

Synopsis

This thesis discusses the international patent law system, in particular the Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS), in relation to *inter alia* development prospects in South Africa. The links between patents, high drug prices and access to HIV/AIDS drugs are investigated. The theoretical foundations for the patent law system are explored and discussed in relation to the concept of national innovation systems and the impact of the sub-Saharan HIV/AIDS pandemic.

Keywords: *Intellectual property rights, national innovation system, HIV/AIDS*

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Introduction

The Human Immunodeficiency Virus (HIV) leads to the Acquired Immune Deficiency Syndrome (AIDS). In December 2002 approximately forty-two million people were living with HIV or AIDS. Five million of them were infected with HIV in 2002. 3.1 million people died of AIDS the same year. Sub-Saharan Africa is the worst affected region, housing 29.4 million people with HIV/AIDS. The estimated number in South Africa is five million. Among adults aged 15 to 49, the prevalence is estimated to be 20.1%. 360.000 South Africans died of AIDS in 2002. (UNAIDS/WHO, 2002). This means that the epidemic has grown to a pandemic, defined as an illness “occurring over a wide geographic area and affecting an exceptionally high proportion of the population” (Merriam-Webster Dictionary Online).

There is no cure for AIDS, but there is medication that can keep infected people healthy for many years. These so called antiretroviral drugs are expensive and very few South Africans have hitherto been able to purchase them. Many international organisations blame the patent law system and the international pharmaceutical companies for these price structures. The pharmaceutical industry, many economists and the World Trade Organisation (WTO) on the other hand defend the system, claiming that patents are necessary to ensure research and development (R&D) that will benefit everybody. This thesis will set out the arguments on both sides.

In the first chapter, the intellectual property system and the World Trade Organisation’s Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) will be presented. The theoretical foundation for the patent system will be investigated and discussed, with special attention paid to patents for pharmaceutical products and the research and development trade-off.

The second chapter will investigate the link between intellectual property rights and economic growth, especially growth in developing countries. The forces behind growth will

be addressed, discussing the role of innovation, science and technology for economic growth. Important concepts like the notion of the national innovation system will also be presented.

In the third chapter I will address the question of why people do not get treatment, and how the intellectual property regime may influence on the rate of people having access to drugs. I will also describe and discuss the impacts of the HIV/AIDS pandemic on the developing countries, with special emphasis on South Africa.

In the fourth chapter the HIV/AIDS-drugs issue will be elucidated from a human rights prospective with special attention to the right to health and medical treatment and the right to enjoy the benefits of scientific progress.

The arguments and facts in these discussions will be found using diverse methods. Theory will be presented, discussed and confronted with empirical data. For the most part, theory and empirical analysis will not be split into different sections, but will follow the logical path from chapter to chapter. This is done because I think proximity makes it easier to grasp the arguments, and to criticise the conclusions made.

Chapter 1

1. Intellectual Property

1.1. The History of Intellectual Property Rights

Intellectual property goes far back in time. Some date the origins back to Aristotle, others to ninth century China. The Venetians institutionalised the first patent laws in 1474. The US Constitution (1787) recognised that the author and inventor's rights should be secured to promote the progress of science.

Traditionally, intellectual property rights (IPRs) have been drafted on a national basis with considerable international differences in the character and strictness of protection. As international trade and communication grew during the nineteenth century, the need for a harmonised system arose. Some bilateral agreements were concluded, followed by the Paris Convention (1883) for patents and trademarks, and the Berne Convention (1886) for the protection of literary and artistic work.

Three diverse sets of thinking about the nature of intellectual property and the protection of it may be identified; the natural rights view, the public rights view and the so-called utilitarian view. The natural rights view concentrates on the moral right to one's own mental creations. The public rights view emphasises that information belongs to society as a whole, and stresses its non-rivalry nature; one person's use does not diminish another's potential use. The utilitarian view emphasises how difficult it may be to exclude unauthorised use of information without legal protection. The World Trade Organization's (WTO) Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) tries to strike a balance between the need for invention and creation (dynamic efficiency), and the need for diffusion and access (static efficiency). Some see IPRs principally as economic or commercial

rights, others as political or human rights. The TRIPS agreement treats them in the former sense (Article 7 of TRIPS).

1.2. The TRIPS-Agreement

The WTO defines IPRs as “the rights given to persons over the creations of their mind” (WTO Website). Patents provide the patent owner with the legal means to prevent others from making, using or selling the new invention for a limited period of time. Patent rights are just one of seven forms of IPRs¹. The treatment of IPRs has varied very much around the world, especially concerning the extent of the protection and the enforcement of these rights. Since the 1960s the world has experienced an enormous growth in international trade and foreign direct investment (FDI) flows, international interdependency has increased and the law differences have been, and still are, considered as a source of tension in international economic relations. WTO’s Agreement on Trade-Related Aspects on Intellectual Property Rights is a part of the trade agreements resulting from the Uruguay Round (1986-94) of the General Agreement on Tariffs and Trade (GATT). It is partly based on the Paris Convention on patents and the Berne Convention on copyrights. TRIPS represents an attempt to establish an international legal framework with similar IPRs around the world. Firms can then apply for patents in each country separately.

The agreement rests on the same common principles as GATT and the General Agreement on Trade in Services (GATS);

1. *national treatment*
2. *most-favoured nation treatment*

(WTO Website).

¹ The others are: Copyright and related rights, geographical indications, industrial designs, layout designs (topographies) of integrated circuits and undisclosed information, including trade secrets.

National treatment implies that foreigners and nationals must be treated equally. This means for instance that foreigners should be granted patents on the same conditions as nationals. The second point emphasises that equal treatment applies for nationals of all trading partners in the WTO. Article 33 of TRIPS states that the patent protection period should be at least 20 years from the filing date. To be granted a patent, the future patentee must disclose the new processes, materials and so on in the patent application. Patents can be granted only on patent applications for new inventions received from 1995 and onwards.

The WTO members were given different deadlines to implement the agreement. South Africa had a transition period of only one year to apply its provisions. In 2001, the implementation of TRIPS concerning pharmaceutical products was postponed until 2016 for the least developed countries (LDCs). South Africa is not listed as a LDC.

1.3. Free Markets and the Property Rights Exception

The neoclassical growth theory, developed by Robert Solow in the 1950s, is a positive model that predicts that long-run growth with full employment was possible as long as market forces were allowed to operate freely (Fagerberg, 2000). There were some assumptions attached to the theory. These include the ideas of profit maximisation by firms, a market with many firms, each of them too small to have a real impact on the market and an idea of perfect competition with corresponding implications for determination of factor prices and the distribution of income. Trevor Swan added the assumption of utility maximisation² by consumers to the model.

² Utility maximisation: “The process or goal of obtaining the highest level of utility from the consumption or use of goods and services. This is based on the seemingly obvious presumption that people prefer more to less, which is intimately tied to the unlimited wants and needs aspect of scarcity. In other words, because people have unlimited wants and needs, because they always have unfulfilled wants or needs, satisfying these wants and needs is a desirable thing to do” (AmosWEB Gloss*arama).

