TRIPPING OVER OUR OWN FEET: A Critical Discussion of Trade Related Intellectual Property Rights (TRIPS) with Specific Reference to their Impact on South Africa's Ability to Combat HIV and AIDS

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ABSTRACT

This thesis aims to look at the agreement on Trade Related Intellectual Property Rights (TRIPS) with specific reference to their impact on South Africa's ability to combat HIV and AIDS. It begins by looking at the history of patents and intellectual property rights and illustrates why and how the TRIPS Agreement came into existence. The TRIPS Agreement exemplifies the disparities between developed and developing countries and this can clearly be seen with regard to the provision of anti-HIV and AIDS drugs. The developing world deals with the bulk of the HIV and AIDS epidemic whilst the developed world holds most of the patents on the medication needed to treat those living with HIV and AIDS. This situation lends itself to a rift between patient rights on the one hand, and patent rights on the other. Traditionally the state has been the provider of rights such as health, but TRIPS alters this to include strong patent protection that is in line with neo liberal doctrine. The thesis examines these tensions with specific reference to South Africa's ability successfully to implement programmes to combat HIV and AIDS.

CONTENTS

The law, in its majestic equality, forbids the rich as well as the poor... to steal bread.
Anatole France (1844 - 1924).

Introduction

With the formation of the World Trade Organization (WTO) in 1995, states either had the option of abiding by its regulations and gaining the advantages offered by the WTO at a certain cost, or refusing the regulations and facing exclusion (Narlikar, 2005: 25). The Agreement on Trade Related Intellectual Property Rights (TRIPS) provided rules governing intellectual property rights (IPRs) on a global scale. It was the first time that such a global patent regime had been enforced and it required governments to change their national legislation (Narlikar, 2005: 81). Many countries had existing laws regarding the protection of IPRs but few pertained to the protection of pharmaceuticals. TRIPS changed this. The inclusion of pharmaceutical products in the agreement was one of the developing countries' main concerns (Alsegard, 2004: 3). This is because health care is one of the prominent concerns faced by a developing country.

It is important to note the main driving forces behind TRIPS. Shiva (2001: 18) argues that in order to maintain its supremacy, the United States (US) made intellectual property (IP) and patents its primary asset for economic growth and for control of world trade. Despite its benefits to the developed world, a heavily regulated global patent system would also provide developmental opportunities for developing countries. TRIPS advocates are quick to point out that the regulations would also provide incentives for developed countries to invest in developing countries. It was only as time progressed that it became clear that TRIPS was not living up to its promise. Patents have been blamed for a whole series of economic ills, real or imaginary, "including high prices, erection of barriers to free trade, foreign domination of national economies, exploitation of developing countries and suppression of worthwhile inventions" (Grubb, 1982: 219).

Since its inception, then, TRIPS has faced criticism- but it was only when South Africa tried to change its legislation in December 1997 to allow cheaper medication costs for the treatment of HIV and AIDS that the global community became more fully aware of the implications of the TRIPS Agreement, particularly for poorer nations (Thomas, 2001: 15).

South Africa, like the rest of the African continent, faces a huge HIV and AIDS epidemic. It has over 5 million people living with HIV and AIDS. Although the problem is not restricted to developing countries, those have a much higher HIV infection and AIDS fatality rate than developed countries. As much as 95 percent of the world's HIV and AIDS population live in developing countries, with 70 percent of those residing in Sub-Saharan Africa (Katz, 2003). All the same, in the US, AIDS is the fifth

leading cause of death in people 25-44 years of age and the total number of reported deaths from AIDS is 438 795 (Thomas, 2001: 11). Furthermore there is more money available in the developed world in relative and absolute terms but this wealth is cartelized and rests in the hands of few. The truth is that, 44 percent of the world's population live under the $2 per day poverty line and consume only 1.3 percent of the global product, whereas the high income countries, which are home to only 4 percent of the world's population, consume 81 percent of the global product (Pogge, 2005: 1). As a former Director-General of the World Health Organization (WHO), Dr Brundtland, state: "never have so many had such broad and advanced access to healthcare. But never have so many been denied access to health. The developing world carries 90 percent of the disease burden, yet poorer countries have access to only 10 percent of the resources that go to health" (The World Health Organization, 2007). While poverty is one of the many reasons why this rate is higher in the developing world, inability to afford medication to combat the disease is clearly a significant factor affecting attempts to curb the disease (Joseph, 2003: 428). But as Grubb (1982: 248) points out, pharmaceutical companies do not pretend to be the Red Cross. They are profit oriented and given the global economy in which they operate, have to be. Whereas high prices might make access to drugs selective, it is better to have a drug that is available to some than not available to any (Joseph, 2003: 431). On the other hand, the pharmaceutical industry is one of the most profitable in the world. In 2000 sales of more than $315 billion were made, which is more than the combined gross domestic product (GDP) of all 13 countries in the Southern African Development Community (SADC) (Geffen, 2001).

The high prices of antiretrovirals (ARVs) and the exorbitant profits made by the pharmaceutical industry were thus called into question. "Growing international condemnation of the excessive price of patented HIV and AIDS medicines finally forced trade ministers to address the thorny issue of global patent rules at the WTO Ministerial Conference" (Mayne & Bailey, 2002: 4). On November 14 of that year the Doha WTO Ministerial Declaration on TRIPS and Public Health (Doha Declaration) was adopted which "affirmed the right of all countries to protect public health" (Alsegard, 2004: 4). This provided for a government to overthrow patent rights (by allowing parallel importation and compulsory licensing) if its country was facing a national health crisis, such as that of HIV and AIDS (Sacco, 2005: 106).

Where South Africa is concerned, as Anderson (2002) argues, the provision of health care is constrained by structural economic problems, wealth being one of these. Pharmaceutical patent abuse is also a central obstacle to implementing treatment programmes successfully (Geffen, 2001). In this way

TRIPS is seen as an obstacle to the realization of the human right to health (Anderson, 2002). Although the TRIPS Agreement does not take developmental, social and environmental concerns into account, there are other factors, such as weak health infrastructure and poor planning that also contribute to the lack of this realization (Khor, 2001: 46). Perhaps the most poignant reason for linking the problem to the human rights issue is the government's failure to provide progressive realization on issues such as the HIV and AIDS link as well as mother-to-child (MTC) transmission (Anderson, 2002). Progressive realization is specified in Section 26(2) of the South African constitution, which outlines the minimum core obligations the government is obliged to take to realize rights such as the right to health (Sacco, 2005: 116). South Africa has also not "invoked the TRIPS flexibilities or utilized flexibilities inherent in its own legislation"; nor has it declared a national emergency regarding HIV and AIDS (Sacco, 2005: 107). Sacco (2005: 110) adds that generally "a state's duties in relation to health can only be judged in terms of whether the state has a policy to progressively realize it obligations, taking into consideration its available resources".

Research question and method

In light of the above, this thesis aims to examine how the TRIPS Agreement, which falls within the precincts of the WTO, hampers a response to the HIV and AIDS epidemic in South Africa.

The main research question that this thesis sets out to answer is, then: what impact, if any, does the TRIPS Agreement have on a developing country, like South Africa and what leverage does South Africa, facing a huge HIV and AIDS epidemic, have in terms of meeting the requirements of the TRIPS Agreement, while also meeting the needs of its citizens? This will be achieved by documentary analysis and is largely a study of secondary literature. Therefore no primary research will be undertaken nor will the study be based on any hypothesis testing. Types of consulted documents include newspapers, books, biographies, papers prepared by organizations such as Oxfam, journal articles, the South African constitution and law reports, the TRIPS Agreement and the Doha Declaration.

Structure

The research question will be considered by providing a historical account of intellectual property rights (IPRs) in order to contextualize the TRIPS Agreement and illustrate the legal and moral tensions between protecting IPRs and ensuring the right to health when treating HIV and AIDS patients in South Africa. The South African government's response to the epidemic will also be discussed to illustrate, not only how domestic factors constrain action, but also how the TRIPS Agreement confines the government's response to the epidemic in South Africa.

In particular, chapter one outlines the history of patents and how IPRs came into existence and begins to illustrate the central issues that arise as a result of the protection of intellectual property by patents. It demonstrates how the TRIPS Agreement developed according to the demands of the pharmaceutical industry and the US government, and starts to explore the so called North-South dichotomy.

The second chapter further discusses the differences between the developed and developing world with reference to HIV and AIDS medication, by citing the factors that led to the Doha Declaration on Public Health which allows a country to place patient rights before patent rights. The provisions outlined in the Doha Declaration are also discussed. However, despite these provisions with regard to the TRIPS Agreement, developing countries are not readily using them.

Chapter three examines the reasons for this and finds that, because of the epidemic and the different pharmaceutical market, equal opportunity to utilize the provisions does not present itself. And precisely because of the HIV and AIDS epidemic, the legitimacy of IPRs are called into question because they directly inhibit the realization of the right to health. The works of Robert Nozick and John Rawls are used to clarify which should take preference.

Finally, in chapter four, it will be shown that, although pharmaceutical companies are guilty of charging excessively high prices for HIV and AIDS medicines, the government is traditionally responsible for ensuring the protection and realization of human rights. Thus this thesis looks at the domestic factors in South Africa that constrain action towards implementing a successful HIV and AIDS programme. However, the external factors that also affect the domestic constituency are not ignored.

In concluding, all of these factors will be linked together in order to show that the TRIPS Agreement has allowed international trade to enter the realm of intellectual property and why this in turn has given developed nations leeway to use trade issues as a bargaining tool to gain stronger intellectual property (IP) protection. Furthermore it will be shown that the Doha Declaration has not been honoured and that it is up to the South African government to resist international pressure to strengthen IP protection in order to address effectively the current HIV and AIDS epidemic.

1. **Don't know much about IP:** a short history of intellectual property rights

Patents as they are known today only really became prominent in the 1980s with the introduction of IPRs during the General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations (Shiva, 2001: 1). However it is important to explain developments prior to Trade Related Intellectual Property Rights (TRIPS) in order to grasp the current intellectual property landscape and consequently why such rights should exist at all. The modern protection for intellectual property rights arose first as national legislation in developed countries, followed by international agreements such as the Paris, Rome and Berne Conventions which eventually led to the TRIPS Agreement[1] (Alsegard: 2004: 3).

Intellectual property deals with products of the mind and one way of protecting such a product or process is with patents. A patent can be defined as a "legal device to encourage and reward invention by giving exclusive rights to inventors" (Black, 1997: 344). Before intellectual property, property law was tied to tangible objects. But intangible objects such as ideas can also be owned, and when ownership of this nature occurs it is known as intellectual property (Martin, 1995). The notion of owning an idea poses many challenges because of its intangibility. For instance some point out, as Hettinger (1989: 37) does, that any piece of intellectual work is always built on and inconceivable without the prior work of numerous people and therefore today's contributor cannot validly claim full credit. Similarly IP protection emerges because unlike physical property (tangible objects), intellectual property cannot be protected as easily. For example a CD could easily be copied and distributed, but the same could not be said for someone's house. Furthermore because of this intangibility, using others' ideas does not seem as unjust as stealing a tangible object such as a car. This can be illustrated by looking at the number of individuals who justify downloading bootlegged movies off the internet but consider stealing a movie in its tangible form (e.g. on DVD or Video) from a store as unethical. The bootlegged movie can also be watched repeatedly while another person who has an original copy can do the same. Ideas can then, unlike tangible objects, be copied over and over again without reducing other people's use of the idea (Martin, 1995). Examples of patent protection can be observed as early as 500BC in Sybaris, Greece, where a food patent was granted which allowed for complete control of production as well as the profit going to the chef who invented any exclusive or peculiar dish (Capsey, 1973: 1). These "exclusive rights" are granted by the state for a limited period of time in respect of a new and useful invention

[1] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization.

(Grubb, 1982: 3). Patents operate under the assumption that people expect rewards for their endeavors, especially when they are risky as they may and often do result in costly failure (Joseph, 2003: 431). Monopolies existed as long ago as the Byzantine Empire but these were not for inventions. It was only in 1449 that a monopoly was granted by Henry II for stained glass manufacture to John Utyman for the introduction of new technology into England (Capsey, 1973: 1-2). The first patent law was only passed in Venice in 1474 which covered both imports and inventions (Shiva, 2001: 14). These examples begin to illustrate that patents have long been used to encourage and reward inventions as well as promote the introduction and support of new industries. By the same token the capacity of patents to generate conflict also has a long history.

In Britain, Queen Elizabeth I granted patent rights at her discretion but this soon led to heavy price increases and in 1601 the Queen was forced to revoke the majority of monopoly grants (Grubb, 1982: 7). King James I continued granting illegal monopolies and thus protests against the granting of monopolies based on royal prerogatives eventually led to the Statute of Monopolies in 1624, which left the allocation of patents bound by common law (Grubb, 1982: 11). Patents of invention were an attempt then to free the economy of the abuses of royal grants of monopoly privileges (Shiva, 2001: 14). Patents were also used by those countries, such as England, which lagged behind in the technology race to catch up with countries which were more technologically advanced (Shiva, 2001: 14). For example, Flemish weavers were encouraged to come into the country with the promise of a monopoly so that they could teach English apprentices their craft (Shiva, 2001: 15). The 14-year monopoly so granted related to the time taken to learn a craft: two cycles of seven year apprenticeships and in this time it was also hoped that the invention would be put to good use (Cornish, 1997: 93).

As a result in Britain, patents no longer related solely to the establishing of new industries and it thus became essential to disclose the invention (Grubb, 1982: 12). This meant that, when a patent was filed, the inventor would have to divulge the processes and methods which were used to produce the final product. Disclosure thus guaranteed a monopoly for the product (Grubb, 1982: 12). Despite these advances, the patent process was still lengthy and expensive, and there were also problems with enforcement. In 1852 a Patent Office was set up, which introduced a new patent system under the Patent Law Amendment Act (Cornish, 1997: 95). Renewal fees were introduced and a grant could be secured for a reasonable fee. There was also a call for an official examination of the invention before any patent was granted (Cornish, 1997: 95). In 1875 the courts decided on the legal scope of the monopoly. The Institute of Patent Agents was founded in 1882 and in the following year the patent office began

examining applications. Complaints could be made with regard to infringements, and fees were reduced (Grubb, 1982: 16-18). All of this fell under the Patents Act of 1883: an indication of how quickly the patent process developed. In 1919 Britain tried to locally produce chemicals that were patented in Germany, based on the argument that the patent was not able to be used domestically (Cornish, 1997: 98). Key patents for many innovations in the chemical industry were held in Germany and therefore high prices for the chemical products were charged which made the chemicals inaccessible in many countries.

Although the global patent system today is largely based on the US's patent system, the US's system was initially based on Britain's (Grubb, 1982: 14). In the US Constitution of 1778, Article 1 Section 8 grants exclusive rights to the inventor, and correct credit of inventorship was of absolute importance (Grubb, 1982: 13). The patent was granted to the first person who made the invention and not to the first who filed the patent for it. Patents were also used to promote technology transfer and provide incentives for the development of new inventions (Grubb, 1982: 25). The first patent system in the US had a strict system of scrutiny which eventually proved ineffective and in 1834 an Act was passed which allowed for a patent request without examination (Grubb, 1982: 20). However, this led to an overlapping of patents and in 1836 an examination system was set up that would be free of its previous faults (Grubb, 1982: 20). With an increase in the number of patents filed for both Britain and the US, and the desire to gain access to new technology from different countries, it became evident that each national patent system needed similar guidelines to adhere to. This became even more evident when foreign exhibitors refused to attend the International Exhibition of Inventions in Vienna in 1873 because they were afraid that their ideas would be stolen and exploited commercially in other countries (The World Intellectual Property Organization, 2006).

In 1883 patenting countries of the 19th century agreed to the *Paris Industrial Convention of 1883* which "guaranteed the nationals of each Member State the same treatment in the others as was given to their own nationals" (Cornish, 1997: 97). This meant that even countries without patent laws could join the Paris Convention and procure benefits for their own nationals abroad. It also allowed the inventor one year to file a patent in any other member nation after a patent had been filed in any member state (Bhat, 2005: 119). The Convention thus provided a framework by which countries could begin to set up their own patent system. It did not however make any arrangements, beyond its priority system, for standardizing or simplifying the process of applying for patents (Cornish, 1997: 100). South Africa joined in 1947.

In 1886 the *Berne Convention for the Protection of Literary and Artistic Works* was signed[2], which set minimum protection standards for its member states but this dealt more with protection of authors' rights and matters such as copyright (Cornish, 1997: 312). This marked one of the first occasions that IP was affected by multilateral covenants because, prior to this, IP regulation was confined to national legislation (Sykes, 2002: 49). Copyright laws would only apply to those objects created in a specific country; thus a book created in Belgium could only be protected by patent laws in Belgium. The aim of this convention was to help nationals of member states to obtain international protection of their right to control, and receive payment for the use of their creative works (The World Intellectual Property Organization, 2006). South Africa became a member in 1928.

