmaceutical manufacturing base. First, a country needs a chemical industry to provide the raw materials required for manufacturing medicines. Second, an efficient, corruption free and scientifically rigorous regulatory system must be established to ensure safety and efficacy of the pharmaceutical products. Third, a country needs technical experts with the appropriate qualifications and experience to go into large-scale manufacturing (African Union, 2007). The vast majority of African countries lack these requirements; realistically South Africa is the only nation that can maintain the required scale of pharmaceutical manufacturing.

Solution 2: South Africa as Africa's pharmacy?

South Africa certainly has the potential to become a centre of excellence for African pharmacology. India, Brazil and to a lesser extent Thailand cater to a global mass generic market. South Africa, however, can limit itself to niche therapeutic areas within a specific continental geography and epidemiology. Having a major producer of safe and affordable medicines on the continent most in need of pharmaceutical security would undoubtedly benefit African health.

South Africa is the regional superpower. The country accounts for almost 50% of the total economic output of Sub-Saharan Africa (Sanders & Chopra, 2006). As such it has the finance, technology and infrastructure to support both a generic and research based pharmaceutical industry that is tailored to the needs of Southern Africa. As indicated in the previous chapter, South Africa already possesses a robust pharmaceutical industry, consisting of both domestic and multinational firms.⁶¹ The

⁶¹ Adcock Ingram and Aspen Pharmacare, two South African companies, hold 25% of the South African pharmaceutical market (Ehrich interview, 5th May 2008, detailed footnote p. 37). Aspen

South African government first raised the idea of catering to its African neighbours' pharmaceutical needs in 1994 in the National Health Plan for South Africa and then again in 1996 in the National Drug Policy. It was not until the National Industrial Policy Framework of 2007 (see Chapter Five), that a comprehensive industrial policy was tabled.

Whilst such policy documents are encouraging, locating a regional production centre in South Africa has to make business sense. Neither domestic pharmaceutical companies nor multinational companies will commit to producing treatments for neglected diseases without a guaranteed market. Whilst there is undoubted need for the medicines, currently the demand is uncertain. African governments and donors have to commit to the purchase of pharmaceuticals before the South African industry responds.

A coordinated approach is necessary. There is currently no harmonization across Africa; a company has to register a product separately in each individual country. Additionally, each country has different intellectual property standards. As a consequence, even local manufacturers find the African pharmaceutical environment a challenge.⁶² Cooperation between AU members, the Southern African Development Community (SADC), industry associations, donors and NGOs is paramount. In this way the regulatory environment can be standardized and efficient distribution achieved. There are, however, regional geopolitical obstacles in the way of such a response to pharmaceutical insecurity. There have been ongoing attempts for nearly a decade to get regional regulatory harmonization. South Africa's dominance of the region has, however, caused problems. SADC nations are wary of South African hegemony.⁶³ They are concerned their sovereignty will be undermined and, although they rely on South Africa, they are nevertheless reluctant to enter any explicit legal commitment.

As South Africa cannot realistically issue a compulsory license for export under its current Patent Act, it must rely on multinational firms issuing voluntary

Pharmacare is the largest manufacturer of generic medicines in the Southern hemisphere. In July 2008, the firm announced a joint licensing agreement with GlaxoSmithKline, one of the most successful pharmaceutical multinationals. The agreement will allow Aspen to penetrate new markets, and greatly improve the company's product portfolio (Khanyile, 2008).

⁶² Ehrich interview, 5th May 2008 (detailed footnote p. 37).

⁶³ Gray interview, 17th June 2008 (detailed footnote p. 51).

licenses. The licenses must allow for export into Africa. In addition, multinational firms should be encouraged, through tax breaks and other incentives (provided by donors or the African community), to locate their research facilities in South Africa. The research arms of South African firms such as Aspen Pharmacare and Adcock Ingram should also be nurtured.

Such suggestions are based on the assumption that the manufacture and distribution of pharmaceuticals from South Africa is advantageous. Some people in the industry are not convinced about local manufacturing being the answer to issues of affordability. In a globalised world geographical distance is less of a barrier to distribution due to better transport and communications technology.

*You would think South Africa would be the logical source of supply in to Africa, but it's not except for the surrounding territories. The countries like Zimbabwe, Namibia, Swaziland will be supplied from South Africa. But for the rest, multinationals supply Africa from elsewhere in the world.*⁶⁴

The proximity of a manufacturing base to its market does not guarantee greater efficiency of distribution. India and China already have established chemical industries and significant pharmaceutical capacity. Distribution costs are insignificant in relation to the costs of building a new facility, importing active pharmaceutical ingredients and training staff.

Establishing South Africa as Africa's pharmacy has to make financial sense. The advantages of having an industry focused on African health problems could be considerable. The South African economy is sure to benefit from growth within the domestic pharmaceutical industry. South Africa must, however, compete against other nations within the international political economy in order to attract investment from the pharmaceutical industry. The donor community could play a central role in establishing a competitive industry on the continent.

⁶⁴ Ehrlich interview, 5th May 2008 (detailed footnote p. 37).

Solution 3: Donor funding

Donor funding for health has increased in recent years, predominantly due to recognition of the HIV/AIDS crisis, but African states require greater commitment from Western governments. Between 1990 and 2005, Development Assistance for Health increased globally from \$2.5 billion (R19.25 billion) to over \$13 billion (R100 billion). Overall, about 10% of Africa's healthcare expenditure is financed by donor aid (Weissman, 2008). Considering the challenges faced by African governments assistance will have to increase if any tangible improvements are to be registered.

African governments face a significant finance gap in their healthcare expenditure and this has been widened by the HIV/AIDS epidemic. This gap means that even if health budgets were radically expanded and all waste and corruption stopped, the majority of Africa's economies could never afford more than a minor percent of the cost of maintaining a fully functioning health service (Attaran & Gillespie-White, 2001; McBeth, 2006). The only way in which pharmaceutical security will be achieved in the region in the short to medium term is if donors account for the shortfall.

After being unveiled with great fanfare in 2003, the Global Fund to Fight AIDS, Tuberculosis and Malaria has received only token support from the majority of countries (Feuer, 2007). The United States has met only half of its pledge. Other nations including Spain, Japan and Germany, are falling behind in their contributions (The Global Fund, 2008). To put the commitment required in perspective: if Asian, European and North American countries redirected just 1% of the \$310 billion (R2,392 billion) they spend on agricultural subsidies this would almost double the foreign aid spent to control HIV/AIDS, malaria and tuberculosis (Attaran, 2004). One view is that donor inaction reveals a continuation of older representations of Africa as 'Other'. A significant body of development literature depicts the continent as devoid of sophistication, totally lacking in capacity to deliver treatment and too poor to consider technologically advanced and expensive treatments (Jones, 2005). This perspective posits that enhancing the availability, affordability and ultimately accessibility of medicines is futile as they will be wasted. Such a view has in the past been put forward by the pharmaceutical industry in defence of its pricing practices. It was an unfortunate irony, therefore, that by failing to respond to demands for ARVs

the South African government only succeeded in reinforcing western donor rationalisation (Jones, 2005).

Achieving pharmaceutical security is not an either/or situation. Capacity building and pharmaceutical delivery need to be enhanced in order to improve health. The development of infrastructure should not exclude processes seeking to make medicines affordable. A coordinated approach that takes a systems perspective is required. Such a system should consider both the global pharmaceutical political economy and factors within a nation state's healthcare apparatus. Without a holistic approach little progress can be made.

A sustainable global pharmaceutical delivery system

The issues surrounding pharmaceutical security are complex, often specific to a certain location and dynamic in their nature. The path towards achieving security can be no less dynamic. The drugs that work today will be ineffective tomorrow. Consequently the political, economic and legal conditions that facilitate the availability of medicines have to be redefined continuously (Shadlen, 2007). A sustainable and flexible global pharmaceutical system must be developed. Developing such a system is likely to be a lengthy process.