The theory regards technology as an exogenous force, coming from outside the economic realm, readily available to everyone free of charge. Business thus exploits technological advances but is not responsible for creating them. The only source of long-run productivity growth, and hence economic growth, is technological advance “through discovery and invention that is purported to be separate from the natural workings of the economy” (p.302). Recently, neoclassical growth theory has become more complex, and has come up with growth models treating technological change as an inherent part of the economic structure³.

The patent law system represents an exception to this liberal market system. It is based on the concept of protection of intellectual property and exclusion instead of dissemination and competition. When a company is granted a patent, it gains the exclusive right to produce and sell a particular product for a period of time. Depending on whether there exists a product which is, or is comprehended as, very similar or not, a monopolistic market is created. Someone else can use the patented knowledge with the authorisation of the patentee. The costs of investment in research and development and the return on that investment are met by charging the consumer a price based on the ability to exclude competition.

Article 27 of TRIPS states that three criteria have to be met for the invention to qualify for patenting; it has to be new, it must involve an “inventive step”, and it must have “industrial applicability”. The agreement does not define these terms, and national patent laws vary in how they interpret them. Narrow patent claims may give room for inventing around the patent. Broad claims on the other hand may have the opposite effect. Countries have different traditions concerning the scope of patents.

³ For a discussion of the definition of the term neoclassical economics, see Maurseth, 2001.

1.4. Implications of the Creation of Monopoly Markets

In the absence of government intervention, the monopolists have a considerable degree of market power, they are free to set any price they choose, and will usually set the price that yields the largest possible profit. The purely "economic" case against monopoly is that it reduces aggregate economic welfare (as opposed to simply making some people worse off and others better off by an equal amount) and probably leads to a loss of efficiency. When the monopolists raise prices above the competitive level in order to reap their monopoly profits, customers buy less of the product, less is produced, and society as a whole is worse off. In short, monopoly reduces society's income.

Consider the case of a monopolist who produces a product, for instance a patented screw bolt at a fixed cost of \$5 per unit. The additional costs for the last unit produced (marginal cost) is \$5 no matter how many units the monopolist makes. The more expensive the product, the less the sales are likely to be:

Price	Quantity Demanded (units per year)
\$7	200
\$6	300
\$5	420

Table 1.1 Demand schedule

In this case, the monopolist is best off when she/he limits production to 200 units, which she/he sells for \$7 each. She/he then earns monopoly profits, an economic rent, of \$400 a year. If the producer wants to maximise his profit, She/he will sell a quantity the marginal cost equals the extra revenue received by the firm for selling one additional unit of a good (marginal revenue). In a competitive market on the other hand, the marginal revenue equals

the price. Selling at a competitive price would transfer \$400 from the monopolist to consumers and create an added \$220 of value for society.

1.5. A Medicine Market Monopoly

The theory on monopolies may seem easy, but when the patented commodity is not a screw bolt but HIV/AIDS medication, the issue gets more difficult. Society will lose value, and the supplier will earn more, like in the screw bolt example. However, the direct consequences for the customers not obtaining the HIV/AIDS medication are very severe. People who suffer from HIV/AIDS will die much faster without access to drugs. In other words; the subsequent effects of a monopoly market situation may be very costly because of the deaths of millions of people in their most productive years of life. On the other hand, if the monopoly profit leads to more R&D, which in turn will benefit society, in this case with better HIV/AIDS drugs, the matters get more complex. Society finds itself in a difficult trade-off situation.

In a monopolistic market, prices will rise. How much is dependent on several factors. The market structure before the strengthening of the IPRs is important. The number of firms competing with right holders and the ease of market entry and exit do vary. The demand elasticity is also a key variable determining market power. The concept of demand elasticity measures how much consumers respond in their buying decisions to changes in price. According to Keith Maskus (2000) the increase in price is dependent on competition, availability of copies of patentable drugs and the demand elasticity. If the local pharmaceutical market had a high level of competition and a large share of copies of patentable drugs available before the strengthening of the patent rights, the new regime will probably lead to a high increase in price. An inelastic the demand for medicines will reinforce this trend (p.161). The competition will diminish, there will be only one or a few products left

on the market, and an inelastic demand implies that many will still buy the product even if prices rise.

Figure 1.1 describes a monopoly medicine market. The competitive quantity in equilibrium is q_c , while under a monopoly it will be q_m . The competitive price is p_c , while the monopolistic one will be p_m . $q_m - q_c$ is the quantity withheld from the producers to maximise the profit for the monopolist. Carl-Erik Schulz (2002) calls this the “economic death row”; because of the monopoly people cannot afford medication and will eventually die. $q_c - q_d$ is the quantity that will not reach the consumers even if the price is lowered to p_c . In fact, $q_m - q_d$ can be named “economic death row”; the people willing to buy the $q_c - q_d$ quantity also do not get the medication because of the price.

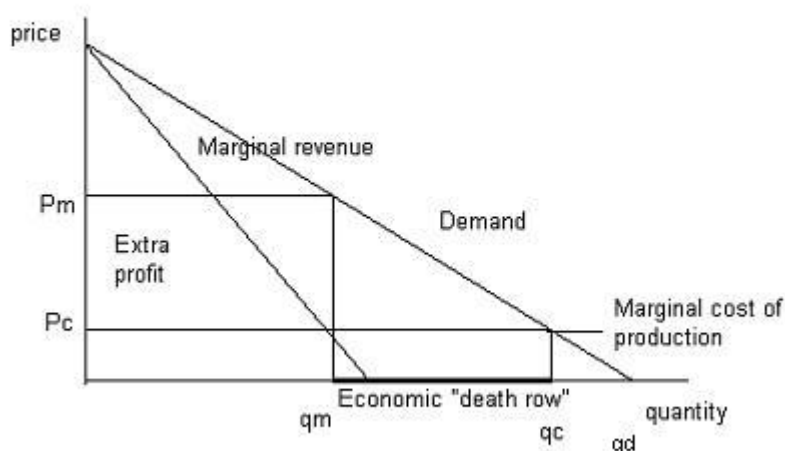


Figure 1.1 The monopoly market for goods (Schulz, 2002)

A monopoly prevents the production of goods that there is both a demand for and a willingness to pay for; it stops a socially efficient distribution of goods. Another aspect is the demand side in the monopoly markets. Concerning HIV/AIDS medication, the demand curve for a developed country like Norway will probably be different from the curve for a

developing country like South Africa. There are several reasons for this. There are not many suffering from HIV/AIDS in Norway, and the government pays for the medication. According to Pluss, the Norwegian Association Against AIDS, a year of antiretroviral treatment costs 200.000 Norwegian kroner (NOK) in Norway (Pluss Website). The patients however pay no more 1.350 NOK a year. This amount covers most of the medical expenses involved, including drugs and hospitalisation. This means that the demand curve is steep, demand is very inelastic, the amount sold may in reality be the same whatever the price is.

The situation in South Africa is entirely different. 5 million people suffer from HIV/AIDS; the need for antiretroviral medication is enormous. People are poor and the government has no chance of paying as much for these medications as the Norwegian government is able to. This will probably result in a situation where the sales are rather dependent on the price asked. The real demand curve in South Africa may possibly look more like in figure 1.2. A demand curve like this can indicate that most patients will not have access to medicines unless the prices fall significantly or the government starts to subsidise the sales of drugs.