In order to process applications, two small bureaus were set up but in 1893 these two merged to form an international organization called the United International Bureaux for the Protection of Intellectual Property (known by its French acronym BIRPI) which later, in 1970, at the Convention Establishing the World Intellectual Property Organization, became WIPO (The World Intellectual Property Organization, 2006). WIPO "is an international organization dedicated to helping to ensure that the rights of the creators and owners of intellectual property are protected worldwide and that inventors and authors are, thus, recognized and rewarded for their ingenuity" (The World Intellectual property Organization, 2006). It is thus an organization dedicated to the promotion of world-wide intellectual property protection. It currently has 183 member states. South Africa joined in 1975. WIPO aims to provide a stable environment for the marketing of intellectual property products and in doing so help to "oil the wheels of international trade" (The World Intellectual Property Organization, 2006).

Despite these advances, problems still remained with unexamined patents and even with those that were examined. The high costs of examination kept low the number of patents filed (Cornish, 1997: 101). The situation was rendered even more complex by the fact that many inventors wanted to file patents in several countries. It soon became evident that "the internationalizing of the patenting process might increase efficiency and reduce costs" (Cornish, 1997: 101).

In 1963 a number of European countries signed the *Strasbourg Convention* "which recommended certain common standards for novelty, inventiveness, and the type of invention which may be patented" (Grubb, 1982: 25). It was this Convention that formed the basis of the *European Patent Convention* (EPC) of 1973 which later led to the establishment of the European Patent Office (EPO) in 1978 (Grubb, 1982: 25-26). The Patent Co-operation Treaty (PCT) which came into effect on

[2] Signatories for 1887 include Belgium, France, Germany, Italy, Spain, Switzerland, Tunisia and the United Kingdom.

June 1, 1978, administered by WIPO, did not set out to create a world patent system but rather attempted to simplify the process (and reduce the cost) of filing for a single patent in several countries (Grubb, 1982: 27). The aims were twofold: the first was to establish a standard international preliminary examination system which would establish the grounds of whether to grant a patent or not (Cornish, 1997: 101). This was seen as an opportunity for developing countries because many did not have their own guidelines for granting patents and could use this as a model. Secondly, the PCT aimed to have an international search conducted by international search authorities which would allow an applicant to institute applications in numerous countries by a single procedure (Cornish, 1997: 101). This was not, however, an international agreement about the grounds of validity for a patent; in the end each national patent office would decide. South Africa became a member in 1999.

Internationally, subsequent discussions of acceptable global patent models focused on two negotiations: UNCTAD's Code of Conduct for the Transfer of Technology and the Revision Conference of the Paris Convention (Cornish, 1997: 99). The first had two drafts in 1980 but was surrounded by controversy because different versions were being preferred variously by the G77 (developing), industrialised and socialist countries (Cornish, 1997: 99). The second held three sessions, but adjourned *sin die* in 1982.

Meanwhile the expansion of trade competition after 1950 brought many advantages to innovators, and patents helped secure immense commercial returns (Cornish, 1997: 17). After the end of World War II the international community wanted to build safeguards and institutions that would protect the world from the recurrence of such disastrous events, and many believed that free trade would provide just such protection (Narlikar, 2005: 10). At the Bretton Woods Conference in 1944, the US and Britain provided the blueprint for structures for maintaining international economic co-operation. The three pillars of the Bretton Woods system were the International Monetary Fund (IMF), the World Bank and the International Trade Organization (ITO) (Vodovnik, 2004). The proposed formation of the ITO was enshrined in the Havana Charter, but this was rejected by the US Congress on the grounds that its broad mandate would compromise US sovereignty (Vodovnik, 2004). With the failure of the ITO, which was supposed to cover areas of commercial policy, employment, economic issues, fair labour standards and humanitarian concerns amongst others, an interim agreement, the General Agreement on Tariffs and Trade (GATT), was set up in 1948 until the ITO could be re-launched (Narlikar, 2005: 12, 15). It was signed by 23 countries, 11 being developing countries.

The GATT applied only to governments and stood firmly outside of the boundaries of states by only dealing with tariff barriers (Narlikar, 2005: 15). Its aim was to reduce national trade barriers and to stop trade policies that had hobbled the global economy prior to World War II (Vodovnik, 2004). This stood in sharp contrast to the ITO's ambitions, which dealt with the monopolistic practices of commercial firms. Furthermore, if any part of the GATT mandate clashed with a state's pre-existing legislation the state would not have to apply the GATT mandate (Narlikar, 2005: 16). GATT analyst Gilbert Winham has described GATT as a "formally-contracted, rule-orientated, non-organizational form of co-operation in international affairs" (Narlikar, 2005: 16). In other words, it was little more than a negotiating forum held together by a multilateral treaty signed by contracting parties, and did not enjoy the same legal framework that an organization would (Narlikar, 2005: 26). For example, collective action could not be organized against individual countries if they did not adhere to a particular part of the GATT mandate. The operations of the GATT, such as its negotiation methods, served to marginalize further the developing countries, but at the same time this marginalization served to ensure the participation and commitment of the major traders: the US, the European Community, Canada and Japan (Narlikar, 2005: 19).

It was precisely because of this marginalization of developing countries, which served the needs of the major traders and thus of GATT's most powerful signatories, that GATT continued to exist for over four decades (Narlikar, 2005: 19). The first seven rounds of negotiations dealt primarily with trade tariffs, and it was only in the Uruguay Round (1986-1994) that agendas of developing countries were considered. This was in response to the changing comparative advantage of the developed countries. In the early 1980s the US faced a decline in market competitiveness due to the rising economic power of Europe and Japan. This meant that US companies no longer dominated their domestic market and instead lost market share to better imports from abroad. When policy-makers reviewed the issues they found that, although technological innovation was still high, US entrepreneurs failed to be competitive (i.e. be first in the market). This led to a shift from the previous view that patent monopolies should be used sparingly, to the view that the patent system was not sufficiently strong to support the commercialization of investment in competitive new technologies (Lehman, 2004: 2). As a result both political parties in the US began to strengthen the patent system, and even pharmaceuticals were included to compensate for the delay in their ability to market drugs due to safety regulations (Lehman, 2004: 3). This strong intellectual property right protection was incorporated into the US position in trade negotiations. The North American Free Trade Agreement (NAFTA) was signed in 1992 and replaced

the US-Canada Free Trade Agreement, which did not include IPRs (Sykes, 2002: 50). NAFTA clearly stipulates what each member state should do to protect IP. According to the US International Trade Commission, if IP rights are protected in developing and least developed countries according to US demands, then US companies stand to gain $61 billion a year at a cost to the South of somewhere between $100-300 billion (Chomsky, 1993). The result of this shift was that the so-called new issues[3] were brought into the GATT mandate: called Trade Related Intellectual Property Rights, Trade Related Investment Measures and services (Narlikar, 2005: 20-21). There was much resistance from developing countries and the European Commission against the inclusion of these new issues because they believed that IP should stay within the boundaries of WIPO (Adede, 2001: 5). The US, on the other hand, pointed to the failure of WIPO to enforce adequate IP protection and maintained that GATT provided the necessary enforcement. The US also argued that developing countries would be able to use their bargaining power to secure favourable terms (Adede, 2001: 9). The inclusion of TRIPS also served to consolidate the US advantage in the cutting-edge knowledge-intensive industries (Bell, 2006).

However, many countries were concerned that GATT did not provide the necessary structure to deal with these new issues. Although a proposal for a new international trade organization was not on the agenda in the Uruguay Round, it was inevitable that one would be needed to handle the new issues created by changing circumstances. International trade lawyer John Jackson recognized that, unless a mechanism for coordinating agreements was found, the current agreements met would be unsustainable, so he proposed the creation of a world trade organization (Narlikar, 2005: 24). It was, then, changing imperatives and the need for a new negotiation process that lead to the creation of the WTO. A world trade organization would also serve to maintain external relations between other organizations such as the IMF and the World Bank. Although Canada and the EU jumped at the opportunity to be part of a world trade organization, many countries, particularly the developing ones, still had to be convinced.

Developing countries were "granted the inclusion of agriculture and textiles, and also special and differential treatment through longer time periods for implementing some of the new agreements" (Narlikar, 2005: 25). Furthermore, they believed that membership would ensure increased foreign direct investment (FDI) and promote technology transfer (Sykes, 2002: 59). Surprisingly, the US resisted and was the last to consent- in return for an EU concession on computer chips and a change in the name from a Multilateral Trade Organization to the World Trade Organization (Narlikar, 2005: 25). Countries

[3] They were called new issues because never before had intellectual property or investment measures been included in global dialogue relating to trade.

then either had the option of abiding by its regulations and gaining the advantages offered by including the new issues, or of refusing the regulations and facing exclusion. The WTO came into existence on 1 January 1995, with a membership of 128 countries, including South Africa. The WTO, although sharing some similarities with its predecessor, GATT, differs in that it concerns itself with areas that have traditionally fallen within the domestic jurisdictions of states, namely non-tariff barriers to trade and IPRs (Narlikar, 2005: 59). It is important to note that, unlike its predecessors, the WTO was not established in response to a global crisis, and as Bell (2006) argues: "it was not global necessity that gave birth to the WTO in 1995". Rather the US realized that its interests were no longer being served by a loosely controlled GATT and that its interests could be better met by including new issues within the WTO, that strengthened and continues to strengthen their position. The Agreement on Trade Related Intellectual Property Rights (TRIPS) provides provisions relating to all IP, introduces IP law into the international trade system and aims to provide minimum standards of protection with regard to IP on a global scale. TRIPS, then, is the international treaty for protecting international property (Shiva, 2001: 95).

TRIPS became final after many negotiations between 1986 and 1994. The decade-long movement, led by a coalition of industries in the US, united "to secure an international standard of intellectual property protections that could be enforced through trade sanctions" (Baker, 2003: 15). The entertainment, publishing, computer software and pharmaceutical industries in the US formed their own internal alliances which in turn strengthened the position of the US which then, using NAFTA (North American Free Trade Agreement) as a model, worked with other developed countries to motivate the importance of globalizing IP protections (Baker, 2003: 15). For this reason the WTO can be seen as blueprint for the global hegemony of corporate America (Bell, 2006). The first proposal of the TRIPS Agreement was tabled by the European Commission (EC) in March 1990, and was entitled the "Draft Agreement on Trade Related Aspects of Intellectual Property" (Alsegard, 2004: 3). The US also submitted a draft of the same title. Many countries disagreed with the proposals in full or in part, filing additional proposals, but what the developing countries were most concerned about was the inclusion of pharmaceutical products in the agreement (Alsegard, 2004: 3). It is important to note that, although the pharmaceutical industry was not party to the agreement, it was a very powerful lobbyist (Alsegard, 2004: 4). The developing countries tried to create a coalition of the unwilling, but the US used its Section 301 Special Trade List to threaten unwilling nations and split the alliance (Baker, 2003: 15). This meant that the US put "IP into the frame of inter-governmental trade negotiation, making it a

prominent part of bilateral agreements with countries such as Korea and Brazil, and using its Trade Act powers to block imports into its territory where a country did not come up to scratch on the IP front" (Cornish, 1997: 100).

In June 1990 a "Chairman's draft" was put forward which combined all of the suggested proposals, and in further discussions it became clear that pharmaceutical patents needed to be discussed and debated at length (Alsegard: 2004: 3). TRIPS was signed at Marrakech in 1994 and caused much controversy. First, it required that governments change their national legislation. Second, the agreement also applied to basic necessities, such as medicines (Narlikar, 2005: 81). TRIPS then changed two important things: it strengthened the international dispute resolution capacity in relation to intellectual property, and it removed the individual state's discretion under the Paris Convention to determine the extent of patent protection (Sacco, 2005: 106). "Under its key patent provisions, member countries must provide patent protection, for a minimum of 20 years from the filing date of a patent application, for any invention, including a pharmaceutical product or process, that fulfils the criteria of novelty, inventive step and usefulness" as stated in Article 33 and Article 27.1 respectively of the TRIPS Agreement (Baker, 2003: 15). Although countries have always had some existing system of protecting IP, because the risk of a free rider problem would deter any would-be inventions and innovations (Narlikar, 2005: 81), it had always been up to each individual country to determine the inclusion of medicines. Article 27.1 now specifically forbids their exclusion. Similarly it is no longer acceptable to discriminate against imports in favour of locally produced products, "thus allowing major pharmaceutical companies to control the place of production" (Baker, 2003: 15). Article 28 secured the pharmaceutical industry's rights to exclude others from making their product.

Despite these limitations, the TRIPS Agreement does contain some flexibility. Article 6 allows for parallel importations and Article 31 gives the right to issue compulsory licenses. Parallel, or 'grey', importing is when country A chooses to import the same patent brand drug from country B because the drug is sold for less in country B. Parallel importing, then, is not the importation of generic drugs in the case of pharmaceuticals. The TRIPS Agreement specifies that none of its provisions, except those dealing with national public health treatment, can be used to address the issue of parallel importing in a WTO dispute. This means that "even if a country allows parallel imports in a way that another country might think violated the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved", as stated in Article 6 of the TRIPS

Agreement (The World Trade Organization, 2003). Compulsory licensing[4] is when a government allows someone else to produce the patented product or process without the consent of the patent holder (The World Trade Organization, 2003). Although mainly associated with pharmaceuticals, it could be applied to other patents. A government is only free to use this option once they have unsuccessfully attempted to obtain a voluntary license from the patent holder (Article 31b). In addition to this, if a compulsory license is issued, an adequate fee must be paid to the patent holder (The World Trade Organization, 2003). However, for a national emergency or for government use there is no need to try for a voluntary license. A provision also exists for a country to begin work on a new generic medicine before the patent of that drug expires; this is known as the Bolar provision[5] (Horton, 2000: 1541). These are only some of the limits and flexibilities that the TRIPS Agreement has to offer. Why, in spite of the drawbacks, would developing countries chose to sign? Narlikar offers three reasons:

- As mentioned before the US imposed unilateral trade sanctions on developing countries for violating US patent law and placed several countries on their priority watch list. Thus developing countries saw TRIPS as an opportunity to curb unilateral trade sanctions with multilateral ones (Narlikar, 2005: 82).
- Secondly there are the concessions that TRIPS offers exclusively for developing nations
- Due to the technicalities of the TRIPS negotiation process many thought that the agreement would deal mainly with counterfeit goods[6] (Narlikar, 2005: 82).

What the above brief history of intellectual property rights has shown is that the protection of intellectual property is in no way novel. With increases in trade, technology and travel (the products of a globalizing world), greater need for intellectual property protection has arisen. When plans for an ITO emerged, which later became GATT, it was hoped that free and fair international trade would be seen as a means to foster international co-operation. With this view on trade being central, however, more commodities would become accessible to more countries and thus the risk or inevitability of copies and counterfeit technology as well as the resulting products would increase. The TRIPS Agreement standardizes IP protection and ensures that individuals have a right to protect their ideas and the

[4] It is important to note that the term "compulsory licensing" does not appear in the TRIPS Agreement; instead, the phrase is "other use without authorization of the rights holder". Compulsory licensing is one form of "other use".
[5] The Bolar Provision allows testing and regulatory approval of generic versions of drugs before the patent expires, to ensure that generic copies can be introduced immediately upon patent expiry (Malpani & Kamal-Yanni, 2006).
[6] At the time developed countries had experienced a severe drop in exports due to the increase in trade of counterfeit goods.

resulting products. The pharmaceutical industry lobbied strongly for medicines to be included in the agreement, and one undeniable effect of TRIPS has been to consolidate the economic power and monopoly privileges of the proprietary drug industry (Baker, 2003: 16). Although there has always been some resistance towards the TRIPS Agreement in one form or another, no factor has more clearly illustrated the negative effects of the TRIPS Agreement than the problem of access to antiretroviral (ARV) treatment in light of the HIV and AIDS epidemic.

2. Big Pharma vs. Little Doha

The TRIPS Agreement was the first time that essential ***processes*** and their resulting products, like medicines, could be patented. Prior to TRIPS, a patent on a new pharmaceutical compound (called a composition of matter patent) would be shorter than the patent for its commercial process (Sykes, 2002: 51). The inclusion of process patents was of particular interest to the pharmaceutical industry because it is not uncommon for a new compound to precede its commercial use. In fact the failure of many developing countries to protect process patents led the US to place them under their Section 301 watch list (Sykes, 2002: 51). The argument for patents, put forward by the (mainly American) pharmaceutical industry, is that the cost of research and development (R&D) for these sorts of products is high, whereas the cost of production is low. For every new successful drug on the market, there are countless numbers of drugs that fail. The cost of these unsuccessful attempts needs to be recouped if the industry is to remain profitable. Patents ensure that the pharmaceutical company will earn back the money spent on R&D and also receive payment for introducing new technology that other companies or individuals can build on to improve the previous drug, thus providing the incentive for more R&D. During the TRIPS negotiations the greatest demands came from the American government (which was under immense pressure from the Pharmaceutical Manufacturers Association PMA) to secure the extension of patent systems to chemical and pharmaceutical products (Cornish, 1997: 100). Despite the inclusion of pharmaceuticals in TRIPS, developing countries signed for reasons already outlined. And although developing countries, including least developed countries, were given concessions such as an extended term to become TRIPS compliant[7], the bulk of the TRIPS Agreement sets up blanket standards that apply to all signatories, despite their apparent differences.