The path towards pharmaceutical security can be split into short-term, intermediate and long-term measures (Figure 6.3). In the short-term the flexibilities allowed for in TRIPS have to be used appropriately and effectively to ensure that patients get the most effective treatment available, whether it is subject to a patent or not. Such a strategy also requires a degree of reliance on the generosity of the multinational pharmaceutical industry. Voluntary licenses and tiered pricing policies can greatly enhance access. This is not, however, a sustainable strategy:

No commercial company can act as a charity without running the risk that it would soon have no more than good intentions to offer either its customers or its owners
(Taylor, 2001, p. 630).

Corporations who are willing to sacrifice profits are at a competitive disadvantage in the current business climate. Appealing to a corporation’s social responsibility “may be whistling in the capitalist wind” (Daniels, 2001, p. 41). In the intermediate and long term, therefore, a more comprehensive and robust pharmaceutical network needs to be developed.

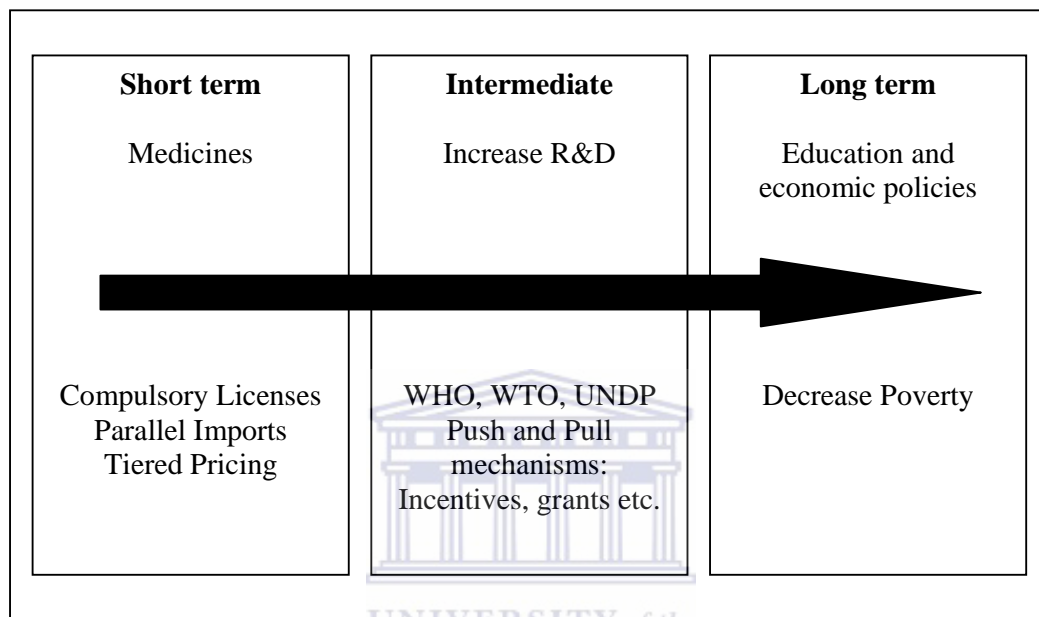


Figure 6.3 A path towards pharmaceutical security, (Source: adapted from Barnard, 2002)

In recent years promising signals have emerged that a public health approach to access to medicines is being recognised rather than a purely trade based strategy.⁶⁵ Needs-driven research and development has been recognised by the WHO and its partner organisations as the most effective way of achieving pharmaceutical security (WHO Intergovernmental Working Group, 2008). In May 2008 the World Health Assembly adopted a global strategy aimed at filling the research gap for neglected diseases. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property has been hailed widely as the most significant step forward in the quest for global pharmaceutical security since the Doha Declaration of 2001. The strategy commits the WHO and its member states to develop incentive schemes

⁶⁵ Sixty minute telephone interview with Mrs M. Childs, Head of European Affairs, The Consumer Project on Technology. August 2006. Transcription checked by interviewee and retained by author. For more information see Appendix B.

for R&D, improve R&D capacity in developing countries, and secure sustainable financing for R&D in developing countries, as well as a number of other mechanisms (WHO Intergovernmental Working Group, 2008). The strategy recognises the importance of national or regional pharmaceutical manufacturing capabilities, whilst acknowledging that without enhanced assistance from the international community it will be very difficult for regions to make the necessary investment to upgrade their capabilities.

In the long-term, medicines provision needs to be incorporated into a wider development agenda. Fundamental to the whole medicines delivery system debate is whether the injustice lies in the price of medicines or in the enormous income inequalities that make medicines unaffordable (Brock, 2001). As has been noted previously the absence of pharmaceutical security in Africa is inseparable from the geopolitical processes and economic forces that shape the current world order. Joseph Stiglitz, a Nobel Laureate in Economics, believes that a fundamental change of attitude is necessary, in which fairness and justice form the basis of relations between the developed and developing world (Lanoszka, 2003). The most efficient and sustainable way to establish pharmaceutical security in the African region is to address the root causes of the pharmaceutical famine. These root causes lie in the inability of a government to provide for its citizens due to poverty. The issuing of compulsory licenses and the donation of medicines are only temporary remedies. Encouraging pharmaceutical self-sufficiency and purchasing power in the region is the only enduring answer to achieving comprehensive medicines delivery.

Conclusion

The Medicines and Related Substances Control Amendment Act, and the 2001 court case that it sparked, had little direct impact on enhancing access to medicines in South Africa. The Act did not deliver a more progressive intellectual property regime as many activists and media commentators believed. If the use of compulsory licenses were ever the intention of the South African government, by 2001 it was no longer on its agenda. Whereas some measures, such as generic substitution, have enhanced the availability of affordable medicines, the Act and the excitement that surrounded the court case has not led to significant changes in the South African pharmaceutical environment.

The court case, however, had less tangible consequences. The legacy is predominantly symbolic. The 2001 court proceedings provided a moment to focus a global campaign, and a 'victory' for the activist community. The case proved to be a public relations disaster for the pharmaceutical industry and the Western governments that stood behind them. The intimidation that characterised the pharmaceutical geopolitical economy was challenged. Pharmaceutical security issues moved from the liberal fringe to high politics, whilst being firmly placed in the media spotlight.

The 'victory' bolstered the global medicines access campaign at a crucial time. The court case coincided with an increasing international awareness of the significance of the HIV/AIDS epidemic, at the same time as effective treatments were being developed. The South African struggle provided a platform for a powerful coalition to develop between HIV/AIDS activists and those striving to achieve pharmaceutical security. Their causes became inseparable. As such the court case became centred on the denial of HIV/AIDS treatment at exactly the time when global opinion was most receptive to these issues.

An explicit link was made between the court case and the death of those infected with HIV/AIDS. Multinational pharmaceutical companies, along with their Western backers, were (and in many cases continue to be) accused of murder. For the activist community it is always easier to generate support if there is a clearly identifiable villain. A campaign needs a focus and multinational firms provide a very public target in a world in which NGOs have carefully constructed an anti-corporate discourse. It is impossible to excuse some of the heavy handed and cynical

machinations of the industry, many of which have been outlined in this study. Yet, there must be recognition that without the multinational pharmaceutical industry the arguments for medicines security would be null and void, as there would be few to secure. Corporations should certainly be held accountable, and due to the nature of the product it produces, the pharmaceutical industry holds peculiar responsibilities. Indiscriminate condemnation of the industry, however, is potentially counter-productive. The only realistic way to enhance pharmaceutical security is to work with and encourage rather than bite the hand that feeds the global medicines delivery system.