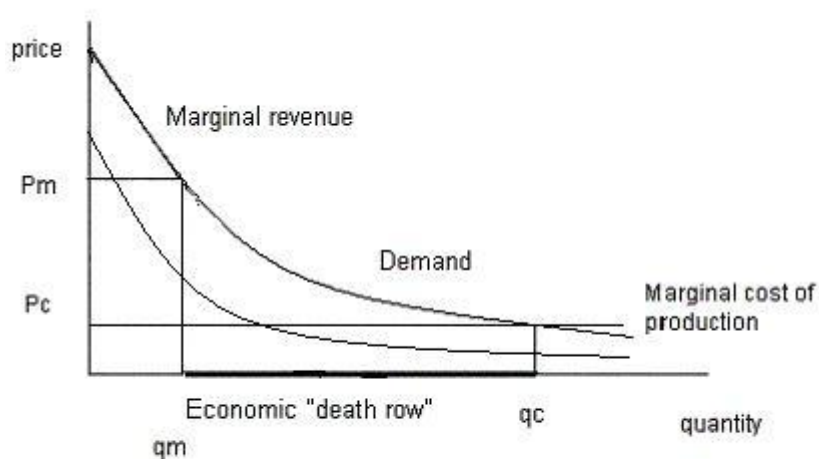


Figure 1. 2 Elastic demand

It can be interesting to look closer at the consequences of different demand patterns. A paradox pointed at by Juan Rovira is that the prices asked in developing countries may be higher than in richer countries. Especially in countries with large income inequalities, the profit maximizing strategy of the firms may be to charge a high price than charged in richer markets, targeting only a small share of high income consumers (Rovira, 2003).

1.6. The R&D Trade-off

A patent system will most likely create monopolistic markets. The motive for this monopolistic exception is not difficult to find. GlaxoSmithKline, one of the world's largest pharmaceutical companies, puts it this way:

We support intellectual property protection because it stimulates and fundamentally underpins the continued research and development (R&D) of new and better medicines, including those for diseases prevalent in the developing world

(GlaxoSmithKline, 2002)

Following this reasoning, technology is regarded as a public good that will generate favourable results, but that the market forces in this case will fail. Left to itself, there will be under-investment in R&D due to the so called free rider problem. R&D is regarded as an external, resource-using activity and the output of this process such as inventions is thought, in the absence of protection of some form, to be freely copyable by others. Without patent protection (and assuming perfect competition), the price of invention will be driven down to reproduction costs, leaving no return to inventive activity *per se*. In this situation there will be little incentive for firms to invest in R&D because their inventions so easily can be imitated at a lower cost by rival firms. Indeed, there may even be a disincentive, since rival firms can obtain the invention without incurring its costs and will thereby be in a superior economic position to the inventing firm (Mandeville, 1996).

The patent system implies a trade-off between the production of technology (dynamic dimension) on the one hand and its use (static dimension) on the other; it asserts that the generation of technological knowledge can be promoted by promises of restriction on its use (Machlup, 1984). Thus, if new inventions are sold at marginal price, which statically is most efficient, this will reduce the amount of new research, hence harming dynamic efficiency. The positive relationship between patent scope and R&D effort is formally proven by Vincenzo Denicolò (1996).

There are obvious problems with these assumptions, what is for instance the optimal degree of patent protection? The protection may be too weak or too strong and the length of the patent term too long or the scope of the protection granted too broad. According to William D. Nordhaus the optimal life of a patent is the point where the social benefits and costs “balance at the margin” (Quoted in Scherer, 1984). In other words; the optimal patent life equalises the marginal dynamic gain of prolonged protection with the marginal static loss. TRIPS has set that optimal patent life to be minimum 20 years for all products in all WTO countries.

The idea that technology is easily imitated is the fundamental assertion underlying the patent system (Mandeville, 1996, p.19). Is this premise valid? Is it valid at all times, for all products, globally? Edwin Mansfield *et al* made an empirical study in 1981 showing that in about one seventh of the cases, imitation costs were no smaller than the innovation costs. The authors explained this by asserting that the innovators had a “technological edge” over its rivals, often due to superior experience and expertise (know-how). They stated that “Such know-how is not divulged in patents and is relatively inaccessible” (Mansfield et al., 1981, p.910). It is important to recognise that knowledge often is embodied in systems or modes of production, it is frequently tacit in the meaning of implied, but not expressed, and hence difficult to spread.

Due to the disclosure rules in TRIPS, the new processes, materials and so on will be described in the patent application. In this sense, the patent can lead to openness about R&D.

Paul David however notes that

although the disclosure of codified information is augmented by patent systems, so is the inducement to curtail the transmission of tacit knowledge that might reduce the commercial value of the patents that have been issued (David, 2002, p.22).

Mansfield found that other firms in general could imitate new products at about two thirds of the cost and time used by the innovator.

The pharmaceutical industry is however special; surveys have shown that patents are considered essential because of the high fixed costs and the fairly easy imitation (Mandeville, 1995, Mansfield, 1986, Maskus, 2001). The industry claims that it costs an average of \$400-\$500 million to research and develop major drugs and that it takes eight years to bring drugs to market (Baker, 2001, DiMasi, Hansen & Grabowski, 2002). These estimates cover many costs, including compounds that have failed. Following this reasoning, strong IPRs are necessary both in the short and in the longer run; they protect the pharmaceutical industry and they ensure R&D activity that in the future will result in new medicines, benefiting society as a whole.

These conclusions are however questionable. Independent estimates of the development costs of new drugs range from \$30-\$160 million (MSF, 2002). The big pharmaceutical companies spend more on marketing and administration than on R&D. Drug R&D is also often funded by the public sector, directly or indirectly through tax concessions. According to the World Bank (WB), half of the current R&D expenditure worldwide, estimated at \$70-\$90 billion, is funded publicly. Many of the drugs marketed by private companies were originally discovered with public funding, including six AIDS drugs (MSF, 2002). Schulz (2000) points to the fact that companies seldom reveal how much funding they actually need to ensure R&D. James Love argues that the patent system has failed in

stimulating basic health research, development of high-risk projects and the research on vaccines or neglected diseases (Love, 2003, p.2). Many argue that the standards of patenting, particularly in the US, have been excessively lowered so that too many patents are issued for trivial inventions. Mariko Sakakibara and Lee Branstetter (2001) claim that there is very little empirical evidence showing the causation between strengthening of the patent system and subsequent effects on R&D. Japan's 1988 patent reforms expanded the patent scope, but Sakakibara and Branstetter found “*no* evidence of a statistically or economically significant increase in either R&D spending or innovative output” (Sakakibara & Branstetter, 2001, p.78, their emphasis)⁴.

1.7. Implications of the Patent System

The patent system seems to imply a linear research process, starting with basic research, going on to applied research and ending with a new product or process. The division between the dynamic and the static dimension of patenting may however be rather artificial. Joseph Schumpeter defined innovation as new combinations of existing knowledge and resources (Schumpeter, 1934). This means that research involves interplay between past and present. The patent system implies disclosure of for instance a new technological process. Other technology producers can look at the disclosure documents and they may learn from them, but they cannot use the new patented process directly until the patent has expired. This may delay the innovation of new products or processes and lead much innovative activity into inventing around the patent.