The TRIPS Agreement served to heighten the so-called North-South divide with regard to intellectual property rights. Developed countries generate the bulk of new inventions and have historically maintained the greatest degree of national patent protection, whereas developing nations generate fewer new inventions, and have had little or no national patent protection (Sykes, 2002: 49). As a consequence developed countries often accused developing countries of piracy because they had benefited from technology developed elsewhere without having to pay royalties (Sykes, 2002: 49). However, not only are there differences within developing countries, developed countries and least developed countries, there are also differences between these categories of country. Evidence seems to

[7] Developing countries had until 2005 and least developed countries have until 2016 to become TRIPS-complaint.

suggest that intellectual property benefits are dependent on the level of development in a country (Mayne & Bailey, 2002: 12). Similarly the markets for pharmaceuticals in countries with different development levels are also different. Kremer (2000: 69) distinguishes between the markets for pharmaceuticals in developing countries compared to those in the developed world. It must be stated that, even though much emphasis is placed on market distinctions, this factor, although dominant is not the only one and is in fact directly interrelated with other factors such as development. Market distinctions, as will be shown, begin to illustrate the problems associated with having a sole mandate governing intellectual property protection.

Firstly, the market for pharmaceuticals in the poorest countries is tiny. Developing countries, where three-quarters of the world population lives, account for less than ten percent of the global pharmaceutical market ('t Hoen, 2002: 28). According to the Pharmaceutical Research and Manufacturers of America (PhRMA) only one percent of their market is in Africa, and this estimate includes South Africa (Kremer, 2000: 70). The majority of PhRMA's market is in America (39.6 percent), Europe (26.1 percent) and Japan (15.4 percent). However, developing countries spend a higher percentage of their health budgets on pharmaceuticals than developed countries (Kremer, 2000: 70). For example, for 2007 South Africa has allocated R48 billion to health, which is 12 percent of GDP. Regardless of the small size of middle income country markets, they are a significant growing source of revenue for pharmaceutical companies (Kremer, 2000: 70). ARV treatment in developing countries is an example. Medicines sans Frontiers (MSF), Oxfam and other NGOs showed that the most affordable and appropriate ARVs were blocked by patents in countries which represented 81 percent of Africa's AIDS burden (Mayne & Bailey, 2002: 8).

Secondly, "developing countries face a significantly different disease environment than developed countries due both to their poverty and their geography" (Kremer, 2000: 70). In low and middle income countries the disease burden consists mainly of infectious and parasitic diseases whereas in high income countries the burden mainly consists of noncommunicable conditions like cancer (Kremer, 2000: 71). Sub-Saharan Africa, unlike the rest of the world, deals with an HIV and AIDS epidemic of astronomic proportions. The region accounts for 70 percent of the world's HIV infections and 90 percent of AIDS-related deaths (Walker et al, 2004: 106). With 4.7 million people living with HIV and AIDS, South Africa has the second largest population of people living with this disease in the

world, surpassed only by India[8]. And although there are many factors that are responsible for the rapid spread of HIV and AIDS in South Africa, one of them is widespread poverty and economic marginalization. There is a causal relationship between poverty and unemployment. Because there are not enough jobs for semi-skilled workers, "short term survival strategies frequently supersede considerations of long term well-being" (Barnard, 2000: 160), and many are thus forced to exchange sex for money or take up casual job offers in risky areas which increases the risk of HIV transmission.

There are thus considerable differences between the economic climates in developing countries and those of developed countries with reference to pharmaceutical markets. Furthermore, the bulk of the HIV and AIDS epidemic exists in the developing world. Although Sub-Saharan Africa comprises only 10 percent of the global population, as has been mentioned the region accounts for 70 percent of the world's HIV and AIDS population (Avafia, 2005: 1). The main problem was that, under TRIPS, ARV treatment was excessively priced, rendering treatment inaccessible for those living with HIV and AIDS. It was thus perceived "as if the greed of the North and its industry was killing people in the South in their millions" (Alsegard, 2004: 4). The AIDS epidemic has made evident the fact that the cost of health care and drugs is becoming prohibitive in the entire world as a result of implementing TRIPS (Shiva, 2001: 86). HIV and AIDS is a global epidemic that defines the excluded of the world and, even more importantly, it defines those who can purchase well-being and those who cannot (Barnett and Whiteside, 2006: 6). While inaccessibility to ARV treatment is also due to stigma, ineffective public health care systems, poorly trained health professionals as well as a lack of generic alternatives, inability to afford treatment is a major factor. As a result, although in theory the TRIPS Agreement has provisions that all countries (developed, developing or least developed) can use, in practice these provisions are harder to implement if initiated by developing countries.

In compliance with the TRIPS Agreement, the South African government introduced the Medicines and Related Substances Control Amendment Act No 90 of 1997 (Medicines Act[9]) in order to fulfill the human rights commitment enshrined in the constitution. The Act arose in the context of increasing pressure on the South African state to provide ARVs to citizens, given a growing HIV and AIDS crisis. The Medicines Act was thus aimed at facilitating access to cheaper medicines in both the private and public sectors (Joni, 2002: 276). The Medicines Act would bring three important measures into place.

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[8] Although India has just fewer than six million people living with HIV/AIDS this is only one percent of the population, whereas in South Africa, nine percent of the population is living with HIV/AIDS.

[9] The act can be found at http://www.gov.za/acts/1997/a90-97.pdf

- Firstly it would allow the South African government access to cheaper drugs by using parallel importation[10]. This was due to the fact that South Africa was facing higher prices for several medicines than were found in neighbouring countries and, in several cases, than in the US and Europe (Love, 2001). Parallel importation then involves shopping around for the cheapest price on a particular brand drug in a different country. This means, to use Love's example, that if South Africa permits parallel imports it will be able to use the Indian version of Glaxo's AZT but not CIPLA's generic version of the same drug[11]. In the pharmaceutical industry price differentiation occurs among countries, with the US being the country with notably highest prices. CIPLA, a company in India, offered a version of a triple cocktail of antiretroviral drugs used to treat HIV to African governments for $600 per person per year and $350 for the same course to an NGO in Africa. The same drugs cost between $10 000 and $15 000 a year per person in the US. This is because "pharmaceutical regulation and prescription requirements in developed countries facilitate price discrimination across countries by making resale across national borders easier to block. As a result, price differentials between countries are often large" (Kremer, 2002: 74).
- Secondly the Act would compel pharmacists to dispense cheaper generic versions of off-patent[12] medicines when presented with a prescription, unless the brand version was requested by the prescribing doctor (Joseph, 2003: 442).
- Finally, and perhaps more importantly, the Act would also have forced the pharmaceutical industry to be more transparent about their pricing mechanisms (Mbali, 2004: 107).

Consequently in response to the Medicines Act, the PMA, supported by 40 drug manufacturing companies (later 39 due to a merger), filed a lawsuit[13] against the South African government. The passing of the Medicines Act was also attacked by the European Commission (EC) and the US[14] by means of economic sanctions. The suit was then filed on 18 February 1998 to force South Africa to drop an amendment to its patent laws (Alsegard, 2004: 4). The complainants claimed that the Medicines Act violated South African patent laws and that, although TRIPS compliant, in addition to parallel imports the Act could be used to allow compulsory licensing. This in turn would lead to the international

[10] Although in this case the South African government argued that they would not use the Act to issue compulsory licenses but rather only for parallel imports.
[11] Glaxo is a brand pharmaceutical manufacturer whereas CIPLA only manufactures generics.
[12] Off-patent means that the patent term has expired and that others are free to use, produce and market the product or process that has been patented. On patent means that the product or process is still protected by the patent.
[13] In the High Court of South Africa, Case Number 4138/98.
[14] The US placed South Africa on its list under Section 301, suspending duty-free access to its South African imports (Narlikar, 2005: 106).

exhaustion of patent rights. "Basically some countries have a 'first sale' doctrine, also known as 'exhaustion of rights', which says that the patent owner's rights are 'exhausted' when the product is sold for the first time, so the products can later be sold in cross border trade" (Love, 2001). A reasonable fee is paid to the patent holder when a compulsory license is issued, but this is only a fraction of the profit that the patentee would receive if the brand product was sold either as is or under parallel importation.

The South African government opposed the lawsuit. Two years after the lawsuit had been filed, in January 2001, the Treatment Action Campaign (TAC) joined the South African government in its defense (Joni, 2002: 276) by being allowed *amicus curiae* (friend of the court) status. The TAC's brief not only clarified the legal issues but also rooted the legal arguments in the reality of the AIDS epidemic in South Africa (Berkman, 2002: 154). Over little more than two months later, and despite going on for over three years, on 17 April 2001 the PMA withdrew their lawsuit and settled out of court.

Although the Medicines Act was passed to make medicines more affordable in South Africa, it was the issue of access to HIV and AIDS medicines that galvanized public opinion (Kasper, 2001: 14). The court case thus illustrated that an interpretation of the flexibilities of TRIPS and their use for public health purposes needed clarification to ensure that developing countries could use its provisions without threat of legal or political challenge ('t Hoen, 2002: 31). While the South African government had won its case, other developing countries were experiencing similar problems.

Brazil was not only one of the first developing countries to implement a national HIV and AIDS plan but also has one of the most comprehensive AIDS plans in the world, which to date has been used as a blueprint by 31 countries[15]. Brazil's programme includes access to free ARV treatment and that country is able to run a successful HIV and AIDS programme because it has the ability and capacity to manufacture drugs locally[16]. Globally, the Brazilian pharmaceutical industry is ranked tenth in terms of expenditure, and manufactures 18 percent of the ARV domestic demand (Bate & Tren, 2005: 2). Brazil is able to do this because pharmaceutical patents and processes were only granted and acknowledged if they were registered after 1996 (Bate & Tren, 2005: 2). Several ARV drugs were registered prior to 1996 and Brazil has thus been copying them legally (Bate & Tren, 2005: 2). The price of AIDS drugs in Brazil has fallen by 82 percent over five years as a result of generic competition whereas the price of drugs with no generic substitute has fallen by only nine percent ('t Hoen, 2002: 32). In the past eight

[15] The director general of the WHO, Dr. Lee, even appointed Mr. Teixiera, head of Brazil's AIDS plan, to formulate WHO's HIV strategy (The Kaiser Network, 2003).

[16] Although Brazil's AIDS program is admirable there has been concern over the quality of the generics that are being produced as well as concern over diminished interest in R&D for ARV treatment. See Bate & Tren 2005 for more detail.

years, the number of AIDS-related deaths in Brazil has been reduced by 50 percent (The Kaiser Network, 2003).

In February 2001, the US took action against Brazil at the WTO Dispute Settlement Body (DSB) over Article 68 of the Brazilian IP law ('t Hoen, 2002: 32). They tried to prevent Brazil from passing a provision in their patent law that requires a patent holder to produce locally (Kasper, 2001: 14). This decision, known as the 'local working' requirement, enables Brazil to continue promoting its local pharmaceutical manufacturing industry and in doing so to keep the costs of ARV treatment down. "This would allow the Brazilian government to issue a compulsory license for the local generic production of a medicine should the patented product not be manufactured within Brazilian territory within three years of the issuance of the patent" (Bate & Tren, 2005: 3). The US argued that Brazilian law not only discriminated against US owners of Brazilian patents but that it was also in violation of Article 27.1 and 28.1 of TRIPS. The US then came under immense pressure from international NGOs, because many felt the US's actions would have a negative impact on Brazil's successful HIV and AIDS programme. Furthermore, Brazil had also offered assistance to developing countries by transferring technology in order to help them increase manufacturing capacity ('t Hoen, 2002: 33). On June 25, 2001, the US withdrew the WTO panel against Brazil, mainly due to strong public pressure.

It is important to realize that the South African and Brazilian government would not have had the success that they did so easily and quickly without global mobilization. An important lesson that can be drawn is that global solidarity on social issues is very powerful (Geffen, 2001). NGOs have ensured this mobilization and thus have played a key role in guaranteeing access to medicines via the provisions in TRIPS. Not only did the TAC play a vital role in ensuring that the PMA withdrew their case against the South African government, but they have also charged large pharmaceutical corporations with excessive pricing. On September 19, 2002, the TAC lodged a complaint with South Africa's Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) (The Consumer Project on Technology, 2006). GSK and BI were found to have abused their dominant positions in the ARV market and had to extend the term of the compulsory license granted to Aspen Pharmacare, as well as grant three other compulsory licenses to different companies (The Consumer Project on Technology, 2006). Many other NGOs have also had similar success stories in various developing countries, but it was only in 1999 that MSF, Health Action International (HAI) and Consumer Project on Technology (CPT) organized the Amsterdam Conference on Increasing Access to Essential Drugs in a Globalized Economy, which brought together 350 participants from 50 countries and focused specifically on

increasing access to medicines ('t Hoen, 2002: 33). The Amsterdam Statement, drawn up at the conference, called for health to be made a priority at the WTO Seattle negotiations and demanded a balance between the rights of patent holders and the rights of citizens in intellectual property rights regulations (The Consumer Project on Technology, 1999). The Amsterdam Statement would ensure that both the implementation and interpretation of the TRIPS Agreement with regard to developing countries would be reviewed, and new avenues for ensuring R&D into neglected diseases would be explored. It has also served as a blueprint for the work of other NGOs. The continuous campaigning against the high prices that pharmaceutical companies were able to charge by NGOs ensured enough negative publicity to guarantee that the pharmaceutical industry would make changes.

Throughout the South African trial, pharmaceutical corporations began offering new discounts to South Africa and other poor countries; for example, BI offered nevirapine for free[17] (Barnard, 2002: 165). Similarly, Britsol-Myers Squibb made an offer to reduce ddI and d4T to US$1 per day, which means that the cost of a month's supply of a cocktail was reduced from R3000 to R1500 (Joni, 2002: 279). However, as Joni points out, this offer only affected the public sector and not the private, which also provides ARV treatment to a large section of the community (2002: 279). To put things into perspective: even at reduced rates, ARV triple cocktail therapy costs between $250 to $300 per person per year. To purchase treatment for four million at the cheapest price would cost $1000 million, and this is only the price for the medication; staff, roll out programmes and other factors and diseases still need to be included and considered. Thus even at reduced brand drug rates as well as generic rates, the government will still require financial assistance.

What all this begins to illustrate is that patient rights can be put before patent rights. Even though IPRs are not a natural right but a statutory right, multi national corporations (MNCs) have naturalized this right to protect what they have defined as their rights as owners of intellectual property (Shiva, 2001: 97). As Toby Kasper, coordinator of the Access to Essential Medicines Campaign of MSF-South Africa, put it: "the case was less about technical provisions to reduce drug prices than it was about the rights of a government to place the health of its people before private interests", and although specifically about South Africa, the same reasoning widely applies to the other factors discussed. These developments served to question the hierarchy of rights that the TRIPS Agreement appears to protect, and illuminated the problems with the TRIPS Agreement and its practical consequences. Such developments thus began to pave the road forward to Doha.

[17] Albeit exclusively for the use of prevention of mother-to-child HIV transmission.

In short, since the emergence of TRIPS, the developing world has been collaborating "to demand that public health be given a more meaningful role in the interpretation and implementation of the TRIPS Agreement" (Baker, 2003: 17-18). It was in particular the African Group (all the African members of the WTO), headed by Zimbabwe, that pushed for clarification on how the TRIPS flexibilities could be interpreted and how far their right to use them would be protected.

As a result, the June 2001 meeting had two clear clashing positions. On the one hand the EU and US advanced pro-pharmaceutical company positions and, on the other, the developing countries advocated the following:

> (1) developing countries have a broad spectrum of public health concerns, not just HIV and AIDS, and they are particularly concerned about the lack of research on so called neglected diseases;
>
> (2) patents raise prices and thus impede access to medicines;
>
> (3) developing countries should be free to use existing TRIPS flexibilities including compulsory licensing and parallel importation without being threatened by developed countries;
>
> (4) least developed members needed an extension of transitional periods beyond 2006;
>
> (5) developing countries need to be able to source generic medicines from exporting countries despite the "predominantly for domestic use" rule in Article 31(f) of the TRIPS Agreement; and
>
> (6) developing countries need assurances that the data protection rules in Article 39.3 would not impede registration of generics[18] (Baker, 2003: 18).