The research has shown how complex and multifaceted the obstacles are to achieving pharmaceutical security. The international political economy approach has proven an effective framework for analysing the intricacies of the global medicines delivery system. By recognising multiple components, pharmaceutical security has been placed in the context of broader issues of health service development. Medical Geography with its concerns for health, welfare and equitable distribution of resources is an ideal vehicle through which to scrutinise the global pharmaceutical political economy. The need for recognition of the geopolitical dynamics of power means that there is potential for Medical Geopolitics to emerge as a significant contributor to the formation of medicines policy.

Adopting a geographical approach in the research has allowed the South African struggle for pharmaceutical equity to be placed within a global context. South Africa's attempts to achieve pharmaceutical security have been subject to global economic and political pressures. South Africa, however, has not been a passive agent within the medicines delivery system. The 2001 court case fed into the dynamics of change that have characterised the global pharmaceutical environment in the last decade. Many of the flows of power and influence that operated across various scales during and following the court action may not have been appreciated had the international political economy framework not been used.

It is all well and good talking about justice, morality and equity, but how can these aspirations be achieved? It is easy to identify injustice and then point fingers. It is a far more difficult exercise to find workable solutions to these problems. There needs to be a move towards pragmatic liberalism. Multinational pharmaceutical companies are here to stay, and are currently the only significant developer of safe, effective and innovative medicines. Activist groups, however, gain more publicity

attacking pharmaceutical companies than by advocating better incentive systems for private developers. Liberal elements often automatically dismiss anything to do with profits, the market or big business when considering public goods. It is an almost impossible task to wade against the flow of the free market. Consequently the market must be used to work for the poor. A middle path must be adopted, based less on ideology but on substance - the processes required to achieve pharmaceutical security.

The key lies in moderating the excesses of the system. Eliminating the drive for excessive profits in the developing world and establishing a system based on therapeutic need can achieve pharmaceutical security. Profits and equity should not be mutually exclusive. It should, however, be realised that firms must make a return on their investment. Doing well (in terms of profits) is a precondition to doing good.

Governments and donors have to commit suitable resources to health. The agonising and irresponsibly slow response of the South African government to HIV/AIDS is unacceptable. Its obtuse attitude towards policies that are almost universally acknowledged has been baffling, standing as an unforgivable blemish on the post-liberation government's record. All stakeholders need to take responsibility for and make a significant commitment to achieving pharmaceutical security.

A consensus must be reached that avoids the dichotomies that have thus far characterised the debate over access to medicines. There are very positive signs emanating from the WTO's Intergovernmental Working Group that consensus is moving towards a need to align the interests of innovators (profits) with the interests of society (new and affordable products). A number of inventive market based mechanisms have been proposed that would stimulate research into neglected diseases as well as encouraging increased affordability of existing products. Philanthropic organisations, such as the Bill and Melinda Gates and the Clinton Foundations, as well as the British government, have committed significant funds to Advanced Market Commitments in an attempt to stimulate innovation by ensuring a profitable return for pharmaceutical firms.⁶⁶ In 2006, the governments of France, Brazil, Chile, Norway and the United Kingdom created Unitaid, an international medicines purchasing scheme, which aims to provide a sustainable and predictable funding mechanism for

⁶⁶ Advanced Market Commitments occur when a donor or government declares that if a pharmaceutical firm develops a medicine for a specific illness it will purchase a fixed volume of the treatment for an agreed price. Such a fixed commitment guarantees a market for a previously neglected disease and thus stimulates research.

international pharmaceutical procurement. Unitaid is partly funded by taxes on airline tickets, and has already made considerable progress.

What is certain is that the existing pharmaceutical production network does not fulfil the needs of Africa and other developing regions. The burden of change cannot and should not be carried by private industry alone. The state must take primary responsibility for the health of its citizens. Lack of commitment to health, particularly in Africa, is a failure of government. The most efficient and realistic way to improve equity is to catalyse and manage demand for pharmaceuticals. This can be done through combining political will at a domestic level with greater international commitment. If a profitable market is established for treatments for diseases of the poor, then the industry is sure to respond. Relying on the good will of private industry and asking industrialists and shareholders to forgo profits is not a realistic proposition. The only option is a proactive solution in which all stakeholders realise their responsibilities towards the health of the global poor, and establish definite commitments to the purchase and development of treatments.

Any system that deals with social goods pertaining to the health of individuals must hold certain ethical considerations at its core. By definition the delivery of potentially life saving medicines cannot operate in a climate that does not consider justice and welfare as its ultimate objective. Pharmaceutical insecurity is a moral, political and economic failure. The belief that morals have no place in business must be discarded for the purposes of medicines delivery. A moral political economy that adopts a middle path between liberal absolutes of equity and freedom and the capitalist dogma of market power is the only way to achieve pharmaceutical security. Thankfully, in recent years there have been significant moves down this path, however there is still a long way to go. Whilst resolutions are being drawn up and declarations published, there are still millions of people waiting for medicines across the globe. The world has the resources; it must show that it has the will to provide a sustainable supply of medicines to all who need them. The benefits are sure to outweigh the sacrifices required to achieve pharmaceutical security.

Appendix A

Note on Methodology

Eight interviews were conducted over two separate periods, the first phase during June and July of 2006 in the United Kingdom and the second from April to July 2008 in South Africa. The interviews were conducted either face-to-face or by telephone and followed a semi-structured format. The chosen format allowed for an in-depth conversation that was a dialogue rather than an interrogation. The intensive nature of the interviews allowed for the identification of processes, activities and relationships.⁶⁷

Those interviewed were selected for their proximity to the issues and unrivalled knowledge of the pharmaceutical delivery system. By talking to informed stakeholders a vivid and textured account of the issues surrounding pharmaceutical security was acquired, allowing for unexpected details to be unearthed.

All the interviews were, with the consent of the interviewees, digitally recorded. With the permission of the interviewees the recordings were then immediately transcribed verbatim and the transcriptions sent to the interview subjects for verification. Following this the transcripts were thematically coded and the results integrated into the secondary research (literature) findings. Where individuals have been cited or directly quoted in the final paper, the relevant sections were highlighted by the author and sent for further verification from the interviewee.

The process of double verification is consistent with ethical research requirements. It was important to ensure that the interviewees were not misinterpreted or misrepresented. By asking the informants themselves to check the context within which they were cited, the author could not be accused of selectively picking material to fit a particular argument, thus preserving the integrity of the research.

⁶⁷ For a fuller account of the advantages of qualitative methods (such as semi-structured interviews) see Baxter & Eyles (1997), Johnston et. al. (2000), Flowerdew & Martin (2005).

Appendix B

List of Interviewees

Name	Position & Organisation	Date & Place	Length
Mrs V Beaumont	Executive Director, Innovative Medicines South Africa. (Pretoria)	May 2008, telephone interview,	45 minutes
Mr J Berger	Head of Policy, Research & Communications, the AIDS Law Project, (Johannesburg)	May 2008, telephone interview,	40 minutes
Mrs M Childs	Head of European Affairs, The Consumer Project on Technology (London, UK)	August 2006, telephone interview	60 minutes
Ms V Ehrich	Chief Operating Officer, Pharmaceutical Industry Association of South Africa. (Pretoria)	May 2008, telephone interview	40 minutes
Mr A Gray	Senior Lecturer, Dept. of Therapeutics & Medicines Management, University of KwaZulu-Natal. (Durban)	June 2008, telephone interview	35 minutes
Dr M Kamal-Yanni	Health Policy Advisor, Oxfam International (Oxford, UK)	June 2006, Oxford, UK.	50 minutes
Mr C Major	Head of Public Affairs, AstraZeneca Plc. (London, UK)	July 2006, London, UK.	90 minutes
Mr M Worall	Public Affairs Executive, Association of the British Pharmaceutical Industry. (London, UK)	June 2006, London, UK	60 minutes