The Human Genome Project (HGP) started in 1990 and wanted to identify all the approximately 30,000 genes in human DNA. It ended in 2003 with the completion of the human genetic sequence. All genome sequence generated by the project has been deposited

⁴ For more empirical evidence on the relationship between strengthening of IPRs and R&D, see Cohen et al (1998), Grabowski (2002), Hall & Ziedonis (2001), Jaffe (2000), Schankerman (1998).

into GenBank, a public database freely accessible by anyone. The parties participating in the project argued that

Disseminating information in the public domain encourages widespread use of information, minimizes transaction costs, and makes R&D cheaper and faster. Of particular relevance to research science, a vigorous public domain can supply a meeting place for people, information, and ideas that might not find each other in the course of more organized, licensed encounters. Information in the public domain is accessible to users who otherwise would be priced out of the market

(Humane Genome Project Homepage).

Love claims that this outcome was due to the growing interest in “open source” development models for software and medicines. These models emphasise the benefits of increased access to information (Love, 2003). According to Robert P. Merges and Richard R. Nelson the process of innovation can be interactive, drawing on a range of prior inventions invented independently, and feeding into further independent research processes by others (Merges & Nelson, 1990). Knowledge evolves through the application of many minds, building often incrementally on the work of others. Isaac Newton stated that “If I have seen far, it is by standing on the shoulders of giants” (Quoted in Scotchmer, 1991, p.29).

The balance between the potentially harmful effects of a monopoly and the prospects of benefit from future R&D seems to vary very much between industries and countries. The appropriate policies to address IPRs will accordingly differ. TRIPS does however set universal minimum standards, valid for all industries globally. Concerning HIV/AIDS, the question of what the workable or optimal scope of the patent system is, is certainly not easily answered. It is important to note that most of the opponents to the international patent system do not question the patent system in developed countries; they simply refuse to accept an expansion of the system to less developed countries. This means that if the importance of patents in for instance the US is proven, which it to a large degree is, this does not imply that the system should be extended to countries that see no need for it. Hitherto, with the current

pre-TRIPS regimes in many developing countries, the pharmaceutical industry is very successful in doing R&D *and* producing large revenues. It is very unlikely that the preservation of this *status quo* beyond 2005 or 2016 will represent a devastating blow to the industry.

Chapter 2

2. Economic Growth and TRIPS

The main argument used to justify TRIPS is its assumed positive effect on economic growth. This growth is supposed primarily to be a result of increasing international trade and new inventions provided for by stronger IPRs. The economic impact of TRIPS in developing countries however is a subject of considerable controversy. The questions to be answered are many. I will try to indicate some answers to the following issues: What may fuel economic growth? How do IPRs contribute to growth? What are the costs of implementing TRIPS? Will TRIPS lead to economic growth in developing countries in the short run, and what about the long run? Are there flexibilities in TRIPS for the developing countries to use? To answer these questions I will partly use Keith Maskus' book *Intellectual Property Rights in the Global Economy* (2000) and the reactions on this publication. Maskus is widely used by the WTO and by the United Nations (UN). The question of how TRIPS will influence the prices of HIV/AIDS medication will be discussed in chapter 3.

2.1. Economic Growth

Economic development is not an easy issue; according to Jan Fagerberg (2000) growth theory is by nature deeply political because a clear idea of development presupposes a vision of what kind of society we strive for. Questions like “what do we want?” and “where are we going?” are very relevant to the view of what development and growth consists of and hence to growth theory.

The conventional definition of economic growth implies the increase in the capacity of an economy to produce goods and services over time, and ideally the improvement of the well-being of its citizens. In almost every economy in the world, the increase of total output,

Gross Domestic Product (GDP), from one year to the next is the official measure of economic growth. GDP is the central measurement currently used in evaluating the position of nation's economy. Whenever economic growth is mentioned in this thesis, the term should be understood as the increase over time in the capacity of an economy to produce goods and services. This idea of growth may of course be questioned, but that is not the aim of this thesis.

Now that the notion of growth is established, the question of what the forces behind growth are can be addressed. This is important if we want to indicate how TRIPS might affect these forces. Fagerberg (2000) claims that the view on what drives economic growth has changed over time. From the Industrial Revolution onward mechanisation was considered to be the main force of growth. More recently, also knowledge, the “human factor”, has been recognised in growth theory and the attention is turning to the production and implementation of science and technology.

2.1.1. The Evolutionary Approach

The evolutionary approach within economics has developed the last few decades and provided a new set of descriptive tools both in the macro- and the microeconomic sphere. Evolutionary economics is named after evolutionary biology; market competition is seen analogous to biological competition and business firms must pass a survival test imposed by the market. This approach, starting with the works of Joseph Schumpeter, focuses on innovation and learning as a source of economic growth. Evolutionary economics experienced a small renaissance in the late 1970s and 80s, when high levels of unemployment and signs of a major economical depression led many to lose faith in Keynesian policies.

According to evolutionary economists, the traditional neoclassical growth theory is based on an outdated understanding of knowledge, growth and how the capitalist system

works. Much of the work based on Schumpeter's writings has focused on policy making economics. Technology advances are seen as endogenous economic factors, caused by factors inside the system and shaping and shaped by the economical environment. Innovation is no longer "manna from heaven" but the result of planned resource investments. This view opens for the contribution to growth from R&D in firms, and for technological spill-over effects. In this framework some firms are seen as innovators while others are imitators. Schumpeter saw how a new innovation would give a firm temporary monopoly and thus economical benefits before the innovation would diffuse to society and fuel the economy. Other evolutionary economists have observed that learning also can occur outside the R&D-departments; within firms, on plant floors or as an interactive process between producers and consumers (Fagerberg, 2000).

2.1.2. The National Innovation System

Rather recently, researchers have begun to see a country's innovation and learning performance as a system, a national innovation system (NIS) where organisations, institutions and national and regional government play different roles. The literature on NIS stresses that to understand technological development and growth mechanisms we need to study the social structures that shape these developments. In this context, the notion of innovation systems has been used to recognise and explain the relations between agents that produce and apply technology.

There are several definitions of NIS, Bengt-Åke Lundvall distinguishes between a narrow and a broad definition. The narrow includes "organisations and institutions involved in searching and exploring - such as R&D departments, technological institutes and universities" (Lundvall, 1992, p.12), the broader includes:

all parts and aspects of the economic structure and the institutional set-up affecting learning as well as searching and exploring – the production system,

the marketing system and the system of finance present themselves as sub-systems in which learning takes place
(Lundvall, 1992, p.12).

The systemic nature of this approach is very important; it focuses not only on the individual institutions and organisations, but also their reciprocal interaction.

There is not written much about NIS in developing countries. The reason for this is probably a mixture of the lack of reliable data and the mere fact that many of the developing countries are on such a low level concerning basic infrastructure, education and governmental capability that it is difficult to distinguish general development policies from specific innovation policies. It is however possible to give some general comments on the national innovation systems in developing countries. These countries are mostly imitators of technology, not innovators. They lag behind the technological leaders. History shows that some developing countries have evolved, and have managed to catch up and fill at least a part of the income gap between them and the developed world.