Initially the US denied that patent protection limited access to treatment due to high prices, insisted on limiting the discussion to diseases known as the big three (HIV and AIDS, tuberculosis and malaria) and tried to restrict parallel importation (Baker, 2003: 18). However, after 9/11 the US experienced an anthrax scare and threatened Bayer, who own the patent on ciprofloxacin, a preferred anthrax treatment, with compulsory licenses if Bayer did not supply the drug at low cost in the required amount. This quickly changed the US's stance, and on 14 November, 2001, the Doha WTO Ministerial Declaration on TRIPS and Public Health (Doha Declaration) was adopted[19].

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[18] See Proposal from a Group of Developing Countries, IP/C/W/312 (October 4, 2001).

[19] It is interesting to note that, after the Third Ministerial Summit talks failed in Seattle in 1999 due to protests, the Fourth Ministerial Summit was held in Qatar, a remote monarchy where public protest is ruthlessly suppressed.

Designed by developing countries to counteract continuing trade threats and a crisis in medical care (Baker, 2003: 18), the Doha Declaration affirmed the right of all countries to protect public health. WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines (The World Trade Organization, 2003). This is outlined in paragraph four of the Declaration and, while the Doha Declaration does not amend the rights and obligations laid down in TRIPS, it provides guidance for the interpretation of the relevant parts of the agreement (Alsegard, 2004: 4). This is because it was agreed "that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health" (The World Trade Organization, 2003).

The Doha Declaration states that each member state has the right to grant compulsory licenses and has the freedom to determine the grounds for such a license (Alsegard, 2004: 5). The Declaration, then, allows for governments to determine what constitutes a national emergency- including, but not limited to, the HIV and AIDS epidemic- in which case the procedure for issuing a compulsory license becomes faster and easier (Mayne & Bailey, 2002: 5). However, no African country, and this includes South Africa, has issued a compulsory license despite the public health crises with regards to HIV and AIDS. Furthermore, the declaration extends the transition period for least developed countries (LDCs) by another ten years, to 2016, on pharmaceutical products (Narlikar, 2005: 105).

Since the Doha Conference there has been much debate on paragraph six of the declaration, which addresses the effective use of compulsory licensing (Alsegard, 2004: 5): "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" (Paragraph six of the Doha Declaration). To reiterate: compulsory licensing is when a "government allows someone else to produce the patented product or process without the consent of the patent owner" (The World Trade Organization, 2003) and thus involves, in the case of pharmaceuticals, the production of generic medicines. Generic in this sense means copies of patented drugs or drugs for which patents have expired (The World Trade Organization, 2003). The Council for TRIPS was given until the end of 2002 to find an appropriate solution but, when the proposal was put forward, the US was the only country to object to it (Alsegard, 2004: 5). The US argued that 'countries with insufficient or no manufacturing capacities' should be limited to LDCs and should not include developing countries or countries that chose, for whatever reason, not to manufacture (Mayne & Bailey, 2002: 10). Conversely the EC suggested that Article 30 be interpreted to allow countries to export health products and that Article 31, which states

that compulsory licenses can only be used to serve the domestic market, should be deleted (Mayne & Bailey, 2002: 10). This would mean that health products can be exported to those countries with no manufacturing capacity. However the EC did argue that this option should be restricted to 'exceptional circumstances'. The African Group (41 members), which was also backed by developing countries such as India and Brazil, proposed that Article 30 should either be deleted or that it should be interpreted in such a manner that exports of health products are permitted (Mayne & Bailey, 2002: 11). Developing countries were offended by the US attack on their sovereignty and by its suggestion that only a few diseases (TB, Malaria, HIV and AIDS) should be covered by the paragraph six solution (Baker, 2003: 22). The majority of diseases listed by the US either had no effective treatment or had no viable medical treatment still under patent. This meant that "disfavoured countries would, according to Northern demands, have to favour AIDS patients over people with diabetes, or people with malaria over people with asthma" (Baker, 2003: 22). Almost all of the major causes of mortality and morbidity in Africa for which patented western drugs exist were excluded from the list (Sassen, 2003). This is problematic for a country with a HIV and AIDS epidemic. AIDS is a syndrome and thus it is opportunistic infections that cause death as a result of a weakened immune system. Hence, the need for treatment for opportunistic infections is equally important, as the necessity for ARV treatment.

However, rich countries would, by such interpretation of Article 30, only be able to issue compulsory licenses because they have the productive capacity to do so, whereas poorer countries with no production capacity, or those which solely rely on imports, would not be able to use the provisions. There are currently only a handful of developing countries that have the necessary manufacturing and innovation capacity; these include Argentina, China, Korea, Mexico and Brazil (Mayne & Bailey, 2002: 7). It is also, as Alsegard argues, "economically insufficient to require domestic production for every medicine a country may need" (2004: 7). And although production capacity is a barrier to local production, other factors such as regulatory barriers, trade secrets and general know-how cannot be ignored. A deadline was set to find a solution, but so far this has been passed several times and no solution has been found.

Even though in many developing countries most drugs are either not patented or off-patent, this does not help those who do not have the necessary infrastructure. Thus Article 31 of TRIPS is of no practical use to most developing and least developed countries. Furthermore those countries that do have the manufacturing capacity will not be able to produce vital new medicines that are put under patent because of the 20 year monopoly grant (Mayne & Bailey, 2002: 5). This illustrates once again that there

is a significant difference in treating countries equally and treating them the same. As Van Eeckhaute comments "What is at stake here is an issue of equal opportunities for all WTO members to enjoy the rights granted by the TRIPS Agreement" (2002: 17).

The Doha Declaration provides guidance for the interpretation of the TRIPS Agreement where applicable and should give developing countries greater confidence to make use of the provisions without the US or drug companies bullying them over patent policies[20]. But since its inception various members (developed country signatories) have interpreted the declaration in very different ways (Alsegard, 2004: 10). The fact that no developing countries or LDCs have used the provisions in the Doha Declaration needs to be examined. The next chapter sets out to explain this and, by doing so, finds that because of the HIV and AIDS epidemic and the different pharmaceutical markets, equal opportunity to use the TRIPS Agreement does not present itself. And precisely because of the HIV and AIDS epidemic, the legitimacy and scope of intellectual property rights is called into question because IP rights directly inhibit the realization of the fundamental human right to health.

[20] See Oxfam's "US Bullying: One Year after Doha" by Mayne & Bailey (2002) which shows that the number of complaints by the US has decreased but bilateral pressure from the US still continues in the form of TRIPS-plus provisions.

3. **Human Rights Patent Wrongs**

Intellectual property rights have to be discussed within the context of the global HIV and AIDS epidemic. When placed in context of the HIV and AIDS epidemic, intellectual property rights are called into question because of the demand for affordable and sustained access to pharmaceuticals needed to treat this disease and its opportunistic infections (Berkman, 2002: 151). While AIDS in an individual is caused by a virus, the epidemic is as much an economic, social and political phenomenon as a medical one (Berkman, 2002: 150). According to Barnett and Whiteside (2006: 171)

> Epidemic impacts are history-changing events. They terminate some lives, incapacitate others and stunt the capabilities of those who have to divert energy and time into care. In the end, sufficient numbers of deaths and illnesses make a society take a path other than that which it would previously have followed. This is impact.

The HIV and AIDS epidemic increases morbidity (sickness) and mortality (death) in populations at precisely those ages where normal levels of morbidity and mortality are low, and it is from this that other impacts stem (Barnett & Whiteside, 2006: 172). It is estimated that each day worldwide there are 1500 new HIV infections and 600 AIDS-related deaths (Walker et al: 2004: 15). Some 13.2 million children are orphaned every year as a result of the virus (Walker b, 2001: 109). This translates into a health sector that is put under immense strain because not only are ARVs expensive and complicated to administer[21], but opportunistic infections also need to be treated.

Overall development is hindered by the epidemic. Household incomes decline as a result of having to care for family members living with AIDS (Walker b, 2001: 110). Prevalence rates show that it is predominantly the breadwinner(s) of families that are at risk of contracting the virus, and as a result their life expectancy and economic activity dwindles. Those who are dependents, namely children and the elderly, have to take up the role of provider. Household budgets are stretched by medical expenses, with less left over for other important necessities such as food, clothing and education. "The financial impacts of HIV and AIDS on households are as much as 30% more than deaths incurred from other causes" (Walker et al, 2004: 16). This means that a family living just above the poverty line will be forced into poverty. In much the same way as individual households are affected, so are the wider economic structures. For example, the South African agricultural sector has seen a decline in output due

[21] i.e. The cocktail needs to be taken at exact intervals daily and treatment cannot stop earlier because then resistant forms of HIV/AIDS will form that cannot be treated.

to farm labourers being sick, and this translates into a potential threat to food security (Barnett & Whiteside, 2006: 238). Similarly in the business sector there have been huge market impacts as a result of employee absenteeism due to HIV and AIDS and this in turn has affected domestic economic growth (Walker b, 2001: 110).

HIV and AIDS are thus an obstacle to realizing the human right to health and life as well as the right to development (Walker b, 2001: 110). Access to treatment is the first step in lessening the impact of HIV and AIDS. Also, it should be recognized that, when treatment is not available, less incentive exists to get tested, since HIV positive status is not only associated with social stigmatization but is also tantamount to a death sentence. Life-extending treatment has the potential to keep families together for longer, which in turn has crucial implications for the well-being of the next generation in countries where the current generation of adults has been decimated by AIDS[22] (Berkman, 2002: 153).

A fundamental conflict exists between two radically different strategies for dealing with the global AIDS epidemic: the dominant strategy is rooted in property and profit maximization and the insurgent strategy is based on the human rights to health and life (Berkman, 2002: 151). The inventors of ARVs have a right to their own ideas, but at the same time individuals also have a right to health.

The pharmaceutical industry is like any other in one sense and, in another, completely different. In the first sense the industry consists of profit-oriented and-maximizing companies. This comes about because any pharmaceutical company has a responsibility to its shareholders to increase returns. The industry argues that, because it operates in the business world, it is unreasonable to expect it to be overly altruistic and charitable (Joseph, 2003: 436). As an executive vice president of Pfizer commented: "We are not the Red Cross. We are a for-profit company" (Cameron & Geffen, 2005: 184). Pharmaceutical companies feel the need to increase their profits, which means focusing on market share, investment returns, etc, and this in turn forces them to become more efficient, which translates into the cutting of costs.

The argument in short is that, like any other company, pharmaceutical companies supply a commodity. Detractors venture to suggest the contrary: that medicine is not the same as I-Pods and shoes. Yet medication is a commodity because it can be owned, consumed, bought, traded, and donated, and to a large extent is subject to market forces. However, it is when the scarcity of a particular commodity has the capacity to threaten human well being on a large scale that its distinctiveness from

[22] For a more detailed discussion on the mitigating effects as well as personal testimonies, see Cameron, 2005, chapter seven.

other commodities becomes apparent (Pellegrino, 1999: 247). Pharmaceutical companies produce and manufacture medicines that improve the quality of people's lives as well as save them. The WHO defines 'essential medicines' as those that satisfy the priority health care needs of the population, and are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness. Essential drugs should "be available at all times, in adequate amounts, in the appropriate dosage forms, with assured quality and at a price the individual and the community can afford" (Matowe, 2004: 718).While in the case of other commodities there is a willing buyer who chooses a product, with prescription drugs there is a captive market (Joseph, 2003: 436). In the case of HIV the absence of real choice is particularly acute. Only a small array of possible treatments exists; the choices are limited and rest on affordability. Moreover, the consequences of treatment being withheld are stark. The patient will die from opportunistic infections as a result of the syndrome if medication is not received. While, in a market-driven economy, ordinary commodities are fungible (any one of them can be substituted for any other similar commodity, provided price and quality are the same) (Pellegrino, 1999: 252), this is clearly not the case with medicines. Medicines have an inelastic demand. What the TRIPS Agreement effectively does is to further contract the already limited array of treatment options available to HIV and AIDS patients. In terms of the TRIPS Agreement, the possibility of using generics is delayed for at least 15 years.

Medication caters to human needs which are much more fundamental to human flourishing than any ordinary commodity (Pellegrino, 1999: 251). In some cases its provision is a matter of life and death. This is why, unlike other industries, pharmaceutical companies receive differential treatment in the form of research funding, monopoly grants and tax breaks at the public's expense.

Since 1996, as a result of research and development conducted by the pharmaceutical industry, a combination of antiretroviral or cocktail therapies has been available, and this has significantly prolonged the lives of those living with HIV and AIDS. These cocktail regimens not only delay the emergence of drug resistance but also lead to a more prolonged benefit than individual drugs (*Consensus statement, 2006*). As a result HIV and AIDS has changed from being an automatic death sentence to a manageable illness (Berger, 2006: 23). At the same time, access to ARV treatment is severely limited in developing countries where the major impact of the HIV and AIDS epidemic has been experienced. While the reasons for limited access vary, inability to afford the drugs is a major factor.

Even in the West, Joseph (2003: 428) argues, the price for ARV treatment is only sustainable due to government subsidies and private health insurance- and this price, is determined by a small group,

namely the world's major pharmaceutical companies. The only reason why such a small group has the power to decide what price to charge is because they have patents on these medicines. The pharmaceutical industry was one of the main lobbyists putting pressure on the US government to include IP protection of pharmaceuticals on the agenda during the GATT Uruguay Round negotiations. Furthermore, they continue to have the largest lobby in Washington and give abundantly to political campaigns, further increasing their power (Angell, 2004). The pharmaceutical industry claims that patents are necessary to cover R&D costs, to provide incentives and to promote technology transfer, so it is to these arguments that we now turn.

One of the most widely appealed-to arguments, when justifying patents for intellectual property, is the utilitarian one based on providing incentives (Hettinger, 1989: 47). The gist of this argument is that patents provide the necessary incentive to produce new objects that are of value to society. "Patents operate on the assumption that people are not inherently altruistic, and expect rewards for their endeavors, especially when those endeavors are risky as they may and often do result in costly failure" (Joseph, 2003: 431). If no patent protection existed, it would be more convenient and less costly to copy other products and then sell them instead of spending unnecessary resources on R&D. This is because patents allow the inventor to sell, produce and distribute the product for a limited period of time at a price and in a quantity they see fit. Patent rights are said to benefit users by making new and improved products available to them, which would not have been the case had no patent protection existed.

It is estimated that a pharmaceutical company will not bring out a new drug unless a return of at least $1 billion can be guaranteed, because for every new drug that is brought out on the market there are at least ten which have failed and consequently have to be compensated for. According to a study conducted under DiMasi, it takes $800 million[23] to develop a new drug (Cameron, 2005: 180). Money that is raised as a result of patent protection is needed to fund current, future and failed R&D costs. The pharmaceutical industry operates in an environment where marginal costs are high and production costs are low. This accounts for the industry's hostile attitude towards generic manufacturers. Generic producers only copy existing medication, and as a result do not have to invest any money in R&D. Similarly, a generic producer only has to prove that the generic drug is bioequivalent to its brand counterpart to be considered safe for human consumption. This eliminates the cost of expensive clinical trials that brand producers must bear. As a result, generics are sometimes 1000 times cheaper than their

[23] This estimate has been disputed and it is said to be more in the $400 million range; but because pharmaceutical companies refuse to make their budgets public, this cannot be validated (Angell, 2004).

brand counterparts. However, the existence of generics has served significantly to lower the price at which many medicines are offered by brand companies. Angell (2004) states that, when generics enter the market, the price usually falls to as little as 20 percent of what it initially was. To counter the threat of using generics as the norm rather than the exception, pharmaceutical companies argue that they will have less incentive to produce medicines for those markets where profit margins are low, because they will not be able to recuperate money spent on R&D (Berkman, 2002: 152).

Another reason why patents are cited as necessary for the pharmaceutical industry is that they promote technology transfer that otherwise would not occur. In return for the monopoly grant, and in order for a patent to be considered, the product description or processes need to be disclosed. This means that others can view information which would previously have been unknown, thus assisting in future developments (Joseph, 2003: 431). Without patents, the different pharmaceutical companies would have to use and keep trade secrets which would lead essentially to the reinvention of the wheel. Trade secrets do not require disclosure, whereas patents do. They are protected for as long as they are held secret, while patents lapse after 20 years. Also trade secrets involve less cost than defending and acquiring a patent (Hettinger, 1989: 33). However, in the pharmaceutical industry it is particularly important that previous innovations are built on and improved in order to combat old and new diseases more effectively. Trade secrets prevent this, because information is not disclosed and thus much money has to be invested in creating the same medication before any advancement can be made[24].