Bibliography

- Abbott, F., & Reichman, J. (2007). The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law*, 10(4), 921-987.
- Achmat, Z. (2004). The Treatment Action Campaign, HIV/AIDS and the government. *Transformation*, 54, 76-84.
- African National Congress. (1994). *A national health plan for South Africa*. Retrieved 4/6, 2008, from http://www.imsa.org.za/health_policy.htm
- African Union. (2001). *Abuja Declaration on HIV/AIDS, tuberculosis and other infectious diseases*. Retrieved 04/17, 2008, from <http://www.uneca.org/ADF2000/Abuja%20Declaration.htm>
- African Union. (2007). *African Union pharmaceutical manufacturing plan*. Retrieved 03/18, 2008, from http://www.doh.gov.za/camh3/docs/african_union_pharmaceutical_%20manufacturing_plan.pdf
- Aginam, O. (2007). Diplomatic rhetoric or rhetorical diplomacy: The G8 and global health governance. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*. Aldershot: Ashgate, (p. 147-155)
- Agnew, J., & Corbridge, S. (1995). *Mastering space: Hegemony, territory and international political economy*. London: Routledge.
- Association of the British Pharmaceutical Industry. (2007). *Global health and the pharmaceutical industry*. London: ABPI.
- Attaran, A. (2004). How do patents and economic policies affect access to essential medicines in developing countries? *Health Affairs*, 23(3), 155-166.
- Attaran, A., & Gillespie-White, L. (2001). Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? *Journal of the American Medical Association*, 286(15), 1886-1892.
- Ayodele, T. (2008). Africa's failing infrastructure render compulsory licensing pointless. *The New Times* (Kigali), 28th April.
- Bakan, J. (2004) *The corporation: the pathological pursuit of profit and power*. London: Constable
- Balaam, D., & Veseth, M. (Eds.). (2001). *Introduction to international political economy*. New Jersey: Prentice Hall.
- Bale, H. (1998). The conflict between parallel trade and product access and innovation: The case of pharmaceuticals. *Journal of International Economic Law*, 1, 637-654.
- Baleta, A. (2001). Drug firms lose patent rights lawsuit against South Africa's government. *The Lancet*, 357(9265), 1347.
- Barber, S. (2001a). If government wants to procure low-cost antiretroviral drugs for the millions of HIV positive South Africans who cannot afford treatment, it does not need the Pretoria high court to uphold section 15C of the 1997 Medicines and Related Substances Control Act. *Business Day*. Retrieved 04/14, 2008, from <http://www.businessday.co.za/Articles/TarkArticle.aspx?ID=270422>
- Barber, S. (2001b). Settlement of the pharmaceutical patents case last week simultaneously changed nothing and everything. *Business Day*. Retrieved 04/14, 2008, from <http://www.businessday.co.za/Articles/TarkArticle.aspx?ID=353663>

- Barber, S. (2001c). Court case: Pharmaceutical industry attempts to overturn 1997 law to make drugs more accessible. *Business Day*. Retrieved 4/14, 2008, from <http://www.businessday.co.za/Articles/TarkArticle.aspx?ID=261767>
- Barder, O., Kremer, M., & Levine, R. (2005). *Making markets for vaccines: Ideas to action*. Washington: Centre for Global Development
- Barnard, D. (2002). In the high court of South Africa, case no. 4138/98: The global politics of access to low-cost AIDS drugs in poor countries. *Kennedy Institute of Ethics Journal*, 12(2), 159-174.
- Basheer, S. (2007). *India's tryst with intellectual property: Towards a "middle path"?* Retrieved 05/10, 2008, from <http://spicyipindia.blogspot.com/2007/08/indias-tryst-with-intellectual-property.html>
- Bathelt, H., Malmberg, A., & Mashell, P. (2004). Clusters and knowledge: Local buzz, global pipelines and the process of knowledge creation. *Progress in Human Geography*, 28(1), 31-56.
- Baxter, J., & Eyles, J. (1997). Evaluating qualitative research in social geography: Establishing 'Rigour' in interview analysis. *Transactions of the Institute of British Geographers*, 22(4), 505-555.
- Beresford, B. (2001a). AIDS suit; state's reply. *Mail and Guardian*, p. 15, 14th September.
- Beresford, B. (2001b). State stands firm on anti-retrovirals. *Mail and Guardian*, p. 10, 8th June.
- Birch, K. (2007). Knowledge, space and biotechnology. *Geography Compass*, 1(5), 1097-1117.
- Blomley, N., Delaney, D., & Ford, R. (2001). Preface: Where is the law? In N. Blomley, D. Delaney & R. Ford (Eds.), *The legal geographies reader*, Oxford: Blackwell Publishers. (p. xiii-xxii).
- Bloom, G., & McIntyre, D. (1998). Towards equity in health in an unequal society. *Social Science & Medicine*, 47(10), 1529-1538.
- Bond, P. (1999). Globalisation, pharmaceutical pricing and South African health policy: Managing confrontation with U.S. firms and politicians. *International Journal of Health Services*, 29(4), 765-792.
- Bourgeois, J. H. J., & Burns, T. J. (2002). Implementing paragraph 6 of the Doha declaration on trips and public health. the waiver solution. *The Journal of World Intellectual Property*, 5(6), 835-864.
- Bradford, C. (2007). Reaching the millennium development goals. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*. Aldershot: Ashgate. (p. 79-85).
- Brint, S. (2001). Professionals and the 'Knowledge economy': Rethinking the theory of post-industrial society. *Current Sociology*, 49(4), 101-132.
- Brock, D. W. (2001). Some questions about the moral responsibilities of drug companies in developing countries. *Developing World Bioethics*, 1(1), 33-37.
- Brown, T., & Duncan, C. (2002). Placing geographies of public health. *Area*, 34(4), 361-369.
- Cahoy, D. (2008). Confronting myths and myopia on the road for Doha. *Georgia Law Review*, 42
- Cerny, P. (2000). Globalisation and the changing logic of collective action. In J. Frieden, & D. Lake (Eds.), *International political economy: Perspectives on global power and wealth* (Fourth ed.), London: Routledge. (p. 446-460)
- Chaves, G. (2007). Case study on the use of TRIPS flexibilities in Brazil. Global Forum on Health Research Conference, Beijing. Retrieved 03/19, 2008, from http://www.utoronto.ca/cphs/China%20Conference/Chaves%20Presentation_Study%20on%20the%20Use%20of%20TRIPS%20Flexibilities%20in%20Brazil.pdf