Moses Abramovitz (1994) has emphasised that the developing countries face varying degrees of difficulty in adapting and adopting the current technological practise of leaders and hence in catching up. The social and technological capabilities of a country are very important in this respect. These capabilities include institutions, political characteristics and social structures and systems.

Titus Adeboye (1997) claims that the sub-Saharan countries have tried to engender a diffusion model “based largely on the transfer, adoption, adaptation and diffusion of existing knowledge” (p.214). This model worked out well for some of the newly industrialising countries (NICs), and may be the most appropriate for the sub-Saharan countries. The model does not depend on the generation of new knowledge nor the creation of technological breakthroughs. Important in such a model is *inter alia* the level of general education, human development in targeted industries and sectors and a high managerial and technical

competence of the bureaucracy. Adeboye claims that R&D activity in the NICs worked as a “facilitator of technology acquisition and deepening rather than as the main engine of innovation” (p.223) and that R&D activity sometimes was used to circumvent foreign patents.

The Schumpeterian technology gap model assumes that both innovation and diffusion of new technology fuels economic growth. This implies that enhanced innovative activity and the scope of imitation and investments may explain growth. John Cornwall defines growth as a process of qualitative and structural change, in which the success of a country is dependent on the ability to transform economic, social and institutional structures (Fagerberg, 2000).

It is important to understand the strength of the forces making for convergence and at the same time expose the conditions that limit and constrain these tendencies. In other words; there is a big difference between a country’s relative *potential* to raise their productivity and to catch up, and its ability to *realise* this potential. The problems concerning realising these potentials lie in what Abramovitz terms “technological congruence and “social capability” (Abramovitz, 1994, pp.6-7). The first concept refers “to the degree to which a leader and follower country characteristics are congruent in areas such as market size, the availability of labour, natural resources and so forth” (Fagerberg, 2000, p.307). The second points to the various facilities the laggard countries have for learning about more advanced methods and for acquiring them, such as levels of general education, infrastructure and the technological capabilities in general.

Adeboye asserts that the model that worked out for the NICs hitherto has proved has proved to be difficult to pursue for the sub-Saharan countries because they have lost their capacity to provide even “the basic traditional services of governance- law and order, basic infrastructure, education, health and a competent bureaucracy” (p.215).Sunil Mani (2001) has classified South Africa as a Type 1 country, together with ten other developing countries. These countries are in most respects imitators of new technology rather than innovators;

imitation of technology is still important in reducing the technology gap. They have however, according to Mani, the potential to create technologies on their own.

In this context, it is a concern that a pandemic like HIV/AIDS may break into the fundamental foundations for the society as a whole, shaking basic premises for development and innovation, and destroying the potential for growth. I will discuss this further in chapter 3. The patent law system is also a part of NIS, directly as a national and international law framework and indirectly by influencing the R&D departments, technological institutes and universities. TRIPS is also very important concerning the possibility of exploiting existing knowledge, the agreement may be a threat to the scope of imitation. How TRIPS affects growth, and how the agreement will work out concerning the access to medications, are very relevant questions.

2.2. How can Strong IPRs lead to Growth?

It seems that today most economists agree on the importance of technology and innovation for economic growth. TRIPS is meant to strengthen the incentives for innovative activity, providing for future innovations that will improve productivity, and hence lead to growth. This view implies that strong IPRs are a second best solution to market failure in the production of knowledge and information. The “best” solution would be that governments subsidised innovators until the cost of the subsidies equalled the benefits of society, and then to allow diffusion of knowledge at marginal cost (Maskus, 2000, p.30). Practically, this would be very difficult; governments generally have less information than firms, and policy matters cannot depend on firm’s private information about their expected costs (Scotchmer, 1991). Strong IPRs is a compromise that has worked well in the past, at least in developed countries.

How will strong IPRs work out for developing countries in the future? First of all, it is vital to see if and how strong IPRs can nurture the development and diffusion of technology

and lead to growth in the short run, and even more important, in the long run. Secondly, it is important to discuss how TRIPS might affect the developing countries besides the direct effects on innovation and technology. Maskus recognises the complex nature of this question:

Strengthening IPRs may expand growth prospects under certain circumstances but may offer no improvement, or even retard conditions for development, under other circumstances

(Maskus, 2000, p. 145).

Maskus admits that a country's relation to the protection of IPRs is dependent on social structures, its position in the global economy and on the "global technology ladder" (Maskus, 2000, p.144).

IPRs may encourage a country's own technological, industrial and cultural development by creating an incentive for inventive efforts. Maskus claims that IPRs are essentially dynamic; it seems that the stronger the economic performance, the more need for strong IPRs. In that sense, Maskus acknowledges that the world is undertaking an unprecedented experiment, to accelerate the introduction of higher IPRs standards into regions that would not ordinarily be expected to adopt them. Stronger IPRs do imply important economic and social costs, costs that in many cases occur earlier than potential benefits. Maskus however denotes that the possible drawbacks may be counterbalanced by the positive effects stronger IPRs can have on the economy.

Maskus asserts that at least five factors are important, namely securing property rights, development and diffusion of new technology, local economic activity and the economical cost of implementing TRIPS. It is crucial to find a causation chain from IPRs to development, or to non-development.

2.2.1. Secure Property Rights

Maskus emphasises that the right to exploit tangible assets (like for instance real estate) and exclude others from using these assets has played a positive role in the progress of developed countries. IPRs will, like general property rights, establish a key platform for high-level business structures important in any national innovation system.

An important question is if IPRs do indeed have the same effects as general property rights. IPRs certainly have characteristics that distinguish them from tangible property rights. It may for instance be easier to exclude others from using intellectual property without protection than is commonly recognised. The advances in information technology make intellectual property internationally mobile at relatively low cost. However, in sectors with rapid technology evolution, the high costs of imitation make IPRs less important. On the other hand, Maskus asserts, weak IPRs can result in foreign owners not making the desired information available at all so that there is in fact less to copy and to diffuse. Securing property rights is also a means to ensure investments, in the same manner as protecting general property rights.

Sanjaya Lall (2002) acknowledges that IPRs may have a “*signalling function*” (Lall and Albaladejo, 2002, p.5, their emphasis), especially in countries previously known for their unclear policy regimes concerning private investment and property rights. Still she emphasises that there is too little proof to conclude that IPRs by themselves are that important as signalling function, and that the overall economic environment probably matters more. She also finds it difficult to believe that strong IPRs in fact cause the business structures to emerge and get more complex; the causation is more likely to go the other way around.

Susan K. Sell (2002) stresses that intellectual property not always has been regarded as equivalent to general property rights. Intellectual property activists however managed to

change this⁵. By doing so, weak IPRs were redefined as a barrier to legitimate trade. IPRs were hence considered essential to free trade and brought under existing trade statues. This link to trade made IPRs important for existing international institutions and for the world trading system as a whole, insisting on a synthesis that seemed “both natural and necessary” (Sell, 2002, p.179).

The discussion on whether IPRs are important to business structures is not at all settled. There is need for more empirical research in this field, but my guess is that the results will not be conclusive. It is important to keep in mind that the idea of IPRs as equivalent to general property rights is a rather new one, and that this is not an ideology-free point of view.