While apparently compelling, these arguments are undermined by the sheer magnitude of the profits in the pharmaceutical industry. The pharmaceutical industry is one of the most profitable in the world with an estimated net worth of $50 billion. In 2002 the combined profits ($35.9 billion) for the ten drug companies in the Fortune 500 were more than the profits for all the other 490 businesses put together ($33.7 billion) (Angell, 2004). While the cited reason for patent protection is to recoup R&D costs so that the incentive to innovate remains, expenditure on marketing is twice as much as that spent on R&D. Furthermore, much R&D is partially publicly funded- either directly by government or through universities.

To sum up, the main argument advanced for patents is that they are supposed to encourage both technology transfer and innovation, although these are seemingly contradictory effects. In any case, recent trends in new drugs seem to show that drugs are being developed that are similar to existing ones which are known to be profitable (Joseph, 2003: 434), so not much innovation is taking place. The

[24] This is obviously different for other commodities, such as Coca Cola which relies on trade secrets to stay in business.

majority of new drugs are not new but are, rather, variations of older drugs already on the market as companies attempt to acquire a share of an established lucrative market by producing a very similar top-selling drug, known as a 'me-too' drug (Angell, 2004). The R&D argument also does not seem to be a very strong one.

The Bill and Melinda Gates Foundation has granted $287 million of five-year grants towards the development of an AIDS vaccine, on the condition that those who receive grants must first agree to share the results of their work (Chase, 2006). However, many researchers turned down the grant because they either already had other funding, saw conflicting commercial commitments or felt uncertainty about the programme's impact on existing partnerships. As the vice president of Wyeth Pharmaceuticals adds, there is already sufficient funding for their vaccine discovery programme and they will continue to operate their own independent research programme (Chase, 2006). Out of the 78 drugs approved by the Federal Drug Association (FDA) in 2002, 17 had new active ingredients and of these only seven were considered to be improvements on older or existing drugs (Angell, 2002). Why should a company invest in an uncertain endeavor when they can change part of an existing drug and get another twenty-year monopoly grant?

Much research thus goes into so-called Western diseases such as cancer, heart disease and obesity, whereas most tropical diseases, found mainly in poorer Third World countries, lack new medicines for treatment. One way to lessen the focus on the development of medicines aimed mainly at the treatment of and cures for diseases that affect the wealthy and affluent parts of society, is to offer pharmaceutical companies tax reductions. This is currently only used for diseases that affect fewer than 200 people, and the drugs developed for these diseases are called 'orphan drugs'. Furthermore, because the major pharmaceutical companies own most of the patents, this in itself provides little incentive for smaller firms to develop new drugs. Smaller firms, particularly those in the developing and less developed world, are not able to recuperate costs on their new innovations because they have to pay patent royalties to the larger pharmaceutical companies who own most of the patents on medicinal products and processes. This leaves little incentive for smaller firms to innovate, and perpetuates the dependence on the large multinationals (Bell, 2006).

Similarly, much R&D is put into drugs that deal with chronic ongoing conditions instead of investing in vaccines which do not have the same ongoing market (Joseph, 2003: 435). Clearly it is more in a pharmaceutical company's interest to develop a drug that requires regular intake (and thus yields a regular income) than one that requires a single dose. Interestingly enough, the major best-sellers of the

pharmaceutical industry are going to come off patent soon, thus theoretically making innovative R&D even more crucial to secure higher returns.

The TRIPS Agreement says patent protection must be available for 20 years, and that protection must be included for both products and processes. Governments are only allowed to refuse a patent for an invention *if its commercial exploitation is prohibited for reasons of public order or morality* and this can also include diagnostic, therapeutic and surgical methods, plants and animals and the biological processes for producing them. This excludes microbiological plants and animals, however. Because of the patent term there is scope for uncompetitive prices and, because the pharmaceutical industry is cartelized[25], the problem of monopolies and high prices is worsened (Joseph, 2003: 428). In some cases patents are used to monopolize industries; for example, bigger pharmaceutical companies buy patents in order to suppress competition, and the power that this brings makes it almost impossible for new firms to enter the industry (Hettinger, 1989: 50). It is worth noting that there are only ten major players in the pharmaceutical industry, half of which are based in the US, while the rest are based in Britain, Sweden and France (Angell, 2004).There has also been a recent tendency for pharmaceutical companies to merge, leaving fewer but more powerful players. For example, in 1995 Glaxo bought Welcome for $14.3 billion and later merged with SmithKline and became known as GlaxoSmithKline (Gewertz and Amado, 2004: 307).

Most patent systems adopt this utilitarian view, which, according to Maskus(2000: 28) can be summarized as follows: "IPRs strike a balance between the needs for invention and creation, on the one hand, and the needs for diffusion and access, on the other". And although the R&D incentive argument has its flaws, it also holds much weight. Consider the opposing public rights view, which asserts that it is inappropriate to assign private property rights to intellectual creations and that information belongs to the public domain (Maskus, 2000: 27). This would limit the incentive to create, because most people are not altruistic, but would definitely promote technology transfer. Conversely, the natural rights view, which exists independently of any thoughts about incentive or economic cost, states that failure to assign ownership to someone's ideas constitutes theft and thus creators have a right to control any reworking of their ideas (Maskus, 2000: 27). This would limit technology transfer, because any diffusion of knowledge would rest on the goodwill of the patent holder, but would promote R&D because there would be financial incentive. The utilitarian argument thus strikes a balance between these arguments

[25] A cartel is a formal or informal agreement between a number of firms in an industry to restrict competition. Cartel agreements provide for a division of markets between firms in terms of their type of product (Black, 1997: 54). In this sense the pharmaceutical industry is the only one that can produce medicines.

and is used to justify protection offered by the state in the form of a patent. However these two utilitarian arguments for patents – incentive for R&D and technology transfer - have both been called into question. It may, however, be possible to defend patents on non-utilitarian grounds: to argue that people have a Lockean right to benefit from the ownership of their private (intellectual) property which cannot be undermined for the sake of social goals, however laudable.

According to Locke, private property is the only thing that individuals do not surrender when they join together in a social contract to establish a common authority (Zelleke, 2003). Objects produced by an individual through the mixing of labour with resources are the property of that individual alone (Ostergard, 1999: 159). But Locke does add in two limitations in his theory of private property rights, which are known as the 'Lockean Provisos'. The first is that one is allowed to appropriate from what is owned in the common without consent if there "is enough, and as good left in common for others" and secondly, one should appropriate only as "much as any one can make use of to any advantage of life before it spoils" (Locke, 1988: 288). Thus when you mix your own labour with something from its natural state, you must leave enough and as good for others and must also ensure that you do not take more than you need. By mixing your labour with something from the 'common good' you add more value to the object than it would have possessed had it been left as is. And it is precisely because of this increase in value that individuals have an exclusive right to their own property (Gewertz & Amado, 2004: 299).

Ostergard argues that the question of ownership in the cumulative inventive process poses a serious problem (1999: 159) for a Lockean defense of intellectual property rights. New ideas are based on and built from other people's ideas. In his theory of justice called the entitlement theory of justice, Robert Nozick has offered a contemporary defense of private property in a Lockean mode. Nozick interprets Locke's first proviso "where there is enough, and as good left in common for others" to mean that the acquisition of property through labour is only legitimate if other people do not suffer any net harm thereby. In other words, no one must be left worse off than they already are as a result of the acquisition. In the case of patents, even though they limit access, this does not constitute a violation of Locke's first proviso because the invention would not have existed without the efforts of the inventor. As Locke pointed out, when you add your own labour to an object and thereby increase its value, at the same time you reduce the pressure on other resources because you are making them available for others (Wolff, 1991: 104). Nozick's interpretation of Locke's proviso is that exclusivity is only allowed if it does not worsen the position of others.

For Nozick. if acquisition and transfer are just, then whatever property distribution results is just. In the case of patented medicines, individuals who cannot afford to buy a medicine at a certain price will not be worse off than they were before without the medicine[26]. Those who profit from selling medicines at this price can therefore not be said to be acting unjustly.

Nozick states that a monopoly grant, in which the inventor is permitted exclusively to produce and sell the product, is fundamental to an individual's right to his own ideas- but adds that it is essential that these rights are not permanent (Gewertz & Amado, 2004: 300). For example, the TRIPS Agreement fulfills this criterion by only allowing a (minimum[27]) 20 year monopoly grant. Nozick continues that monopoly grants are not exclusive for an infinite period of time, because the same ideas can be invented independent of each other. For example, an American virologist, Dr. Gallo, and a French virologist in Paris, Luc Montagnier, both independently discovered the AIDS virus which led to competing claims and a lawsuit by the French for credit and a share of patent loyalties from the HIV blood test (Chase, 2006). According to Nozick, the time limit placed on patents should correspond with the time that it would take for an independent discovery to occur (1974: 182). The reason for this limitation is to ensure that a just acquisition of property ensues, and not because the patent worsens the conditions of others (Gewertz & Amado, 2004: 301).

Nozick therefore emphasizes the importance of private property rights and, consequently, of the state's role in protecting these rights. The state provides this protection of IP rights in the form of patents. A patent prevents others from unjustly using an invention by giving the holder the exclusive right for a number of years to produce the good or use the process (Black, 1997: 344). As long as the acquisition of the patent- and the discovery of the innovation- has arisen from a previous just distribution, then entitlement is considered just. This means that any infringement of the patent by the state or otherwise is unjust, because the protection of IP is seen as the patent holder's basic right. There can be no justification for intervention or redistribution, because such an act will violate the individual's right to benefit from the labour of their own ideas (Gewertz & Amado, 2004: 302). The state, then, has no moral obligation or justification for violating intellectual property rights in order to produce desirable social outcomes such as healthcare benefits for the poor. One cannot justify policy outcomes that result from a violation of the principles of justice. Significantly, Justice Edwin Cameron, a respected high court judge in South Africa, refused to break patent laws when members of the TAC decided to import

[26] However, as a result of not having access to ARV treatment, individuals will arguably be worse off as time passes because their condition will deteriorate without medication.
[27] In South Africa it is 20 years, while in the US it is 25 years.

cheaper generic life saving drugs illegally, even though these actions partly led to the government making ARVs available in the public sector (See Cameron, 2005, Chapter 7 for more detail).

As we see, Nozick is concerned that the initial acquisition should be just: in other words, property should be acquired in accordance with recognized legal procedures rather than, say, stolen or acquired through deception. Because pharmaceutical companies file patents legitimately under the TRIPS Agreement and national legislation, they are the rightful owners of the medicine on patent and therefore are entitled to profit from their ownership. "Any distribution will be just as long as each possession was acquired either through a proper initial acquisition or through a just transfer" (Wellman, 2002: 70). Even though it would be noble of a pharmaceutical company to reduce ARV treatment to a price that developing countries and LDCs can afford, Nozick argues that they have no moral obligation to do so. Therefore as long as a patent is held, justice requires that pharmaceutical companies are allowed to use the product as they see fit (Wellman, 2002: 68).

Nozick stresses the separateness of persons, and argues that individuals have absolute control over themselves. It is for this reason that rights are inviolable: they can never be justly overridden (Wolff, 1991: 19). This libertarian theory of justice, focusing as it does on procedures for acquisition and transfer, is regarded as unsatisfactory by those who are discomforted by the highly unequal outcomes that such a theory allows. Furthermore, some argue that IPRs have less moral substance than forms of property rights, and that physical property cannot be equated with IP (Cameron & Geffen, 2005: 168). When a global standard is applied to intellectual property, such as occurs with the TRIPS Agreement, inequalities are worsened. Denying medication to the poor, who are more likely to get sick, further exacerbates the problem. The libertarian view thus implicitly reiterates the notion that the poor are undeserving (Cameron & Geffen, 2005: 197). Moreover, globalization accelerates the pace at which inequalities have been widened[28]. Globalization has also forced international law and institutions to acknowledge the emergence of MNCs as human rights violators, thus recognizing that companies also have human rights obligations (Ferreira, 2003: 1159). Ferreira (2003: 1163) points out that the UN passed a resolution stating that a lack of ARVs limits the realization of a right to health, and thus, however justly acquired, if an outcome results in a human rights abuse, surely this still constitutes a human rights abuse? This perhaps convincingly shows that outcome does indeed matter.

John Rawls (2003: 5) offers a different account of distributive justice which attempts to argue for a just outcome. Rawls' theory of justice rests on what he calls 'fundamental intuitive ideas' because he

[28] See Pogge for a more detailed description on the effects of globalization and the idea of global justice.

believes that these ideas can be agreed upon by different people with different conceptions of justice[29]. Those ideas that we use to organize and to give structure to justice as fairness as a whole is what Rawls says count as fundamental ideas. These are:

> 1. The idea of society as a fair system of social co-operation over time from one generation to the next
> 2. The idea of citizens (those engaged in co-operation) as free and equal persons
> 3. And the idea of a well-ordered society, one where a society is effectively regulated by a public conception of justice (Rawls, 2003: 5).

Justice as fairness takes the primary subject of political justice to be the basic structure of society; that is, the structure of society comprises its main political and social institutions and how they fit together into one unified system of co-operation (Rawls, 2003: 40). It is the basic structure of society which has an influence on people's life prospects; how well someone fares in life depends in part on their place in the basic structure and on the way that it is regulated (Brighouse, 2004: 37). For example, the poor are more deeply affected by HIV and AIDS because of their initial position in society and their inability to afford ARVs.

Rawls famously begins with the hypothetical 'contract of the original position'. He uses this idea to illustrate what restrictions on the principles of justice rational beings would agree to. We enter society by birth and only leave by death; thus society is not entered by choice. Furthermore, the basic structure influences other chosen contracts by influencing the principles of justice (Brighouse, 2004: 39). The original position then models two things: the first sets up the fair conditions under which we would agree the basic structure should be regulated, and the second stipulates acceptable restrictions on the reasons for putting forward certain principles of justice and rejecting others (Rawls, 2003: 80). But what would ensure that no one would set up principles that would be only advantageous to them? Rawls introduces the idea of a 'veil of ignorance'. This veil of ignorance ensures that no individual is aware of their own or others' talents and positions in society. It also ensures that the principles are impartial (Brighouse, 2004: 40). And because of this ignorance, all parties involved would want resources to be distributed so that the least advantaged in society would benefit because they may fall into the least

[29] Unlike Nozick's argument which appeals to the libertarians.

advantaged category[30] (Wellman, 2002: 67). In other words, the original position would make all of us, Rawls contends, "risk minimisers".

Who then counts as the least advantaged in society, and how does one ensure that the least advantaged are benefited? Rawls describes what he calls a 'thin theory of the good' which is "a theory of primary goods, which are the goods that people would have reason to care about having regardless of whatever else they have reason to care about" (Brighouse, 2004: 44). Primary goods are divided into three categories, namely: natural primary goods, social primary goods and self respect. The first, natural primary goods, are things such as health, intelligence, body parts, talent, etc. and are not available for distribution. Social primary goods can be distributed, and self respect depends on the distribution of social goods but is not itself distributed (Brighouse, 2004: 45).

Rawls uses two principles of justice that govern the assignment of rights and regulates distribution of social primary goods: the liberty principle and the difference principle. The first, the liberty principle, states that "each person has the same indefeasible claim to a fully adequate scheme of equal basic liberties, which scheme is compatible with the same scheme of liberties for all" (Rawls, 2003: 42). This means that we all have equal rights to basic liberties such as the right to health and freedom of speech. The second principle is twofold. Rawls states that social and economic inequalities are only permissible if they satisfy two conditions: first they are to be attached to offices and positions open to all under conditions of fair equality of opportunity; second, they are to be to the greatest benefit of the least advantaged members of society (2003: 43). The first part implies that each person should be able to compete on an even playing field, or that each person should have fair equality of opportunity (Wellman, 2002: 66). The second part, known as the 'difference principle', claims that social and economic inequalities are to be arranged so that they are to be of the greatest benefit to the least advantaged or worst-off members of society. In order for any inequality to be justified, it must benefit the least advantaged person in society (Gewertz & Amado, 2004: 302).

Patents are there to reward invention and promote technology transfer. The case of ARV provision illustrates that, as a result of this patent protection, many cannot afford the necessary treatment. Thus the least advantaged people in society do not only *not* benefit, but, because HIV and AIDS is left to run rampant in their bodies, they are further harmed. It is important to note that the first principle trumps the second. For example, I cannot infringe on someone's right to health by offering

[30] Although hypothetically this may be sound, once people are in their various positions in society, many do not feel that they are compelled to help the poor; it is not a matter of duty but rather of charity.

them a large sum of money in return for violating their basic liberty: financial or any other compensation would not be satisfactory, according to Rawls. In other words, the principles are ordered in lexical priority.