- Chiaroni, D., & Chiesa, V. (2005). Forms of creation of industrial clusters in biotechnology. *Technovation*, 26, 1064-1076.
- Chien, C. (2003). Cheap drugs at what price to innovation: Does the compulsory licensing of pharmaceuticals hurt innovation? *Berkeley Technology Law Journal*, 18, 853-907.
- Chirac, P. (2003). Debate that "this house believes the essential drug concept hinders the effective deployment of drugs in developing countries: translating the essential concept into the context of the year 2000.". *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 97, 10-12.
- Chirac, P., & Torrelee, E. (2006). Global framework on essential health R&D. *The Lancet*, 367(9522), 1560.
- Cleary, S. (2001). *The South African government, the pharmaceutical companies and access to HIV/AIDS drugs*. Unpublished MA (Economics), University of Cape Town, Cape Town, South Africa.
- Coenen, L., Moodysson, J., & Asheim, B. (2004). Nodes, networks, and proximities: On the knowledge dynamics of the Medicon Valley biotech cluster. *European Planning Studies*, 12(7), 1003-1018.
- Cohen, J., Illingworth, P., & Schuklenk, U. (Eds.). (2006). *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing*. London: Pluto Press.
- Commission on Intellectual Property Rights. (2002). *Integrating intellectual property rights and development policy, report of the commission on intellectual property*. London: CIPR.
- Constitutional Court of South Africa (2000) *Pharmaceutical Manufacturers Association of South Africa and another: In Re Ex Parte President of the Republic of South Africa and Others*. SA 674(CC) 674 2000 (2)).
- Cooke, P. (2006). Global bioregions: Knowledge domains, capabilities and innovation system networks. *Industry and Innovation*, 13(4), 437-458.
- Cooper, A., Kirton, J., & Schrecker, T. (2007a). Governing global health in the twenty-first century. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*, Aldershot: Ashgate. (p. 3-12).
- Cooper, A., Kirton, J., & Schrecker, T. (2007b). Toward innovation in global health governance. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*, Aldershot: Ashgate. (p. 229-239).
- Coriat, B., Orsland, F., & Weinstein, O. (2003). Does biotech reflect a new science-based innovation regime? *Industry and Innovation*, 10(3), 231.
- Correa, C. (2001). The TRIPS agreement: How much room for manoeuvre? *Journal of Human Development*, 2(1), 79-107.
- Correa, C. (2007). *Trade related aspects of intellectual property rights: A commentary on the TRIPS agreement*. Oxford: Oxford University Press.
- COSATU. (2001). *COSATU slams government for undermining drugs victory*. Retrieved 03/11, 2008, from <http://www.cosatu.org.za/news/weekly/20010629.htm>
- Curtis, S. (2004). *Health and inequality: Geographical perspectives*. London: SAGE.
- Dalby, S. (1998). Geopolitics, knowledge and power at the end of the century. In G. O'Tuathail, S. Dalby & P. Routledge (Eds.), *The geopolitics reader*, London: Routledge. (p. 303-312).
- Daniels, N. (2001). Social responsibility and global pharmaceutical companies. *Developing World Bioethics*, 1(1), 38-41.

- Deloitte Consulting. (2007). *The economic and socio-economic benefits of R&D-based multinational pharmaceuticals on the South African economy*. Retrieved 5/4, 2008, from http://www.imsa.org.za/library_1.html
- Dentico, N., & Ford, N. (2005). The courage to change the rules: A proposal for an essential health R&D treaty. *PloS Medicine*, 2(2), 96-99.
- Dicken, P. (2002). 'Placing' firms – 'Firming' places: Grounding the debate on the 'global' corporation. Paper presented at the Conference on 'Responding to Globalization: Societies, Groups, and Individuals.' University of Colorado, Boulder, April 2002. Retrieved, 05/24, 2008, from <http://www.colorado.edu/ibs/pec/gadconf/papers/dicken.pdf>
- Dicken, P. (2003). *Global shift: Reshaping the global economic map in the 21st century*. (4th ed.). London: SAGE.
- Dickson, D. (2007). *Now is the time for international action on patents*. Retrieved 05/11, 2008, from <http://www.scidev.net/en/editorials/now-is-the-time-for-international-action-on-patent.html>
- DiMasi, J., & Grabowski, H. (2004). *Patents and R&D incentives: Comments on the Hubbard and Love trade framework for financing pharmaceutical R&D*. Geneva: WHO.
- DiMasi, J., Hansen, R., & Grabowski, H. (2003). The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 22, 151-185.
- Dodds, K., & Atkinson, D. (2000). *Geopolitical traditions: A century of geopolitical thought*. London: Routledge.
- Dodgson, R., Lee, K., & Drager, N. (2002). *Global health governance: a conceptual review*. Geneva: World Health Organization and the London School of Hygiene and Tropical Medicine.
- Drager, N., & Fidler, D. (2007). Foreign policy, trade and health: At the cutting edge of global health diplomacy. *Bulletin of the World Health Organization*, 85(3), 162.
- Drager, N., & Sunderland, L. (2007). Public health in a globalising world: The perspective from the world health organization. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*, Aldershot: Ashgate. (p. 67-78).
- Drahos, P., & Braithwaite, J. (2002). *Information feudalism: Who owns the knowledge economy?* London: Earthscan.
- Drèze, J., & Sen, A. (1989). *Hunger and public action*. Oxford: Clarendon.
- Dumnett, H. (2002). *An overview of supply and demand in South Africa's pharmaceutical industry - opportunity or risk?* Washington DC: World Market Research Centre.
- Eagleton, D. (2006). *Under the influence: exposing undue corporate influence over policy-making at the world trade organization*. Retrieved 11/08, 2006, from http://www.actionaid.org.uk/doc_lib/174_6_under_the_influence_final.pdf
- Elliot, R. (2006). Medicines for all? commitment and compromise in the fight for Canada's law on compulsory licensing for export. In J. Cohen, P. Illingworth & U. Schuklenk (Eds.), *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing*, London: Pluto. (p.227-238).
- Epstein, R. (2006). *Overdose: How excessive government regulation stifles pharmaceutical innovation*. New Haven: Yale University Press.
- Ernst, D., & Kim, L. (2002). Global production networks, knowledge diffusion, and local capability formation. *Research Policy*, 31, 1417-1429.

- Eyles, J., & Woods, K. (1983). *The social geography of medicine and health*. Andover: Croom Helm.
- Feuer, C. (2007). *Tuberculosis research and development: A critical analysis of funding trends, 2005-2006*. Retrieved 04/10, 2008, from www.stoptb.org/researchmovement/assets/documents/tbradd2.pdf
- Flowerdew, R., & Martin, D. (Eds.). (2005). *Methods in human geography*. Harlow: Pearson Education Ltd.
- Ford, N. (2006). The enduring crisis in neglected diseases. In J. Cohen, P. Illingworth & U. Schuklenk (Eds.), *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing*. London: Pluto. (p. 109-116).
- Foreman, M. (2002). *Patents, pills and public health: Can TRIPS deliver?* Retrieved 3/8, 2008, from http://www.panos.org.uk/PDF/reports/TRIPS_low_res.pdf
- Forman, L. (2007). Trade rules, intellectual property, and the right to health. *Ethics and International Affairs*, 21(3), 337-357.
- Frieden, J., & Lake, D. (Eds.). (2000). *International political economy: Perspectives on global power and wealth* (Fourth ed.). London: Routledge.
- Friedman, S., & Mottiar, S. (2004). *A moral to the tale: The Treatment Action Campaign and the politics of HIV/AIDS*. Durban: Centre for Civil Society.
- Gandhi, U. (2008). *Supplying generic AIDS drugs called pricey process*. Retrieved 05/11, 2008, from http://www.theglobeandmail.com/servlet/Page/document/v5/content/subscribe?user_URL=http://www.theglobeandmail.com%2Fservlet%2Fstory%2FRTGAM.20080508.wdrugs08%2FBNStory%2FspecialScienceandHealth%2Fhome&ord=51136065&brand=theglobeandmail&force_login=true
- Gatrell, A. (2002). *Geographies of health*. Oxford: Blackwell.
- Gereffi, G., & Korzeniewicz, M. (Eds.). (1994). *Commodity chains and global capitalism*. Westport: Praeger.
- Gertler, M., & Levite, Y. (2005). Local nodes in global networks: The geography of knowledge flows in biotechnology innovation. *Industry and Innovation*, 12(4), 487-507.
- Gesler, W., Bird, S., & Olieski, S. (1997). Disease ecology and a reformist alternative: The case of infant mortality. *Social Science & Medicine*, 44(5), 657-671.
- Goddard, C., Passe-Smith, J., & Conklin, J. (Eds.). (1996). *International political economy: State-market relations in the changing global order*. London: Lynne Rienner.
- Grabowski, H. (2002). Patents, innovation and access to new pharmaceuticals. *Journal of International Economic Law*, 849-860.
- Grabowski, H. (2004). Increasing R&D incentives for neglected diseases: Lessons from the orphan drug act. In K. Maskus, & J. Reichman (Eds.), *Intellectual public goods, and transfer of technology under a globalised intellectual property regime*. Cambridge: Cambridge University Press. (p. 93-115)
- Grace, C. (2004). *The effect of changing intellectual property on pharmaceutical industry prospects in India and China: Considerations for access to medicines*. Retrieved 04/28, 2008, from <http://www.dfid.gov.uk/pubs/files/indiachinadomproduce.pdf>
- Gray, A., Matsebula, T., Blaauw, D., Schneider, H., & Gilson, L. (2002). *Policy change in a context of transition: Drug pricing in South Africa 1989-1999*. Johannesburg: Centre for Health Policy, University of Witwatersrand.