2.2.2. Development of New Technology

The most important argument supporting TRIPS is the well-known one concerning incentives for R&D which I have discussed in chapter 1:

Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits

(WTO Website, TRIPS and pharmaceutical patents: fact sheet).

Maskus however expands this argument, claiming that TRIPS will give an incentive for innovative activities also in developing countries and on products aimed at markets there, hence leading to growth in these areas. I have already mentioned the sophisticated business structures emerging from stronger IPRs. The main argument for Maskus is that the developing countries need to build up economies based on innovation, not imitation. He asserts that a strategy based on “free riding on the technical advances of others ... has short-run

⁵ Sell claims that the change in governance of intellectual property should be understood as a result of changing structures in global capitalism; representatives of leading economic sectors are becoming the most important agents and are gaining enhanced political power, especially in the US (Sell, 2002,p. 178-179).

competitive advantages but suffers from inadequate access to new technology and a growing inability to develop local strategies for fostering R&D and technical change” (Maskus, 2000, p.176).

Today owners of patents in developing countries are mostly foreign because developing countries have preferred diffusion of new technology and knowledge through low-cost imitation of foreign products and technologies. The technology gap approach precisely emphasises that a country on a low technological level can increase its rate of economic growth and catch up through imitation (Fagerberg, 1987). This is not to say that innovation is not important in developing countries, but that the main focus and the main possibilities still must lie within imitation. It is important to note that imitation may involve a rather high level of know-how, organising talent and technological skills. Mansfield *et al* (1981) and Christopher Freeman (1982) stress that a certain scientific base is a precondition for successful imitation in most areas. Imitating is hence not necessarily related to “a growing inability to develop local strategies for fostering R&D and technical change” (Maskus, 2000, p.176).

Maskus also emphasises the importance of firms in developing countries getting competitive in their local markets, and that strong IPRs can be of importance here. He argues that weak IPRs can destroy the possibilities of technical change even in developing countries because “much invention is aimed at local markets and can benefit from local patent or utility model protection” (Maskus, 2000, p.147). Maskus also states that the disclosure requirement in TRIPS leaves information accessible to all, hence allowing rival firms to use the information as a basis for further inventions. Maskus thus assumes that firms in developing countries must get competitive using locally produced knowledge and by reading patent disclosure documents, not by directly using new technology built up in developed countries.

Historically, developing countries have used various levels of IPRs in their growth periods. The East Asian countries used weak forms of IPR protection throughout the critical phase of rapid growth. Between 1960 and 1980 Taiwan and Korea emphasised the importance of imitation and reverse engineering as an element in developing their local technological and innovative capacity. Korea implemented a weak patent legislation in 1961; the scope of patenting excluded foodstuffs, chemicals and pharmaceuticals and the patent period was only 12 years. In the mid-1980s were the IPRs revised, particularly as a result of action taken by the US under Section 301 of its 1974 Trade Act. A comparable process took place in Taiwan. In India, the weakening of IPR protection in pharmaceuticals in its 1970 Patent Act is widely considered to have been an important factor in the subsequent rapid growth of its pharmaceutical industry, as a producer and exporter of low cost generic⁶ medicines and bulk intermediates (CIPR, 2002).

Generally, weak forms of IPRs have been prevailing in the formative periods of the economic development in the NICs. Even a country like Norway did not introduce patent protection for pharmaceutical products until 1992 (Lanjouw, 2002, p.9) Lall asserts that it will mainly be the NICs that will need TRIPS to increase and protect local R&D. She claims that the least developed countries do not have the capability of benefiting of TRIPS in any technological sense. The in-between countries, like South Africa, still building technological capabilities by imitating and reverse engineering will probably lose the most.

New technology, for instance new medications targeted at diseases widespread in developing countries, may also be of great importance to these economies. Maskus claims that global innovation on for instance pharmaceuticals may be stimulated by strengthening the IPRs because the aggregate market for pharmaceuticals will be large enough to ensure more R&D aimed at “poor people’s illnesses”. The pharmaceutical industry is one of the most

⁶ A generic is a medicine that can be medically interchanged with a branded product (Haddad, 2003, p.1). For a discussion of the term, see Vázquez, 2003.

profitable in the world. In 1998, the top ten companies enjoyed \$108.1 billion in sales, of which \$34.7 billion was profit. This is one of the highest average profit margins of any industry worldwide (MSF, 2002). Developing countries make up a small part of drug industry revenue. 77% of the \$406 billion worldwide drug market projected for 2002 will be in North America, Europe, and Japan. All of Africa accounts for just over 1%.

The WHO Commission on Macroeconomics and Health (CMH) has concluded that IPRs offer little incentive for R&D on developing country diseases, because of insignificant markets (CMH, 2001, p.77). The Commission on Intellectual Property Rights (CIPR) stated that they “do not think that the globalisation of IP protection will make a significant contribution to increasing R&D expenditure by the private sector relevant to the treatment of diseases that particularly affect developing countries” (CIPR, 2002, p.39). The UN, the World Bank and Médecins sans Frontière (MSF) claim that innovators so far have done very little R&D of specific interest to poor countries because it is not profitable enough (UNDP, 2001, World Bank, 2001a, MSF, 2003) The examples of neglected diseases like sleeping sickness, Chagas disease or leishmaniasis show that “the argument for a patent system encouraging R&D for medical needs in their countries [poor people’s] falls far short” (MSF, 2003, p.5).

It looks like the \$4 billion drug market in Africa is not enough to spur innovative activity. Probably is the *need* for these medications large enough to ensure more R&D, but the purchasing power is not large enough to handle high medication prices resulting from stronger IPRs. Maskus somehow recognises the shortcoming of his own argument, claiming that a development towards more R&D on e.g. pneumonia may take a long time to achieve and admitting that “additional research into cures for their [the poorest countries] may not be forthcoming if left to the private market” (Maskus, 2000, p.157).

2.2.3. Diffusion of New Technology

Maskus asserts that poor countries can attract inflows of advanced foreign technology through the strengthening of IPRs. There are three prevailing sources for these inflows; trade in commodities and services, foreign direct investments (FDI), mostly from multinational enterprises (MNEs), and licensing. Maskus states that it is widely accepted by economists that imports of goods and services will transfer and diffuse technology. He further argues that international trade in many commodities is dependent on a strong patent system; the stronger the regime, the more trade. He recognises that this pattern first and foremost applies for large developing countries. The evidence for this is mainly econometric data showing a positive correlation between the strength of IPRs and capital goods imports, inward FDI and licensing payments.

According to Lall these studies have been questioned and other studies have more ambiguous results (Lall, 2002, p.6). Concerning *capital goods*, Lall points to the fact that the positive correlation may be due to other aspects. A higher level of income and strong technical competence will in general lead to larger imports, rather than stronger IPRs *per se*. A country with a growing GDP will in most cases strengthen IPRs as a means to protect their new technology industry, the industry and the growing imports related to the industry has not emerged as a *result* of the strong IPRs; the strong IPRs are a result of the new growth. They are at the time becoming an appropriate part of the national innovation system. Moreover, without a prior growth stronger IPRs *per se* will not lead to larger capital imports, because the new regime most likely will result in higher prices, and without additional purchasing power fewer products will be sold. This applies for instance in the pharmaceutical markets.