Here it is important to observe the characteristics of basic rights or liberties. Buchanan (1984: 56) cites four: firstly a basic right is entitled and owned; secondly it must be protected and failure to do so is an injustice; thirdly a basic right cannot be infringed upon because doing so would maximize overall utility; and finally a right applies to all humans regardless of race, gender, class or geographical location. From this it is clear that the right to health is an absolute right, whereas the right to intellectual property is not. MNCs are so powerful that, according to Ferreira (2003: 1160) they have become "organs of society" and, like individuals who enjoy certain rights, so do they. As Shiva argues, MNCs have thus naturalized IP as a right and in doing so have placed IPRs on par with fundamental human rights[31]. But even though intellectual property is a right, it is not a basic liberty in the Rawlsian sense of the term (Gewertz & Amado, 2004: 302). Furthermore because IP is not a liberty it is then not protected by the second principle. It is not protected from redistribution. Redistribution is only permitted if the action will create a more just situation, and it is the function of the state to provide (re)distribution (Gewertz & Amado, 2004: 303). For example, the state already does this in the form of taxes. But further redistribution is justified for two reasons: firstly because of the right to IP conflicts with an individual's right to health in light of the HIV and AIDS epidemic and, secondly, because redistribution of ARVs will create a more just situation.

Although this course of action would alleviate many of the immediate problems associated with the epidemic, such as less pressure being put on the public health system (because more people on ARVs means less people suffer from opportunistic infections), further repercussions (outcomes) need to be considered. As already stated, incentive is needed to develop new drugs, but nothing justifies the current excessive level of patent protection that the TRIPS Agreement outlines (Cameron & Geffen, 2005: 170). However, pharmaceutical companies insist that the current level of patent protection is essential to cover costs. Yet not only is the pharmaceutical industry one of the most profitable in the world overall, but percentage net profit is also high. For example in 2004 Pfizer, Merck, GSK and Roche all had profit margins of over 20 percent (Davidson & Greblov, 2005). If the state readily issued a compulsory license to begin the manufacture of on-patent ARVs, in the future companies will be reluctant to invest in drugs that cater for predominantly non-Western diseases, because the threat of not

[31] Even though MNCs receive these benefits it is not obligatory to return them, only commendable.

covering costs or securing returns would be constant. This would serve further to reduce the nominal research that does go into Third World diseases.

Ten of the top 15 pharmaceutical companies reside in the US and, as illustrated when the South African government was forced to take on the PMA, they were not only taking on corporate America but also the US government. South Africa is currently seen as the face of Africa and, according to Bond (2007), president Mbeki is seen as the George Bush of Africa, showing that South Africa is a country the US can work with. This poses challenges. Firstly, the US was one of the main advocates of IPRs and, not surprisingly, it is also one of the main beneficiaries thereof. If the South African government were to declare HIV and AIDS a national emergency, this would seriously undermine US confidence in the ability of the patent system to secure high returns. It would also expose the high prices of brand ARV medicines and this could cause public outrage in the US, where almost as much as 50 percent of the top 15 drug companies' medicines are bought (Davidson & Greblov, 2005). Furthermore "the growing inequality in poor countries under the context of neo-liberalism increases the market share for more expensive patent-based drugs among the wealthy" (Katz, 2003). Secondly, as the US has stated many times before, a country is either on their side or not- and if South Africa did issue compulsory licenses or used any other means necessary to distribute ARVs cheaply, the government risks losing the backing of the US[32].

In light of all of this, the next chapter sets out to examine what the South African government's response to the HIV and AIDS epidemic has been, and what factors (domestic and international) have constrained action.

[32] Previous actions of placing South Africa on their special watch list despite being TRIPS compliant support this.

4. "AIDS could have a more devastating effect on South Africa than apartheid".

Health and well being are not individual concerns: they are global issues (Barnett & Whiteside, 2006: 374). The HIV and AIDS epidemic "may be the epidemic that enables us to respond to the need for a common global public health. The epidemic makes us think how to bend global forces to provide more 'goods' for more human beings and in areas beyond what is usually thought of as health" (Barnett & Whiteside, 2006: 374). Many believe that it is the pharmaceutical companies' responsibility to lower prices and make medication more accessible to poorer countries, whereas others believe that pharmaceutical companies should work closely with NGOs and governments. The government thus faces conflict with big business over who is to pay for ARVs, with all sides having an incentive to persuade others to shoulder costs (Bond, 2002). Ultimately, however, it is the role of the state to protect the rights of its citizens. As Toby Kasper (2001: 14) comments: "it is clear that having flexible laws in place only leads to improved access to medicine if they are greeted by a government that is willing to act". For instance, under the Doha Declaration the South African government has a right to declare HIV and AIDS a national emergency and gain access to more affordable treatment as a result. But despite having ten percent of its population living with HIV and AIDS, the South African government has yet to declare a national emergency. Much criticism has been directed at the South African government regarding its approach to HIV and AIDS. However, government policy arises in the context of both *external* and *internal* inhibiting factors, and these factors are all connected in a symbiotic relationship. Both external and internal factors play out in the context of the current global economic institutional order, i.e. capitalism accelerated and powered by globalization.

Scholte (1997) argues that the state has altered its constituency in the face of globalization, and surrendered most of its sovereignty to forms of global governance that have, as a result, had bad effects for distributive justice. For example, South Africa had to adopt TRIPS in order to become a WTO signatory, which meant that national legislation had to be changed accordingly. The WTO and other intergovernmental regulatory frameworks, such as the IMF and the World Bank, illustrate global governance on a suprastate level. This top down approach detracts from a state's sovereignty, but another form of global governance known as 'marketized global governance' has the most influence on the state and emanates from the private sector. Examples include think tanks, foundations, supervisory

agencies and advisory councils (Scholte, 1997: 26), and corporations. Under marketized global governance, markets step in where states and global governance agencies have left gaps. At the same time, the construction and implementation of rules imposed by the private sector are rarely effectively regulated or challenged (Scholte, 1997: 24). The main beneficiaries of marketized governance are corporations. It is not surprising, then, as Anderson and Cavanagh (in Barnett & Whiteside, 2006: 397) observe, that, of the 100 largest economies in the world, 51 are corporations and only 49 are countries and that the top 200 Corporations' combined sales are bigger than the combined economies of all countries minus the biggest ten. This illustrates the power that corporations have and, more importantly, shows the power that pharmaceutical companies - as some of the largest of these corporations - have.

The pharmaceutical industry's campaign contributions and lobbying expenses in the US are second only to the insurance industry's (*The New York Times*, 28 March 2006) and, during the Uruguay GATT negotiations, the pharmaceutical industry put immense pressure on the US government to include IPRs in the discussion. In the recent documentary *The Corporation (2005,)* it is argued that corporations have displaced politicians and politics by the mere fact that they have gone global. Governments simply cannot control them. We therefore have a situation where industry and government are working together, and in this case it is the pharmaceutical industry and the US government. However, a separation has to be made between the institution and the individual. In the same documentary, Noam Chomsky illustrates this with an example of slavery and the slave owner. He states that the slave owner might be a charismatic person and may treat the slave well, but the slave owner is in no way responsible for pioneering slavery. In the same way the institution, in this case capitalism, which benefits and ensures the pharmaceutical industry's survival, has to be distinguished from the pharmaceutical companies' CEOs or employees.

Globalization is accelerated by capitalism, and pharmaceutical companies operate within a neoliberal capitalist framework. This means that the pursuit of profit is endemic to capitalism; it would not be capitalism if it did not do that (Nielsen, 2005: 191). This is the environment in which pharmaceutical companies find themselves operating. Similarly, South Africa also operates within this neo liberal capitalist framework and thus has to succumb to its various demands. But unlike pharmaceutical companies, whose main aim is to promote and protect IPRs in order to create research incentives and thus secure higher returns, South Africa has different domestic issues that complicate its response to protecting IPRs as well as the right to health. As Barnett and Whiteside (2006: 381)

comment, it seems that today the function of the state is to explain why it is not possible to do things that citizens may wish to have done on their behalf.

The state has been the traditional human rights duty-bearer (Joseph, 2003: 438), and it is thus not surprising that, according to a recent survey[33], citizens in a democracy expect the government to deliver all of their basic needs including health care. HIV and AIDS places increasing burdens on already strained health care systems. A government can only use resources that are available to it, and realizing each citizen's right to health can be taxing due to factors such as poverty and inequality. South Africa is a middle-income country with a population of 44 million and is not dependent on donor aid for its social services (Schneider & Stein, 2001: 724). The South African government has been able to fund educational health programmes, such as Love Life and Khomonani as well as free condom and femidom distribution. Yet South Africa remains the most unequal country in the world with a Gini score[34] of about 0.6, and has the second highest number of people living with HIV and AIDS. It is also then not surprising that HIV and AIDS prevalence is highest among those living in poverty.

The first AIDS cases in South Africa were reported in 1983, and at first the epidemic had its greatest impact among minority groups such as intravenous drug users, prostitutes and gay men (Walker et al, 2004: 12). The origins of HIV are surrounded by controversy because of what is implied about the epidemic. Different accounts have different implications. What is certain is that Africa, particularly Sub-Saharan Africa, now deals with the bulk of the epidemic. As South African President Thabo Mbeki asked: why has Africa had the world's most terrible HIV and AIDS epidemic (Illife, 2006: 58)? It is important to note that, as with Chomsky's distinction between the institution and the individual, a similar distinction can be made between the HIV and AIDS epidemic and the individual who is HIV positive or living with AIDS. An epidemic has what Barnett and Whiteside call 'impact' and, even though the government will be assisting individuals, it is crucial that HIV and AIDS policies are directed at the epidemic and not just at the individual or the disease.

Epidemics are in no way new to South Africa. In the 20th century hundreds of thousands of people died of smallpox, Spanish flu, TB and sexually transmitted infections (STIs). However, what is different about the AIDS epidemic is that, firstly, the illness develops very slowly with few apparent symptoms and, secondly, there is no vaccine or cure available (Walker et al, 2004: 61). These factors differentiate the AIDS epidemic from any other epidemics that South Africa - and the world at large -

[33] See www.afrobarometer.org

[34] The Gini coefficient varies between 0 and 1 - the closer to 1, the more unequal a society; the closer to 0, the more equal a society. For a more detailed explanation visit < http://www.warmafrica.com/index/geo/5/cat/1/a/a/artid/557>.

has had to face before. A short history of the HIV and AIDS epidemic in South Africa will reveal the factors that gave HIV and AIDS, the disease, epidemic status and will also illuminate the responses to the epidemic that served to develop the HIV and AIDS policy agenda.

In the 1930s and 1940s South Africa experienced a venereal syphilis epidemic[35]. Dr Kark, observing the epidemic, said: "without an understanding of the economic factors involved and the historical factors of the vast social pathological changes brought about during the last seventy years, no treatment will save the spread of syphilis in South Africa" (in Walker et al, 2004: 62). One of these factors was human migrancy. Unlike other industrializing countries, that used migrant labour only when in economic transition, South Africa used migrant labour as a continuous source of cheap labour in many industries but particularly in the mining industry (Walker et al, 2004: 62). South Africa was also governed along racial lines, with the 'white' minority controlling the 'black' majority. In 1948, under white minority government, migrant labour was formalized and legislated[36]. The so called infamous pass laws (influx control legislation) were imposed, and the Land Acts of 1913 and 1936 had already seen black people restricted to overpopulated rural areas except where their labour was needed in the urban economy (Schoeman, 2001: 323). The new job opportunities in the cities led to an increase in, at first, predominantly male (in the mining industry), then female labour (as domestic workers) in urban areas (urbanization). This served to unsettle and destabilize rural communities as well as disrupt social relations. In addition, labour migration contributed to the further impoverishment of rural areas in relation to urban areas[37] (Schoeman, 2001: 325). The preconditions for an epidemic, however, were already in place. The disruption of family life and both rural and urban overcrowding created by apartheid legislation set the stage for any sexually transmitted disease to reach epidemic proportions. South Africa was wide open to HIV and AIDS.

During the late 1980s South Africa was already witnessing the demise of apartheid. The then president, P.W. Botha, declared two unsuccessful states of emergency to try to control the breakdown of order. In 1985 the Government set up the country's first AIDS Advisory Group in response to the increasingly apparent presence of HIV amongst South Africans (Avert, 2006). While apartheid still ruled, if diseases broke out in 'non-white' areas, and it appeared as though the outbreak would affect

[35] Venereal syphilis was not differentiated from endemic syphilis, which was a pre-existing disease, but it was venereal syphilis that spread to epidemic proportions (Walker et al, 2004: 67).
[36] The term 'apartheid' was only coined in the 1950s, and the government was only 'apartheid' after the laws of the period had been passed.
[37] Much later, legislation was even passed which allowed HIV testing of foreign workers entering the country and, if found positive, they were prevented from entering and working in South Africa (Head, 1993: 25).

'white' areas, it was assumed that the diseases would be controlled (Walker et al, 2004: 73). Shockingly, during the Truth and Reconciliation Commission (TRC) it was revealed that HIV had been used as a weapon by the 'white' minority against the 'black' majority (Barnett & Whiteside, 2006: 166), further serving to racialize the disease. The year 1986 saw the collapse of the pass laws, but instead of improving living conditions, the effect was to increase the number of shack and informal settlements, particularly around urban areas (Walker et al, 2004: 83). It was these conditions that favoured even more the spread of STIs[38] and made it clear that HIV and AIDS would no longer be an epidemic confined to the marginalized, but that it would become a heterosexual epidemic.

Apartheid policies were engineered to benefit the white minority at the expense of and to the detriment of black majorities, as well as Indian and coloured populations. By the 1980s it became clear that a system based on 'separate but equal' policies – the polite face of apartheid - would no longer be sustainable, and talks with the aim of transforming South Africa into a democracy began. Many political leaders were returning from exile, and had witnessed at first hand what the epidemic could do. Speaking at an AIDS conference in Maputo, in 1990, Chris Hani showed that he knew this all too well: "We cannot afford to allow the AIDS epidemic to ruin the realization of our dreams" (in Marais, 2000: 4). In 1991 the Health Secretariat of the African National Congress (ANC) began discussions about possible actions around AIDS with the Department of Health, and in October of the following year, the two jointly hosted a conference on AIDS in South Africa (Schneider & Stein, 2001: 725). As a result of the conference, which brought together the ANC, the United Democratic Front (UDF) and the National Party government's ministry of health, the National AIDS Committee of South Africa (NACOSA) was founded, to develop a national strategy to deal with HIV and AIDS. The goals of this plan were to (a) prevent HIV transmission, (b) reduce the personal and social impact of HIV infection, and (c) mobilize and unify provincial, international and local resources (*HIV/AIDS/STD Strategic Plan for South Africa 2000-2005*, 2000). The AIDS plan was drawn up at a time when the National Bill of Rights was being formulated and debates around human rights were at their height (Schneider & Stein, 2001: 725). Many gay rights advocacy organizations, trade unions, NGOs and community based organizations (CBOs) were already working together to combat HIV and AIDS, and realized that any successful preventative and treatment programmes had to be situated within their broader social context. The struggle for a humane policy on HIV and AIDS thus informed the debate on and the struggle for constitutional rights (Head, 1993: 25). Furthermore, the government also had to admit that, in order to initiate a successful

[38] If a person has an STI then they become more susceptible to contracting the HI virus.

and comprehensive national HIV and AIDS programme, it had to work with NGOs and unions. NACOSA thus represented "a coordinated national effort that straddled political differences and included the major political players of the time" (Walker et al, 2004: 86).

In 1994 the new government immediately adopted the National AIDS Plan and declared it a Presidential Lead Project, which gave the AIDS programme special status and early access to resources (Schneider & Stein, 2001: 725). Significantly, the plan did not view the epidemic solely as a medical issue but also as an economic, political and social issue that permeated all aspects of society. The AIDS programme would thus offer a multisectoral response to combat effectively HIV and AIDS. At first there was tremendous support for the AIDS plan. The then minister of health, Dr Zuma, used the plan as the national framework for action; a programme director was appointed; and the AIDS budget was doubled (Marais, 2000: 13). However, the need for a smooth democratic transition overshadowed the need for a HIV and AIDS programme. Similarly, conservatism and the fear of talking about sex also contributed, as then President Mandela admitted: "I wanted to win and I didn't talk about AIDS" (Heywood, 2004) Thus, against NACOSA's recommendation, the HIV and AIDS plan was placed within a transforming health sector. This meant that the "power over AIDS policymaking was in fact concentrated in the Department of Health and the Treasury, and later the Presidency, rather than in Cabinet" (Butler, 2005: 600). The *raison d'être* was that HIV and AIDS could be dealt with more effectively in the health sector because then there would be no competing interests, as would be if it were placed across sectors. Because health is in part a provincial prerogative, AIDS was then vulnerable to further administrative obstruction, since many people from the old civil service were used to staff the new civil service and the provincial departments were unable to accommodate the required inter-sectoral challenges posed by HIV and AIDS (Butler, 2005: 593, 600). Indeed, as Schneider & Stein (2001: 726) note, one of the "ongoing difficulties experienced by the government AIDS infrastructure was in defining responsibilities and coordinating actions between spheres of government".