- Grimwood, A., Almeleh, C., Hausler, H., & Hassan, F. (2006). HIV & tuberculosis treatment update. In P. Ijumba, & A. Padareth (Eds.), *South African health review 2006*. Durban: Health Systems Trust. (p. 77-94).
- Guzzini, S. (1998). *Realism in international relations and international political economy*. London: Routledge.
- Haffejee, F. (2003). *Universal antiretroviral drugs for HIV: What are the obstacles to its implementation in South Africa?* Unpublished Masters in Public Health, University of Western Cape, Cape Town.
- Hanefield, J. (2002). Patent rights vs. patient rights: intellectual property, pharmaceutical companies and access for treatment for people living with HIV/AIDS in Sub-Saharan Africa. *Feminist Review*, 72, 84-92.
- Hassan, F. (2005). 'Let them eat cake' - A short assessment of provision of treatment and care 18 months after the adoption of the operational plan. Retrieved 05/01, 2008, from <http://tac.org.za/Documents/ALP-TAC%202nd%20updated%20report%20on%20ARV%20plan%20June%202005.doc>
- Hassim, A., Heywood, M., & Berger, J. (Eds.). (2007). *Health and democracy: a guide to human rights, health law and policy in post-apartheid South Africa*. Cape Town: SiberInk.
- Health Action International. (2007). *Medicines prices in Africa*. Retrieved 4/9, 2008, from http://www.haiweb.org/medicineprices/pdf/Africa-synthesis-report-FINAL_10-September-2007.pdf
- Heller, M., & Eisenberg, R. (1998). Can patents deter innovation? The anticommons in biomedical research. *Science*, 280(5364), 698-701.
- Hogerzeil, H. (2006). Essential medicines and human rights: What can they learn from each other? *Bulletin of the World Health Organization*, 84(5), 371-375.
- Hunt, P. (2007). *Human rights guidelines for pharmaceutical companies in relation to access to medicines, draft consultation*. Retrieved 3/11, 2008, from http://www.essex.ac.uk/human_rights_centre/rth/docs/PH%20draft%20guidelines%2019%20Sept%202007.doc
- Idris, K., & Arai, H. (2006). *The intellectual property-conscious nation: Mapping the path from developing to developed*. Geneva: World Intellectual Property Organization.
- IFPMA. (2007). *Partnerships to build healthier societies in the developing world*. Retrieved 05/11, 2008, from <http://212.3.246.100/Objects/2/Files/IFPMAbrochure2007.pdf>
- Innovative Medicines South Africa. (2005). *Submission by innovative medicines SA on compulsory licenses in national emergencies to the South African department of trade and industry*. Retrieved 4/5, 2008, from http://www.imsa.org.za/library_1.html
- International Federation of Red Cross and Red Crescent Societies. (2008). *World disasters report: Focus on HIV and AIDS*. Vernier, Switzerland: ATAR Roto.
- Johnston, R. (1983). *Philosophy and human geography: An introduction to contemporary approaches*. London: Edward Arnold.
- Johnston, R. J., Gregory, D., Pratt, G., & Watts, M. J. (Eds.). (2000). *The dictionary of Human Geography* (4th ed.). Oxford: Blackwell Publishing.
- Johnston, R. J., Taylor, P. J., & Watts, M. J. (2002). *Geographies of global change: remapping the world*. Oxford: Blackwell Publishing.

- Jones, K., & Moon, G. (1987). *Health, disease and society: An introduction to medical geography*. London: Routledge and Kegan Paul.
- Jones, P. S. (2005). "A test of governance": rights-based struggles and the politics of HIV/AIDS policy in South Africa. *Political Geography*, 24(4), 419-447.
- Joseph, S. (2003). Pharmaceutical corporations and access to drugs: the "fourth wave" of corporate human rights scrutiny. *Human Rights Quarterly*, 25(2), 425-452.
- Kahn, T. (2003). Health minister paves way for cheaper medicines in SA. *Business Day*. 19th August.
- Khanyile, S (2008) Aspen to piggyback to GlaxoSmithKline markets. *Business Report*. 24th July.
- Kickbusch, I. (2003). Global health governance: Some theoretical considerations on the new political space. In K. Lee (Ed.), *Health impacts of globalisation: Towards global governance*. Basingstoke: Palgrave Macmillan. (p. 192-203).
- Koski, E. (2005). Renegotiating the grand bargain: Balancing prices, profits, people and principles. In M. Santoro, & T. Gorrie (Eds.), *Ethics and the pharmaceutical industry*. Cambridge: Cambridge University Press. (p. 393-404).
- Kremer, M., & Glennester, R. (2004). *Strong medicine: creating incentives for pharmaceutical research on neglected diseases*. Princeton: Princeton University Press.
- Labonte, R., Schrecker, T. & Sanders, D. (2005). *Who really cares about African health?: Post-Glennegles, the question remains*. Retrieved 3/16, 2008, from <http://acas.prairienet.org/bulletin/bull71-04-labonte.html>
- Lanoszka, A. (2003). The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *International Political Science Review*, 24(2), 181-197.
- Leach, B., Paluzzi, J. & Munderi, P. (2005). *Prescription for healthy development: increasing access to medicines*. Retrieved 04/11, 2008, from www.unmillenniumproject.org/reports/tf_essentialmedecines.htm
- Lee, K., & Zwi, A. (2003). A global political economy approach to AIDS: Ideology, interests and implications. In K. Lee (Ed.), *Health impacts of globalisation: Towards global governance*. Basingstoke: Palgrave Macmillan. (p. 13-32).
- Lee, M. (2007). *Putting health on the fast track: compliance with the Doha Declaration on public health as a principal negotiating objective for trade promotion authority*. Retrieved 4/9, 2008, from www.ciel.org/Publications/Lee_DohaUSTR_25July07.pdf
- Lexchin, J. (2006). The pharmaceutical industry and the pursuit of profit. In J. Cohen, P. Illingworth & U. Schuklenk (Eds.), *The power of pills: social, ethical and legal issues in drug development, marketing and pricing*. London: Pluto. (p. 11-24).
- Litva, A., & Eyles, J. (1995). Coming out: Exposing social theory in medical geography. *Health and Place*, 1(1), 5-14.
- Loeppky, R. (2004). International restructuring, health and the advanced industrial state. *New Political Economy*, 9(4), 493-513.
- Lorenzen, M. (2005). Knowledge and geography. *Industry and Innovation*, 12(4), 399-407.
- Love, J. (2001a). *Compulsory licensing: Models for state practice in developing countries, access to medicine and compliance with the WTO TRIPS accord: prepared for the united nations development programme*. Retrieved 04/28, 2008, from <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html>