Regarding *FDI*, Maskus argues that the strength of IPRs affects the decision-making in the MNEs on where to invest and whether to transfer advanced technologies. Strong IPRs can for instance ensure greater contract certainty. Most studies however suggest that IPRs do not affect the location decisions in a large degree. Kondo (1995) for instance found no

statistical relationship between membership in IPR conventions and FDI. This may however be industry specific; surveys have showed that the chemical and the pharmaceutical industries are rather IPRs sensitive. According to Lall FDI is related to other industries “not likely to be affected by IPRs” (Lall, 2002, p.6). MNE response to IPRs also seems to be function specific. High-level R&D seems more likely to be affected by the IPR regime than basic production or marketing. The relocation of R&D is thus somewhat insignificant to developing countries; very few can hope to receive high-level R&D functions. This means that only the more advanced NICs may suffer from lax IPRs.

There still remain some important questions concerning FDI. Do FDI flows really provide spill-over benefits to host countries, and how might IPRs influence this process? Maskus claims that IPRs, investment, and human capital accumulation work together to raise productivity and growth. The issue has been widely studied and there exists a large and controversial literature. I will not go into detail on this subject, but confine myself to mentioning some of the overall conclusions.

The positive impacts of FDI on domestic investment are not assured. Daniele Archibugi argues that the impact of FDI and trade “depends crucially on the sectoral profile of the home and host economy” (Archibugi & Iammarino, 1997, p.8). Adeboye (1997) claims that the NICs used FDI in various ways. Some countries, like Singapore and Indonesia used FDI liberally, while for example South Korea, Japan and Taiwan were very selective and even restrictive in the use of FDI. All of them used imported technology, but the most selective countries in choice and use of technology turned out to be the most innovative (Adeboye, 1997).

It seems that the main lesson is that a country is more likely to benefit from FDI if it is integrated into its national development and technological plans, as a conscious part of the national innovation system. Archibugi stresses that the government and the public

administration has the task of creating a local infrastructure and sustaining domestic technological collaboration and education. He further emphasises that developing countries can be interesting technological partners if they have adequate infrastructure, including *inter alia* communication networks and qualified research personnel.

Diffusing new technology through *formal licensing* of technologies and trademarks to unaffiliated firms seems to be an opportunity. Maskus emphasises that lax IPRs may deter licensing in developing countries. Lall however claims that IPRs are “unlikely to affect technology transfer to other developing countries [others than the leading NICs], which generally purchase more mature technologies” (Lall, 2002, p.7).

2.2.4. Local Economic Activity

I have mentioned how strong IPRs may boost sophisticated business structures, a basic feature in economies which, according to Maskus, must get competitive using locally produced knowledge, not by using technologies built up in developed countries. Local diffusion of technology will benefit from stronger IPRs because of the clearer legal framework, another basic feature in any national innovation system, it provides. Stronger IPRs will however impose an immediate penalty on the developing countries depending on imitation because IPRs will raise the cost of technology transfer, thus limiting diffusion of simple technologies. TRIPS will also possibly hit local industry in many countries. India has e.g. a thriving pharmaceutical industry based on imitation and the new IPRs regime will impact medicine prices. When India implements TRIPS in 2005, much of the industry will be illegal and a patent market monopoly situation will probably raise the prices.

Another aspect is the fact that companies now may spend considerable amounts on investigating how to do research without infringing other companies' patent rights, or

defending their own patent rights against other companies. For smaller companies in developing countries this may be an obstacle extremely hard to overcome.

2.2.5. Costs of Implementing TRIPS

United Nations Conference on Trade and Development (UNCTAD) concluded in 1996 that the direct and administrative costs of complying with the TRIPS Agreement will depend on the country's level of development and state of existing IPR institutions. In general, developing countries will need to introduce reforms in legislation, administration and enforcement. The expenditures will be split between the immediate costs of implementing TRIPS and the annual costs of maintaining the system. The immediate costs involve the creation of infrastructure and institutions. The legal framework must be changed, staff needs to be trained and equipment must be purchased and installed. UNCTAD calculated Chile's estimated fixed costs to \$718,000, with an annual cost of \$837,000. The same numbers for Bangladesh, exclusive of training, were \$250,000 and \$1.1. Tanzania's immediate costs were estimated to between \$1 million and \$1.5 million (UNCTAD, 1996, pp.23-26).

These costs can be met by charging various fees for services related to processing applications for IPRs and also for renewing those rights once awarded. When the patent institution in place, it can be self-maintaining. A well functioning patent system can become an important part of the national innovation system.

2.3. Overall Impact of IPRs on Growth

The overall impact of IPRs on growth is difficult to predict. The relationships are complex, and there is a limited body of evidence. Maskus admits that "In nations where information

diffusion comes largely through copying and imitation, growth prospects could be diminished” (Maskus, 2000, p.167).

The short-term effects for the developing countries include the implementation costs of TRIPS, but also static rent transfers. Based on McCalman’s study the estimated static rent transfers from TRIPS-induced strengthening of 1988 patent laws (in 1995 US dollars) show South African net loss of 168 million dollars (McCalman, 1999). The ownership of intellectual property is concentrated in firms in some developed countries, Maskus claims that

The effect of TRIPS will be to shift the terms of trade in their [the firms in developed countries] favor, away from the intellectual property importers. In turn, profits will be shifted from both developing countries and developed countries with a comparative disadvantage in intellectual property marketing, toward a few developed countries, the United States in particular

(Maskus, 2000, p.181).

The extra market power granted to foreign interests “*must reduce short-run welfare in technology-importing countries*” (Maskus, 2000, p.182, added emphasis). These rather discouraging conclusions rest on calculations made even without assessing any spill-over costs from reduced health status as a result of higher-priced medicines.

In general the long-term consequences of TRIPS must be considered as very uncertain. The US, Japan and South Korea engineered effective technological catch-up with weak IPRs. This does of course not imply that the developing countries must have weak IPRs. The point is that the implications and results of TRIPS will vary from country to country. An analysis of the national innovation system in South Africa concluded that the real problem is a “severe shortage of scientists and engineers who can engage in R&D” (Mani, 2001, p.7). A stronger IPR system will not remedy this shortage. Stronger IPRs will change the whole structure of market competition and the results are unknown.

There is evidence that strong IPRs probably are beneficial beyond a certain level of industrial sophistication, while below this level their benefits for development are unclear.

Moreover, the poorer the countries are the less evident the benefits become. Adeboye argues that the development efforts “have to agree with the model of innovation that a country intends to pursue” (Adeboye, 1997, p.234). Developing countries are far from homogeneous. Not only do their scientific and technical capacities vary, but also their social and economic structures, and their inequalities of income and wealth. They have different forms of national innovation systems. The reasons for poverty, and therefore the appropriate policies to address it, will vary accordingly between countries. The same applies to policies on IPRs. Policies required in countries with a relatively advanced technological capability, for instance India or China, may well differ from those in other countries with a weak capability, such as many countries in sub-Saharan Africa. What works in China, will not necessarily work in Burkina Faso or Botswana. TRIPS however is a one-size-fits-all IPRs system, all national innovation systems are exposed to the same drastic remedy.