The new democratic government inherited a system that was meant to be authoritarian and was also corrupt. The new South Africa thus had to be built using a highly inefficient system which severely constrained and restricted what could and could not be achieved. The fundamental flaw of the AIDS plan was that it over estimated the implementation capacity of the new government during the transition period (Schneider & Stein, 2001: 726), and this served to deepen the tribulations. Moreover, although the financial commitment to the AIDS plan was weak, the failure to implement the plan cannot be linked directly to government funding (Marais, 2000: 26). Many government departments had problems with

spending the large budget allocations. For example, in 1995/6 only 51 percent of the total budget was spent, and this increased to 88 percent the following year, still leaving R10 million unspent (Schneider & Stein, 2001: 727).

Similarly, donors were discouraged from donating funds directly to NGOs but were encouraged rather to give any donations directly to the health department, which would then redistribute the funds. Yet central to any successful HIV and AIDS plan is that it needs to function at a grass roots level. Although NGOs and CBOs function in this way, the government's actions severed any strong ties that they had formed with civil society prior to 1994. This can be attributed partly to the belief that transformation lies, not with civil society *and* the state, but solely with the state. Despite this, the most cited explanation for the failure to implement the AIDS plan and for general inaction towards HIV and AIDS from the government is lack of political will. But, as will be shown, this is often used as a political scapegoat.

Marais argues that political will is an essential factor but by itself insufficient (2000: 28). Hindsight shows that projects initiated at presidential level are not necessarily successful. For example, take the failure of the Reconstruction and Development Programme (RDP) and the 'presidential lead' projects (Schneider & Stein, 2001: 726). Furthermore, commitment at national level would not guarantee that an initiative would filter down to provincial or municipal level (Marais, 2000: 29). Calling for more political commitment in a climate that is rampant with HIV and AIDS, although essential, has led to what Schneider & Stein (2001:727) describe as "searching for short term solutions". Scandal after scandal has erupted; these have not only questioned the government's commitment to combating the epidemic in South Africa but have also undermined any progress that has been made.

In 1996 a contract for R14 million was signed to produce the musical Sarafina II, intended to educate scholars about HIV and AIDS. This generated an enormous amount of negative press, and was the first subject to be investigated by the new office of the Public Protector (Walker et al, 2004: 87). As a result of the report, the contract was terminated and the show aborted. The uproar was not so much about the money (representing a cost of R2-R3 for every pupil who saw the show), but rather about the complete disregard for bureaucratic procedures (Marais, 2000: 33). Firstly the contract was not tendered for, and secondly the effectiveness of the play was questioned.

As the scandal behind Sarafina II started to die down, in February 1997 the South African government backed several domestically developed but ineffective AIDS drugs (Kremer, 2000: 73). The Medical Research Council denied applications for further testing on humans due to the drugs' toxicity

and questionable effectiveness (Walker et al, 2004: 87). It was revealed that Virodene (an organic solvent) had not even passed the most basic animal and biological testing (Schneider & Stein, 2001: 728). Despite these warnings, the government tried to speed up the release of Virodene, which breaches both ethical and procedural guidelines for releasing any new medication, not only in South Africa but also the world (Marais, 2000: 34).

In August of the same year, the Minister of Health announced that AIDS (not HIV) would be made notifiable. This was in stark contrast to the 1997 National Review and to the AIDS plan that worked within a human rights framework, so that both valued confidentiality (Marais, 2000: 42-3). According to Cameron "stigma - a social brand that marks disgrace, humiliation, and rejection - remains the most ineluctable, indefinable, intractable problem in the epidemic" (2005: 53). Dr Zuma reasoned that by making AIDS notifiable, stigma would lessen as a result. Various bodies proposed more efficient and less problematic methods, and these proposals were put to the Minister through the AIDS Advisory Committee (AAC) - which was terminated shortly after it commenced, with a response still pending (Schneider & Stein, 2001: 728).

In 1998 and 1999 the scandal continued when the government questioned the safety, feasibility and practicality of Azidothymidine (AZT). In 1998 the government withheld funding supposedly due to budget constraints. In response the TAC was formed, and it was found that the reasons cited for denying AZT were unjustified. GSK, the patent owner of AZT, had lowered the price by 70 percent (Mairais, 2000: 40). Then in October 1999 President Mbeki said AZT was toxic and dangerous, and in November of that year the newly appointed health minister, Manto Tshabalala-Msimang, said that tests showed that mice given AZT developed cancer (Marais, 2000: 40). At this time the PMA took the South African government to court when it tried to provide cheaper ARV treatment to its citizens by manufacturing generic drugs locally, clearly allowed by a clause in the TRIPS Agreement. The case was dropped by the PMA in 2001, which settled out of court in favour of the South African government. It is important to realize that the South African government would not have won the court case so easily and quickly without global mobilization. The victory seemed to illustrate support from the government for providing ARV treatment, but in 2000 President Mbeki shocked the world by announcing plans to the contrary.

The National AIDS Committee (SANAC) was launched but it excluded scientists and activists and consisted mostly of so called 'AIDS dissidents', i.e. those who held controversial views on the epidemic. The President's spokesperson, Parks Mankahlana announced that the panel would answer questions that included whether or not AIDS exists, what it is, and what the causes are (Cameron, 2005:

106). One such dissident on the panel, US-based David Rasnick, claimed that "they [Africans] are not suffering and dying from something new called AIDS", adding that AIDS was caused by recreational drug use, ARVs and poverty (*Mail & Guardian*, 9 April 2001). At the 13th international AIDS conference held in Durban later that year, the world anxiously awaited for clarification. President Mbeki openly questioned the causes of AIDS. In an interview with Time magazine, when asked about his dissident views, he replied: "No, I am saying that you cannot attribute immune deficiency solely and exclusively to a virus" and maintained that factors such as poverty, poor nutrition, contaminated water and other diseases were to blame (*Mail & Guardian*, 11 September 2000). The socio-economic causes of HIV and AIDS were investigated and not the viral causes (Butler, 2005: 594). In response to this, 5000 researchers and scientists world wide issued a 'Durban Declaration'[39] stating that HIV causes AIDS, full stop (Schechter, 2000). Similarly there was a call for treatment to be made available in resource poor settings (Barnett & Whiteside, 2006: 366). Schechter (2000), who often reports on Mbeki and regards him highly, said that President Mbeki questioning the cause of AIDS reminded him of when P W Botha was supposed to end apartheid in 1989 with his 'crossing of the Rubicon' address; "Botha blew it then too, refusing to satisfy world opinion".

Although Mbeki never directly said HIV does not cause AIDS, and much can be said about factors such as poverty that may indeed increase the risk of HIV infection,

> The fact that the president flirted with, or even bought into, the dissident position on HIV and AIDS, is his business and his business alone. The fact that he left the marks of his lapse of good judgment not only on AIDS policy but on the reputation of South Africa affects us all (*Mail & Guardian*, 9 June 2000).

Departing from the scientific medical norm, as is the case in South Africa, widens existing problems and causes new ones. At first the South African government would not supply Nevirapine to pregnant HIV positive mothers, citing as reason that the drug was toxic. Yet Nevirapine prevents mother-to-child HIV transmission. This is made worse by the fact that many 'doctors' like Mathias Rath claim to have invented a cure for AIDS which many believe to be true, partly due to President Mbeki's failure to denounce such 'cures'. Rath promoted vitamins as a substitute for ARVs. The TAC filed a lawsuit against the Medicines Control Council (MCC) because it failed to take any action against Rath's illegal activities, which it is obliged to do (Meerkotter et al, 2006: 13). Despite of all these goings-on, however, condoms were still distributed, public health awareness campaigns were sponsored and medicines to

[39] See www.durbandeclaration.org

treat STIs were purchased (Walker et al, 2004: 125). Such reactions by the South African government[40] (as well as some independent constituencies) breed uncertainty and undermine public confidence with regard to the effectiveness of ARV treatment, and arguably worsen the epidemic.

These factors serve to intensify the division between the state on the one hand, and scientists, along with those in favour of treatment, on the other (*Mail & Guardian*, 8 August 2003). Butler proposes that post-apartheid HIV and AIDS policy making in South Africa falls within two paradigms: the first is a "nationalist/ameliorative paradigm that focused on poverty, palliative care, traditional medicine, and appropriate nutrition", and the second is a "mobilization/biomedical paradigm that emphasized societal mobilization, political leadership and antiretroviral treatment" (2005: 591). Although Butler concludes that the ANC accommodates proponents of each paradigm and that the dangers of a faulty ARV programme best explain the government's continued adherence to a cautious prevention and treatment policy[41], this thesis argues that there are other factors at play that prevent the successful implementation of an HIV and AIDS programme.

Firstly, why would someone deny the link between HIV and AIDS? As Mbeki put it: "the problem is that once you say immune deficiency is acquired from that virus your response will be antiretroviral drugs" (*Mail & Guardian*, 11 September 2000). In 2001 the use of ARVs in the public sector was rejected by the Minister of Health despite reports from the Medical Research Council and World Health Organization (WHO), which support the use of ARVs. These reports arise from the premise that HIV causes AIDS (*Mail & Guardian*, 10 March 2003). Furthermore, the mortality statistics released with regard to HIV and AIDS were questioned by the president: "I think we should wait for the work of the scientists about this because that is precisely the question they are raising, these scientists - How are these figures arrived at" (*Mail & Guardian*, 23 March 2003).

Mbali (2004: 104) argues that denialism[42] in South Africa can be understood to be driven by five factors. The first comprises the medical findings of dissident scientists, the second is the extent of the epidemic, the third is a strategy to avoid conflict over IPRs, the fourth a way to allow the government to continue adopting poverty-sustaining neo liberal policies, and the final factor is the idea that the 'African' is inherently a diseased racial and sexual 'other'. It is important to see that all of the above factors are linked and cannot be viewed in isolation.

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[40] The South African government is not united in its responses to HIV and AIDS. There has been much criticism from both inside and outside of the ANC.

[41] Butler refutes the idea that denialism can explain the government's actions.

[42] Denialism refers to the set of dissident views regarding HIV and AIDS.

If the government believes that ARVs are toxic, then there appears to be no reason to confront the powerful pharmaceutical industry and the constituencies that strongly support them - i.e. the US government, - for cheaper or generic drugs (Mbali, 2004: 108). In the year 2000 the *HIV and AIDS/STD Strategic Plan for South Africa 2000-2005* was launched, and showed promise because of its multi-sectoral approach. However, even though the plan was based on a template provided by the United Nations (UN), "it lacked concrete commitments and timeframes, and created controversy by evading analysis of ARV options" (Butler, 2005: 595). Strangely enough, in August 2003 the government did announce a national public ARV roll-out programme, even though they had not denounced their dissident stance on the use of ARVs. This position was adopted, following protests by the TAC, and it was suggested that there would be 53000 people on treatment by April 2004[43] (Barnett & Whiteside, 2006: 366). This includes providing ARV treatment to rape survivors, pregnant women and to those with a CD4 count of 200 or less[44].

It must be reiterated that ARV administration is a complex process, and more importantly, requires good nutrition as well as a strong public health service infrastructure to be effective. The Department of Health has acknowledged the importance of nutrition repeatedly, but has thus far failed to place the value of proper nutrition in context. Granted that good nutrition has been proven to be essential for the effective use of ARV treatment, this is only one piece of the multi-dimensional puzzle. The South African government has reiterated that poverty is a bigger problem than HIV and AIDS and consequently needs to have priority over it. Indeed, as Chomsky adds: "I think there would be general agreement among specialists that he [Mbeki] is right in pointing out that hunger is a much worse killer than AIDS, and that hunger and other consequences of poverty contribute materially to AIDS" (Chomsky, 2006). People living in poverty, which is 70 percent in rural areas and 50 percent overall (South Africa Information, 2007), are more susceptible to disease due to their inability to afford basic services such as water and medication. As Farmer (2001) explains AIDS is a disease of inequality and poverty because "in an unequal world AIDS disproportionately affects the poor" (in Mbali, 2004: 109).

However, solely fighting poverty will not reduce the scale of the epidemic. Studies by Stillwaggon (2000:1006) show that the chain of causation between poverty and epidemic infection passes through a link of poor nutrition and related subsequent immunosuppression, and that this occurs before HIV infection (in Barnett & Whiteside, 2006: 19). Thus there is a need to fight poverty *and* AIDS

[43] Because of this commitment, HIV/AIDS was left out of politics during the elections. However, by April 2004 an estimate of only 6000 people were receiving ARV treatment (Barnett & Whiteside, 2006: 366).
[44] In the US, ARV treatment begins at a CD4 count of 800. A low CD4 counts indicates that the patient is unhealthy.

together, and not one or the other alone (Walker et al, 2004: 129). As Marais (2000: 54) warns, contextualizing HIV and AIDS and linking it to socio economic and socio cultural dynamics are crucial platforms in locating an effective response. Controversy arises when the disease is solely portrayed as a disease of poverty. Doing so creates notions of high and low risk groups, which leads some people in low risk groups to believe that they are exempt from the virus and its impact[45].

Fighting poverty and AIDS together requires a long-term commitment. Again, it is not only the price of ARVs that inhibits treatment or allows the spread of HIV and AIDS. Opportunistic infections, such as TB, also need to be treated. But the truth is that the state health care system does not have the capacity or infrastructure to treat those with HIV and AIDS.

South Africa has a large public health sector that is under-resourced and over used. While the public sector services 80 percent of the population, most of the resources are concentrated in the private health sector, which services only 20 percent of the population (South Africa Information, 2007). It is important to note that, during apartheid, the public health system was built to service the 'white' minority as well as prevent 'black' diseases from spreading to 'white' areas. Thus when the new government came into power, grave inequalities already existed in terms of infrastructure between rural and urban areas. What is making matters worse is that South Africa has a lucrative private health sector which is constantly growing but is only available to middle and high income individuals who can afford medical aid. HIV and AIDS places more pressure on an already weak public health care system because people get opportunistic infections, infants require care if the mother is HIV positive or has AIDS, counseling is required to get tested in the first place, treatment literacy needs to form part of ARV administration, etc. Furthermore, most skilled medical professionals (excluding nurses) choose to work in the private sector and thus a shortage of skilled staff exacerbates the problem. Consequently, any successful HIV and AIDS programme in South Africa requires a drastic improvement in the public health care system. Denialism allows the government to overlook the scale at which reconstruction in the public health sector is required, and thus 'lessens' the impact. This in turn serves to justify the expenses required to sustain neo liberal policies.

"What this rhetoric[46] ignores and often disguises is that the background for increasing HIV transmission is a background of neo-liberalism - a context where the rapid movement of capital is privileged over long-term investment and the ability of persons to secure their own livelihoods" (Basu,

[45] "We are all more alike than different, even if only on the basis of all being equally at risk" (Jones in Marais, 2000: 59).
[46] This includes statements about poverty, culture, high prices of ARVs and denialism, which are all used to ignore the magnitude of HIV and AIDS and delay a response to it.

2003). Bond argues this point further when he says, it is "that the class/race/gender character of South African health and social policy under conditions of a failing free market (known here as neo liberal) economic strategy is inhibiting prevention" (Bond, 2007). Ironically, Mbeki cites poverty and inequality as major problems that need to be dealt with in order to reduce HIV and AIDS in South Africa, yet it is the government's neo liberal policies that sustain and amplify poverty and inequality. Neo-liberalism encompasses values such as privatization, deregulation, a reduction in public expenditure (usually in social services), and allows activities to be controlled by the invisible hand of the market. For example, the South African Customs Union (SACU) trade agreement with the US "promotes rapid liberalization and the movement of capital over the securing of stable investment and employment, privileging companies who wish to set up base temporarily and shift capital at will" (Basu, 2003).

Evidence seems to suggest, that even though the South African government cites poverty reduction as more crucial than dealing with HIV and AIDS, its actions suggest otherwise. As Cameron notes, a dualism exists between governmental statement and action concerning AIDS, which the above factors illustrate. "HIV has the eerie capacity of magnifying our social ills, of underscoring our deepest fault lines, and so it is not surprising that it has been on the stage of the AIDS epidemic that the most contentious leadership dramas of our post-apartheid society have been played out" (Walker et al, 2004: 108). South Africa has both internal and external factors that constrain action, and these all play out in a globalizing world powered by neo liberal capitalism. Sadly, it appears as though those living with HIV and AIDS are "deemed unnecessary for capitalism's reproduction" (Bond, 2007). The requirements to combat HIV and AIDS go against neo liberal values and the relentless pursuit of profit, and instead necessitate emphasizing the value of human life regardless of monetary status. This is in opposition to the current *status quo*, an environment where intellectual property rights held by those in power thrive. As Mark Heywood comments: "the post-apartheid transition and the drama of political and social reconstruction has been accompanied by attempts to ignore, hide and marginalize the advance of the HIV and AIDS epidemic ". Thus any successful response to HIV and AIDS will force South Africa to deal with all of its problems and confront the consequences of apartheid while at the same time remaining a global player.