- Love, J. (2001b). *Report on court case over South Africa's medicines act*. Retrieved 04/24, 2008, from <http://lists.essential.org/pipermail/pharm-policy/2001-March/000740.html>
- Love, J. (2004). Monopoly medicine: the built-in inefficiencies of a patent-based pharmaceutical R&D system. *The Multinational Monitor*, 25(7 & 8), 1-5.
- Love, J. (2006). Round table discussion: Drug development incentives to improve access to essential medicines. *Bulletin of the World Health Organization*, 84(5), 408.
- Love, J., Herrling, P., & Pecoul, B. (2007). Research and development: searching for alternative models. *MSF Access News*, May/June 2007, 4.
- Mannan, A., & Story, A. (2006). Abolishing the product patent: A step forward for global access to drugs. In J. Cohen, P. Illingworth & U. Schuklenk (Eds.), *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing*. London: Pluto. (p. 179-189).
- Mbali, M. (2004). AIDS discourses and the South African state: government denialism and post-apartheid AIDS policy-making. *Transformation*, 54, 104-122.
- McBeth, A. (2006). When nobody comes to the party: Why have no states used the WTO scheme for compulsory licensing of essential medicines? *New Zealand Yearbook of International Law*, 3, 69-100.
- McDonald, L. (2004). Update on the pharmaceutical industry. *The Southern African Journal of HIV Medicine*, March, 46-47.
- McIntyre, A. (1999). *Key issues in the pharmaceutical industry*. Chichester: John Wiley and Sons.
- McIntyre, D., & Gilson, L. (2002). Putting equity in health back onto the social policy agenda: experience from South Africa. *Social Science & Medicine*, 54(11), 1637-1656.
- McIntyre, D., Thomas, S., & Cleary, S. (2004). Globalisation and health policy in South Africa. *Perspectives on Global Development and Technology*, 3(1-2), 131.
- Meade, M., & Earickson, R. (2000). *Medical geography* (2nd ed.). London: Guildford Press.
- Médicins sans Frontières. (2006). *Neither expeditious nor a solution: the WTO august 30th decision is unworkable*. Retrieved 11/08, 2006, from http://www.msf.ch/fileadmin/user_upload/uploads/communiqués/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf
- Momberg, E. (2008). *South Africa: new stats show millions more HIV positive*. Retrieved 06/15, 2008, from <http://www.africafiles.org/article.asp?ID=17960>
- Mugambe, L. (2002). *The exceptions to patent rights under the WTO-TRIPS agreement: Where is the right to health guaranteed?* Unpublished Human Rights and Democratisation in Africa, University of Western Cape, Cape Town.
- Ngwena, C. (2000). The recognition of access to health care as a human right in South Africa: Is it enough? *Health and Human Rights*, 5(1), 26-44.
- O'Manique, C. (2007). Global health and universal human rights: The case for G8 accountability. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*. Aldershot: Ashgate. (p. 207-226).
- Orbinski, J. (2007). Global health, social movements and governance. In A. Cooper, J. Kirton & T. Schrecker (Eds.), *Governing global health*. Aldershot: Ashgate. (p. 29-40).
- O'Tuathail, G. (1998). Thinking critically about geopolitics. In G. O'Tuathail, S. Dalby & P. Routledge (Eds.), *The geopolitics reader*. London: Routledge. (p. 1-14).

- Outterson, K. (2006). Fair followers: Expanding access to generic pharmaceuticals for low- and middle-income populations. In J. Cohen, P. Illingworth & H. Schneider (Eds.), *The power of pills: Social ethical and legal issues in drug development, marketing and pricing*. London: Pluto. (p. 164-178).
- Oxfam. (2007). *Investing for life*. Retrieved 12/15, 2007, from http://www.oxfam.org/en/policy/briefingpapers/bp109_investing_for_life_0711
- Painter, J. (1995). *Politics, geography and 'political geography': a critical perspective*. London: Arnold.
- Parry, E., Godfrey, R., Mabey, D., & Gill, G. (Eds.). (2004). *Principles of medicine in Africa* (3rd ed.). Cambridge: Cambridge University Press.
- Pecoul, B. (2001). Fighting for survival: access to essential medicines in poor countries. *Harvard International Review*, 23(3), 60-65.
- Pecoul, B., Chirac, P., Trouiller, P., & Pinel, J. (1999). Access to essential drugs in poor countries: a lost battle? *The Journal of the American Medical Association*, 281(4), 361-367.
- Petchesky, R. P. (2003). *Global prescriptions: gendering health and human rights*. London: Zed Books.
- Phillips, N. (2005). "Globalising " the study of international political economy. In N. Phillips (Ed.), *Globalising international political economy* (p. 1-19). Basingstoke: Palgrave MacMillan.
- Pogge, T. (2005). Human rights and global health: a research program. *Metaphilosophy*, 36(1/2), 182-209.
- Prusak, L., & Cohen, D. (1998). Knowledge buyers, sellers and brokers: the political economy of knowledge. In D. Neef, G. Siesfeld & J. Cafola (Eds.), *The economic impact of knowledge*. Oxford: Butterworth-Heinemann. (p. 137-159)
- Reekie, D. (2000). *South Africa's battle with AIDS and drug prices*. (No. 334). Washington DC: National Centre for Policy Analysis.
- Republic of South Africa. (2008). *Media statement: R3,6 billion ARV tender awarded*. Retrieved 06/26, 2008, from www.health-e.org.za/news/article.php?uid=20032001. Pretoria: Department of Health
- Republic of South Africa (2007a). *Industrial policy action plan*. Retrieved 05/10, 2008, from http://www.dti.gov.za/nipf/IPAP_r1.pdf. The Department of Trade and Industry
- Republic of South Africa (2007b). *National industrial policy framework*. Retrieved 05/10, 2008, from www.thedti.gov.za/nipf/NIPF_r2.pdf. The Department of Trade and Industry.
- Republic of South Africa. (1997). *Medicines and Related Substances Control Amendment Act*. Retrieved 02/15, 2008, from <http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf>
- Republic of South Africa. (1996a). *The Constitution of the Republic of South Africa*. Retrieved 03/16, 2008, from <http://www.info.gov.za/documents/constitution/1996/index.htm>
- Republic of South Africa. (1996b). *Growth, Employment and Redistribution: a macroeconomic strategy*. Retrieved 04/28, 2008, from <http://www.info.gov.za/otherdocs/1996/gear.pdf> Pretoria: Department of Finance
- Republic of South Africa. (1996c). *National drugs policy for South Africa*. Pretoria: Department of Health.

- Resnik, D. B. (2001). Developing drugs for the developing world: an economic, legal, moral, and political dilemma. *Developing World Bioethics*, 1(1), 11-32.
- Rimington, S., & Weissman, R. (2008). *Thailand lowers medicine prices; faces U.S./E.U. pressure*. Retrieved 04/16, 2008, from <http://www.essentialaction.org/access/uploads/AccessBulletinNo3.rtf>
- Ringer, J. (2007). *Intellectual property implications on pharmaceutical innovation and investment*. Retrieved 04/08, 2008, from [http://www.imsa.org.za/files/library/presentations%20\(3\)/2007/Intellectual%20Property%20Implications%202007.pdf](http://www.imsa.org.za/files/library/presentations%20(3)/2007/Intellectual%20Property%20Implications%202007.pdf)
- Ruggie, J. (1998). *Constructing the world polity: essays on international institutionalisation*. London: Routledge.
- Ruxin, J., Paluzzi, J., Wilson, P., Tozan, Y., Kruk, M., & Teklehaimanot, A. (2005). Emerging consensus in HIV/AIDS, malaria, tuberculosis and access to essential medicines. *The Lancet*, 365, 618-621.
- Sanders, D., & Carver, R. (1985). *The struggle for health: medicine and the politics of underdevelopment*. Oxford: Macmillan Education.
- Sanders, D., & Chopra, M. (2003). Globalisation and the challenge of health for all: A view from sub-Saharan Africa. In K. Lee (Ed.), *Health impacts of globalisation: towards global governance*. Basingstoke: Palgrave Macmillan. (p. 105-119)
- Sanders, D., & Chopra, M. (2006). Key challenges to achieving health for all in an inequitable society: the case of South Africa. *American Journal of Public Health*, 96(1), 73-78.
- Satardien, M. (2006). *A critical analysis of the trade related aspects of intellectual property rights agreement, and has South Africa complied with this agreement with special reference to patented pharmaceuticals?* Unpublished Faculty of Law, University of the Western Cape, Cape Town.
- Schneider, H. (2002). On the fault-line: The politics of AIDS policy in contemporary South Africa. *African Studies*, 61(1), 145-167.
- Selgelid, M., & Sepers, E. (2006). Patents, profits, and the price of pills: Implications for access and availability. In J. Cohen, P. Illingworth & U. Schuklenk (Eds.), *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing*. London: Pluto Press. (p. 153-163).
- Sen, A. (1999). *Development as freedom*. Oxford: Oxford University Press.
- Senona, J. (2005). *Human rights and the WTO: incorporation or cooperation? Is there a need for an agreement on trade-related aspects of human rights?* Unpublished Faculty of Law, University of Western Cape, Cape Town.
- Shadlen, K. (2007). The political economy of AIDS treatment: intellectual property and the transformation of generic supply. *International Studies Quarterly*, 51, 559-581.
- Sidley, P. (2001). Antiretrovirals will not reduce overall expenses, especially in the public sector. *Business Day*, p. 6. 1st March.
- Sinclair, S. (2006). The GATS and South Africa's national health act. In P. Ijumba, & A. Padareth (Eds.), *South African health review 2006*. Durban: Health Systems Trust. (p. 19-30).
- Singh, J. A., Govender, M., & Mills, E. J. (2007). Do human rights matter to health? *The Lancet*, 370(9586), 521-527.
- Sinha, T., & Condon, B. (2005). Global diseases, global patents and differential treatment in WTO law. *(Northwestern) Journal of International Law and Business*, 26(1), 1-24