Recent developments and Conclusions

"The future of Southern Africa is dependent on governments in the region halting the effects of HIV and AIDS" said James Morris, the United Nations special envoy for humanitarian needs in Southern Africa (*Mail & Guardian*, 13 December 2006). Since South Africa's embarrassing display of garlic, lemon, African potatoes and beetroot as treatment for HIV and AIDS at the International AIDS Conference in Toronto in August 2006, the South African government has once again come under scrutiny from the international public with regard to its response to the epidemic. Shortly after the conference, 82 international scientists and 11 South African researchers composed a letter to President Mbeki, arguing that garlic and lemons are not an appropriate response to the disease and that people were dying unnecessarily because they do not have access to ARVs that slow down the progression of the disease (Koenig, 2006: 1378). The international pressure appears to be working. Locally, activists, organizations (notably the TAC) and scientists called for Health Minister Manto Tshabalala-Msimang's resignation or, failing that, for her to be fired, although neither action has been taken so far. Furthermore, SANAC was revived with the Deputy President at the head instead of the Health Minister (Koenig, 2006: 1378). In October of that year, represented by a team headed by Deputy President Phumzile Mlambo-Ngcuka and Deputy Health minister Nozizwe Madlala-Routledge, the government altered its usual reluctance to work with civil society. However, the founder of the TAC, Zackie Achmat, commented: "There's no question there's been a sea change [by the government] in terms of dealing with civil society, but there hasn't been a sea change yet in saving lives" (*IOL*, 6 November 2006). Though its actions are commended, the South African government's failure to provide an effective and timely response to the epidemic has led to the country having nine out of the ten highest prevalence rates in the world. A recent report by the United Nations Children's Fund (Unicef) states that, around the world, there are a total of 15.2 million AIDS orphans with the majority, 1.2 million, residing in South Africa (*IOL*, 17 January 2007). Although the government eventually agreed to provide ARVs in the public sector in 2003[47], only 200 000 people are currently on treatment, but a further 800 000 need it (*Mail & Guardian*, 29 November 2006). A UN report showed that 79 percent of those who required ARV treatment in South Africa were not receiving it (*IOL*, 24 December 2006). This is a direct result of the South African government's delay in taking action to curb the epidemic effectively.

[47] The government only began its roll out programme in April 2004.

On World AIDS Day in 2006, the South African government launched its new and improved HIV and AIDS policy. The *Broad Framework for HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011*[48] "represents the country's multi-sectoral response to the challenge with HIV infection and the wide-ranging impact on AIDS" (*Broad Framework for HIV and AIDS and STI Strategic Plan for South Africa 2007-2011*, 2006). The plan aims to reduce the new HIV infection rate by 50 percent (prevention), reduce the morbidity and mortality rates and lessen the socio economic impact of the epidemic by providing support to 80 percent of those who need it (amelioration), provide monitoring and evaluation on the scale of the epidemic (planning) and finally to uphold legal and human rights by lessening stigma and discrimination (amelioration again). Though the effectiveness of the new plan has yet to be tested, and activists still view the government's response to HIV and AIDS with skepticism, Tony Leon, until recently head of the opposition party in South Africa, the Democratic Alliance, said its mere existence "can only be considered a mammoth step forward from the moribund, not to say vegetative, policies of the health minister" (*Mail & Guardian*, 1 December 2006). Yet despite this, critics point out that Mbeki himself is still silent on the issue and this continues to breed uncertainty. Furthermore, the infamous health minister, dubbed "Dr Beetroot", issued a statement in November 2006 "lashing out at her critics and reaffirming her commitment to nutrition and traditional medicine in HIV and AIDS treatment" (Koenig, 2006: 1379). These opposing views within the government further serve to breed not only confusion but also cast doubts about the effectiveness of the new AIDS plan and the government's commitment to it. Moreover, it is clear that issues of infrastructure and state capacity need to be looked at to ensure that the goals set out in the new AIDS plan will be achieved. South African policy-makers definitely have a blueprint for what a successful HIV and AIDS plan *should not* look like but, like its predecessor, the new AIDS plan requires changes across sectors and on broad issues such as race, class, gender, poverty, unemployment and inequality in order to be successful. Nattrass (in van Wyk, 2004) notes that "the burden of AIDS will thus continue to be borne unevenly in South Africa. This is largely because of South Africa's high unemployment rate and the strong connection between unemployment, poverty and HIV infection". Complicating matters further is the fact that there is a newer more virulent strain of TB emerging as an epidemic amongst those who are HIV positive (Koenig, 2006: 1379). There is also the threat of a drug resistant form of TB. In November 2006, the National Health Department said 303 cases of the extreme drug-resistant strain of tuberculosis (XDR-

[48] The full text can be found at http://www.info.gov.za/issues/hiv/framework.pdf

TB) had been identified nationally[49] (*Mail & Guardian*, 30 November 2006). This is particularly threatening for those who are HIV positive and already have compromised immune systems. "We've got two epidemics clashing in a dangerous way. We can't carry on with business as usual," says immunologist Linda-Gail Bekker, co-director of the Desmond Tutu HIV Center in Cape Town (in Koenig, 2006: 1379). Undeniably AIDS "is a public health crisis, which not only has deep social roots, but challenges the very notion of what it means to be a society" (Nattrass in van Wyk, 2004), not only on a national level but on an international level as well.

In its annual report for 2006, the New York based human rights group, Human Rights Watch (HRW), commented that South Africa had failed to implement its human rights obligations as outlined in the constitution. "Particular areas of concern relate to the rights of migrants, refugees and asylum seekers, sexual violence against women and children, access to primary education in rural areas, and the government's response to one of the world's most serious HIV and AIDS epidemics" (*IOL*, 11 January 2007). All of these factors are intertwined and relate to the ever-increasing HIV and AIDS prevalence rates. For a while poverty was given higher priority than the epidemic but, as the Brazilian example suggests, a multi-sectoral response, like the one initially outlined by NACOSA and now present in the new HIV and AIDS plan, is required to combat the epidemic. This is because HIV and AIDS knows no boundaries. It crosses class, race and gender margins and unfortunately, because of the appalling living conditions the poor find themselves in, they are most adversely affected by the epidemic. As Nelson Mandela proclaimed at the International AIDS Conference in Paris in 2003: "AIDS is no longer a disease, it is a human rights issue". HRW adds that the world needs to acknowledge that human rights abuses fuel the epidemic, and calls for countries to crack down on human rights abuses (*Mail & Guardian*, 21 July 2006).

Although different factors vary in scope, none illustrates more evidently a denial of human rights, more evidently than the high prices pharmaceutical companies are able to charge for ARV treatment. This is due to the 20-year monopolies they receive on new drugs when filing for a patent, as outlined and protected in the TRIPS Agreement. Even the Doha Declaration on Public Health, which affirmed the right of a country to put patient before patent rights, has not helped to ensure that more countries facing a HIV and AIDS epidemic use its provisions. Significantly, it is the developing countries that experience the bulk of the HIV and AIDS epidemic, and therefore all of the issues surrounding access have been experienced by developing countries. This phenomenon has exacerbated

[49] Of those, 263 cases were reported in KwaZulu-Natal.

the North-South divide at a time when we live in a globalizing world. It comes about because one of the biggest consequences of globalization is the expansion of international trade (Pastor, 2006). So that MNCs have come to play a more prominent role in world politics, and in most cases surpass the power of the state[50]. Against such a background, the pharmaceutical industry was instrumental in bringing about the TRIPS Agreement, which outlines the minimum patent protection standards a WTO signatory can have. This patent system adheres to a utilitarian notion of patents, which states that patents are needed to provide incentive for R&D as well as to promote technology transfer. In the case of medicines, much money is needed for R&D to cover both successful and failed attempts and the exercise of patents allows MNCs to charge for medicines as they see fit. The state protects new ideas by issuing a patent which, under TRIPS, grants a 20-year monopoly for a product or process. Although patents are not called into question, what is questioned are the excessive levels of patent protection given to drugs which could ameliorate the HIV and AIDS epidemic. Medicines are not just another commodity. They save lives. Failure to gain access to essential medicines, such as ARVs, results in a violation of the human right to health, and sometimes to life itself.

This creates a dichotomy. On the one hand, there is an outcomes-based approach which looks past patent protection in favour of human life, and on the other hand, there is a process-based approach which holds the view that IP is a fundamental right and must be protected by the state. This places the state in the middle of the debate, because it needs to uphold IPRs as outlined in TRIPS as well as defend human rights which are protected by the South African constitution and the Universal Declaration on Human Rights. According to Rawls' theory of justice, basic human rights trump IPRs, and if redistribution will benefit the least advantaged in society, then the distribution is just. Even in South Africa, where a HIV and AIDS epidemic is rife, providing ARVs to the public sector poses many challenges. If, on the other hand, Nozick's libertarian view is followed, patent protection remains strong and the epidemic may be allowed to run unchecked as a result of high-priced ARVs. Nattrass successfully shows that the South African government cannot afford not to provide ARVs, and whilst research demonstrates that any HIV and AIDS policy cannot be successful without including ARVs. In South Africa, the majority of people who need ARVs cannot afford them. It is thus up to the state to administer treatment. However, as has been shown, the government for the most part has been reluctant to administer ARVs to the public sector. It was only in response to fierce public campaigning and activism that the government recently changed its stance. The same applies to pharmaceutical

[50] Even though the state is needed in order for a MNC to function.

companies. In Thailand, for example, it took activists three years of hard work before Britsol-Myer Squibb (BMS) gave the patent on Didanosine[51] (ddI) to the people of Thailand. As this example, the PMA case and countless others illustrate, offers of reduced prices on ARVs by pharmaceutical companies are the result of hard work and not corporate benevolence (Cameron & Geffen, 2005: 178).

Something thus needs to be done because one cannot rely on the goodwill of pharmaceutical companies. But is there an alternative? If patents impede access due to the high prices that patent owners are allowed to charge, which in turn makes the medication largely unavailable to those who need it, surely the patent holder can be rewarded in another way? A way needs to be found which would not only cover R&D costs but also acknowledge the inventor's efforts. Examples which come to mind include public funding, acknowledgment, research grants, status, etc. This view, however begs the question of what a fitting payment would be, and that would require an investigation into alternatives other than patents. In today's capitalist society, where the main incentive is profit, what reward could be more fitting than that which a patent offers? This is not to say that profit is the only factor, but it is the main one. Also to be considered is the fact that, in the pharmaceutical industry, money is needed to fund R&D, and patents at present appear to provide the best means to do this.

Although a great deal has been done to lower the prices of life-saving anti-AIDS drugs, much more effort is still needed to ensure that patents do not impede access to essential medicines. Recently Novartis[52], a multinational pharmaceutical company, legally challenged India's patent laws (*IOL*, 20 December 2006). India only began granting patents under the TRIPS Agreement in 2005, and has a large generic manufacturing sector which supplies most of the world with generic medicines. For example, India produced 80 percent of the generic medicines used to treat the 80 000 people for MSF's AIDS projects in over 30 countries (*IOL*, 20 December 2006). When urged to drop the case by MSF, Novartis said that they had a "strong commitment to defending international intellectual property standards" and that they had a right to do so under the TRIPS Agreement (*IOL,* 20 December 2006*).* This serves as warning that, despite previous victories that were hailed as benchmarks, pharmaceutical companies will keep testing the limits of the TRIPS Agreement. And it is this relentless pursuit of increased IP protection by pharmaceutical companies that serves to undermine the ethos of the Doha Declaration as well as developing countries' ability to use its provisions and safeguards. Because TRIPS sets a global

[51] ddI stops the growth of HIV, so helps fight AIDS, and is usually used in combination with other groups of HIV medications.

[52] Novartis was also one of the pharmaceutical companies which sued the South African government regarding the Medicines Act.

patent standard, a single pharmaceutical company's actions has repercussions for the rest of the world, and in this case, if Novartis is successful, access to life-saving drugs will once again diminish.

Moreover, the coupling of trade issues with intellectual property issues has not allowed the TRIPS Agreement to set minimum blanket standards, but has instead permitted other trade issues to be used as bargaining tools by mainly developed countries to gain more stringent protection for intellectual property laws on a global scale. For example, the US has utilized many Free Trade Agreements (FTAs) with countries such as Peru (specifically on knowledge production), Australia (specifically on copyright) and Chile (on pharmaceuticals). Chile's local pharmaceutical industry accounts for 90 percent of the country's public health sector. It is worth noting that the Chilean United States Free Trade Agreement (CHUSFTA) has no reference to the Doha Declaration of Public Health and uses IPR as an end instead of an instrument to promote economic development (Pastor, 2006). It is becoming clear that these TRIPS-plus provisions produce clear winners (US) and losers (Chile). Furthermore, even though the US is the only state enforcing TRIPS-plus provisions, pharmaceutical companies situated in other developed countries still reap the benefits of the TRIPS-plus provisions by remaining neutral. A recent report by Oxfam International agrees that FTAs and inaction on the part of rich developed countries undermines and disrespects the Doha Declaration, and goes further to recommend that pharmaceutical companies need to stop campaigning for stronger IP protection (Malpani & Kamal-Yanni, 2006). By pressuring developing nations to enter FTAs that require more stringent IP protection, the US - as well as rich nations and pharmaceutical companies - constrain the policy space available to developing countries to devise and implement policies that are in line with their developmental goals (Pastor, 2006).

The quest to curb the HIV and AIDS epidemic begins with getting treatment to those who need it. Treatment does not only lessen the impact of the epidemic on the public health care system, but also allows many to live a longer life in some dignity. Granted that ARVs are toxic and do have serious side effects, they also more often than not save lives. However, securing access to such medicines in order to combat HIV and AIDS is only the tip of the iceberg. The South African government needs to fight two battles, one internationally and one domestically, because unless the dichotomy between IPRs and accessible treatment is acknowledged, any efforts will be short-lived, and the 320 000 people that died of AIDS in South Africa in 2006 will only be last year's much lower statistic.

During the writing of this thesis 2.9 million died of AIDS, 4.3 million new HIV infections occurred, 39.5 million people are currently living with HIV and AIDS and out of the 6.8 million people who need life saving AIDS drugs, only 1.65 million are receiving them (based on statistics supported in Avert, 2007).

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Appendix 1:

Glossary of acronyms and abbreviations

AAC - AIDS Advisory Committee
AIDS – Acquired Immuno Deficiency Syndrome
ANC – African National Congress
ARVs – anti-retrovirals
AZT - Azidothymidine

BI - Boehringer Ingelheim
BMS – Bristol Myer Squibb

CBOs – Community Based Organization
CD4 – Cluster of Differentiation 4
CEO – Chief Executive Officer
CHUSFTA - Chilean United States Free Trade Agreement
CPT – Consumer Project on Technology

ddI - Didanosine

EC - European Commission
EPC – European Patent Convention
EPO - European Patent Office
EU – European Union

FDA - Federal Drug Association
FDI – Foreign Direct Investment
FTA – Free Trade Agreement

GATT - General Agreement on Tariffs and Trade
GDP – Gross Domestic Product
GSK - GlaxoSmithKline

HAI - Health Action International
HIV – Human Immunodeficiency Virus
HRW – Human Rights Watch

IMF – International Monetary Fund
IP – Intellectual Property
IPRs – Intellectual Property Rights
ITO – International Trade Organization

LDCs – Least Developed Countries

MCC – Medicines Control Council

MNCs – Multi National Corporations
MSF – Medicines sans Frontiers
MTC – Mother-to-child

NACOSA - National AIDS Committee of South Africa
NAFTA – North American Free Trade Agreement
NGO – Non Governmental Organization

PCT – Patent Co-operation Treaty
PMA – Pharmaceutical Manufacturers Association

R&D – Research and Development
RDP – Reconstruction and Development Programme

SACU - South African Customs Union
SADC - Southern African Development Community
SANAC – South African National AIDS Committee
STIs – Sexually Transmitted Infections

TAC – Treatment Action Campaign
TB – Tuberculosis
TRC – Truth and Reconciliation Commission
TRIPS – Trade Related Intellectual Property Rights

UDF - United Democratic Front
UN – United Nations
Unicef - United Nations Children's Fund
US – United States

WHO – World Health Organization
WIPO – World Intellectual Property Organization
WTO – World Trade Organization

Appendix 2:

Relevant TRIPS Articles referred to in text

Article 6 Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[53] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28 Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

[53] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[54] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 30 Exceptions to Rights Conferred

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

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[55] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-

[54] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.
[55] "Other use" refers to use other than that allowed under Article 30.

commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

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

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 33 Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[56]

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[57] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

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[56] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

[57] For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.