- Smith, N. C., & Duncan, A. (2005). GlaxoSmithKline and developing country access to essential medicines (A). *Journal of Business Ethics Education*, 2(1), 97-122.
- South African High Court. (1998). *Pharmaceutical company lawsuit (forty-two applicants) against the government of South Africa (ten respondents)* 1998. Retrieved 04/03, 2008, from <http://www.cptech.org/ip/health/sa/pharmasuit.html>
- Sprague, C., & Woolman, S. (2006). Moral luck: Exploiting South Africa's policy environment to produce a sustainable national antiretroviral treatment programme. *South African Journal of Human Rights*, 22, 337-379.
- Tandon, Y. (1999). The world trade organisation and Africa's marginalisation. *Australian Journal of International Affairs*, 53(1), 83.
- Taylor, D. (2001). Poor world health and rich world wealth. *British Medical Journal*, 322(629), 630.
- Taylor, P. J. (1993). *Political geography: world economy, nation-state and locality*. Harlow: Longman.
- Tetteh, E. k. (2008). Providing affordable essential medicines to African households: the missing policies and institutions for price containment. *Social Science & Medicine*, 66(3), 569-581.
- The Global Fund. (2008). *Pledges*. Retrieved 07/01, 2008, from <http://www.theglobalfund.org/en/files/pledges&contributions.xls>
- The Nation. (2008). *Generic drug debate intensifies*. Retrieved 05/03, 2008, from http://www.nationmultimedia.com/2008/03/06/business/business_30067304.php
- The South Centre. (2007). *Rwanda and Canada: leading the implementation of the august 2003 decision for import/export of pharmaceutical products under compulsory license*. Retrieved 04/11, 2008, from <http://www.ciel.org/Publications/pubipqu.html>
- t'Hoen, E. (2002). TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha. *Chicago Journal of International Law*, 3(1), 27-46.
- t'Hoen, E. (2006). *Intellectual property implications for access to new treatments - legal and economic aspects*. Document supplied by t'Hoen, Head of the Médicins sans Frontières Access to Essential Medicines Campaign.
- Traulson, J., & Almarsdottir, A. (2005). The argument for pharmaceutical policy. *Pharmaceutical World Science*, 27, 7-12.
- Trouiller, P., Oliaro, P., Torreele, E., Orbinski, J., Laing, R., & Ford, N. (2002). Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet*, 359(9324), 2188-2194.
- Tshabalala-Msimang, M. (2005). *Medicine pricing: A mandate to make quality medicine accessible and affordable*. Retrieved 04/16, 2008, from <http://www.doh.gov.za/docs/pr/2005/pr0124.html>
- Ugandan Ministry of Health. (2008). *The burden of malaria in Uganda: why all should join hands in the fight against malaria*. Retrieved 06/30, 2008, from <http://www.health.go.ug/malaria.htm>
- UK Department for International Development. (2008). *A picture of health*. Retrieved 05/10, 2008, from <http://www.developments.org.uk/downloads/A%20picture%20of%20health.pdf>
- United Nations. (2007). *The least developed countries report*. Retrieved 04/16, 2008, from www.unctad.org/Templates/WebFlyer.asp?intItemID=4314
- United Nations Commission on Human Rights. (2001). *The impact of the agreement on trade-related aspects of intellectual property rights on human rights: report of the high commissioner* (No.

- E/CN.4/Sub.2/2001/13) Retrieved, 13/16, 2008 from [www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument)
- Vachani, S., & Smith, N. C. (2004). Socially responsible pricing: Lessons from the pricing of AIDS drugs in developing countries. *California Management Review*, 47(1), 117-144.
- Vaver, D., & Basheer, S. (2006). *Popping patented pills: Europe and a decade's dose of TRIPS*. University of Oxford Faculty of Law Legal Studies Research Paper Series., Working Paper No. 25/2006
- Vawda, Y. (2003). From Doha to Cancun: The quest to increase access to medicines under WTO rules. *South African Journal of Human Rights*, 19, 679-690.
- Verschraegen, G. (2006). Systems theory and the paradox of human rights. In M. King, & C. Thornbill (Eds.), *Luhmann on law and politics: Critical appraisals and applications*. Portland: Hart Publishing. (p. 103-125).
- Weissman, R. (2008). Cheaper drugs are as important as improved health infrastructure. *The New Times* (Kigali), 6th May.
- Werner, D., Sanders, D., Weston, J., Babb, S., & Rodriguez, B. (1997). *Questioning the solution: The politics of primary health care and child survival*. Palo Alto: HealthWrights.
- WHO. (2007). *Draft global strategy and plan of action on public health, innovation and intellectual property*. Retrieved 01/18, 2008, from www.who.int/gb/phi/pdf/igwg2/PHI_IGWG2_ID6-en.pdf
- WHO (2008a) *122nd WHO Executive Board Session*. Retrieved 02/10, 2008 from <http://www.who.int/mediacentre/events/2008/eb122/en/index.html>
- WHO. (2008b). *Essential medicines*. Retrieved 04/08, 2008, from http://www.who.int/topics/essential_medicines/en/
- WHO Intergovernmental Working Group. (2008). *Draft global strategy on public health, innovation and intellectual property*. Geneva: World Health Organization.
- Wijnberg, B. (2007). *Access to medicines, human rights and trade rules: comparative and international perspectives*. Global Forum on Health Research Conference, Beijing. Retrieved, 05/13, 2008 from www.utoronto.ca/cphs/China%20Conference/Forman%20Presentation_Introductory%20Remarks.pdf
- Williams, K. (2007). Pharmaceutical price regulation. *South African Journal of Human Rights*, 23, 1-33.
- WTO. (1994). *Agreement on Trade-Related Aspects of Intellectual Property*. Retrieved 02/11, 2008, from http://www.wto.org/english/docs_e/legal_e/27-trips.pdf
- WTO. (2005). *Understanding the WTO- intellectual property: protection and enforcement*. Retrieved 11/05, 2005, from http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
- Yamin, A. (2003). Not just a tragedy: access to medications as a right under international law. *Boston University Law Journal*, 21, 325-33



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