2.4. The Implementation of TRIPS

The way a country implements TRIPS will be of great importance. It is interesting to see if a country is allowed to adjust the provisions of TRIPS to their national innovation system, and can address special problems like the HIV/AIDS pandemic. Article 8 of TRIPS states that members may “adopt measures necessary to protect public health and nutrition ... provided that such measures are consistent with the provisions of this Agreement”. What is possible within the boundaries of the agreement? Two measures seem relevant in the HIV/AIDS case, namely parallel imports and compulsory licensing.

2.4.1. Compulsory Licensing

Compulsory licenses are licenses granted by a government to make, use or sell a patented invention without the consent of the patent-holder. The Doha declaration of the Fourth

Ministerial Conference in November 2001 addresses issues concerning the implementation of the present agreements. Paragraph 4 of the Doha declaration on public health states that

The TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose (WTO, 2001).

Article 31 of the TRIPS agreement allows compulsory licensing when the negotiations with the patent holder to get a permission to use the invention “on reasonable commercial terms and conditions” have been unsuccessful. It also states that a member “in the case of a national emergency”, “extreme urgency” or for “non-commercial public” use may use the “subject matter of a patent” without authorization of the right holder. The user must pay an “adequate remuneration” to the patent holder (Article 31(h)). The term “adequate remuneration” is not defined.⁷

Article 40 of TRIPS states that the WTO members also may take appropriate measures, including compulsory licensing, if the patent owner abuses the IP rights with “adverse effect on competition in the relevant market”. The term “abuse” is not defined, but the European legal traditions imply that failure to supply or license a patented product, or supplying it at unreasonable high prices, might be termed abusive (Scherer, 2003, p.2). Paragraph 5(b) of the Doha declaration specifies that each member has “the freedom to determine the grounds upon which such [compulsory] licences are granted”. The same paragraph further expresses that the members themselves can determine what a national emergency is, specifying that “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other

⁷ For a discussion of the term, see Scherer and Watal, 2002.

circumstances of extreme urgency” (WTO, 2001). Each compulsory licensing case must be treated individually.

Ironically, developed countries have been the most active users of compulsory licensing for a number of purposes, including in anti-trust cases in the US. In 2001, the US threatened to grant compulsory licences when the multinational pharmaceutical company Bayer did not meet the price reduction demands on Ciprofloxacin, the antibiotic though to be most effective against anthrax. Bayer subsequently reduced the price by 50% (Abbott, 2002). There are many reasons why developing countries have not yet used this possibility. Besides a large domestic market, an active use of compulsory licensing involves an administrative and legal infrastructure that is missing in many developing countries. The country also must have the know-how to reverse engineer and manufacture the drug without the cooperation of the patent owner. For several countries this simply is impossible. Many countries have also feared that the use of compulsory licensing may lead to bilateral or multilateral sanctions. The mere fact that the patent right holder must be paid adequate compensation for the compulsory licence may represent a last barrier.

TRIPS allows for compulsory licences for importation as well as for domestic production, but Article 31(f) of TRIPS states that any compulsory licences granted to generic producers in other countries shall be "predominantly for the supply of the domestic market of the Member" granting the compulsory licence (WTO, 1994). This means that TRIPS gives countries the right to manufacture generic drugs, or to import them, but limits other countries from exporting them. The limitation is not complete; a non-predominate amount may be exported. The interpretation of Article 31(f) is important; in principle a compulsory licensee in a market like Brazil or India can export a substantial amount of relatively cheap drugs to

other developing countries⁸. Today India and a few other countries can freely export copies of medicines that are patented elsewhere. This exemption will expire after 2005 when India implements TRIPS. India has already modified its patent laws for medicines, and other countries are also under pressure both from WTO rules and bilateral trade negotiations to enact new and tougher patent rules.

In paragraph 6 of the Doha Declaration the implementation of TRIPS concerning pharmaceutical products was postponed until 2016 for the LDCs. The members also recognised that a special problem exists for countries with insufficient manufacturing capacity to make use of compulsory licensing. The declaration instructed the TRIPS Council to find a solution to this problem by the end of 2002. August 30th, 2003, the TRIPS Council decided on the implementation of paragraph 6. They recognised that “exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products” (WTO, 2003a).

This decision clarified some of the concepts used in TRIPS, stating that for instance active ingredients necessary for manufacturing medicines are pharmaceutical products, and hence included in the agreement. It stated that when a compulsory licence is granted by an exporting country, adequate remuneration “shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member” (ibid). The decision emphasised that the countries must prevent re-exportation of products imported into the country under a compulsory license.

The most important part was however the decision that the obligations of an exporting country under Article 31(f) should be put aside to with respect to the grant of a compulsory licence “to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out ... in

⁸ For a discussion on whether it is possible to import drugs produced under compulsory licensing, see Abbott (2002), pp. 490-504.

this paragraph” (ibid). These terms include that the member must have made a notification to the TRIPS Council confirming that it intends to make use of Article 31, specifying the names and expected quantities of the product and confirming that the importing country, other than the LDCs, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product. Only the amount necessary to “meet the needs” (ibid) of the importing country may be manufactured and these products must be “clearly identified as being produced under the system ... through specific labelling or marking” (ibid).

According to the WTO, this decision will “make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves” (WTO, 2003b). NGOs like Oxfam and MSF do not agree with the Council. They react the most on how difficult and time consuming it may be to get the permission to override Article 31(f). How does a country for example establish that it has “insufficient or no manufacturing capacities in the pharmaceutical sector” for a product? They claim that the decision rather throws up new obstacles, “legal, economic, and political” (MSF & Oxfam, 2003) to ensuring production and export of generic medicines in the future. Céline Charveriat of Oxfam noted that

the burdensome system being put in place does nothing to ensure that generic production will happen in the future. Rather, developing countries will have little alternative to the high prices and long-term monopolies of brand-name pharmaceutical companies

(ibid)

It will be very interesting to see what actually will happen concerning compulsory licensing. The TRIPS Council is obliged to do annual reviews of the functioning of the system to ensure that it works effectively, so there is certainly hope.

2.4.2. Parallel Imports

Parallel imports are relevant if a drug manufacturer provides drugs at a lower price in for instance India than in Mozambique. Bayer, one of the big pharmaceutical companies, sells 100 units of the antiretroviral drug Ciprofloxacin (500mg) for \$740 in Mozambique but in India, the company sells it for \$15, due to vigorous generic competition (MSF Access Website). Many European countries, such as the United Kingdom, benefit from significant parallel trade to reduce the overall cost of medicines. Parallel importing does not involve the purchase of generics. The technical issue is the so-called “exhaustion” of IPRs, also referred to as the “first sale doctrine”. The theory states that the owner of intellectual property cannot control the *resale* of a legally purchased good. Under TRIPS rules countries are permitted to decide for themselves how to handle parallel imports (CPTECH, 1999).

2.4.3. Conclusion

The implementation of TRIPS will restrain the supply of generic copies of patented pharmaceuticals. This will remove an important element in restraining and reducing the prices of patented products in developing countries. The right to grant compulsory licenses is stated in TRIPS and the Doha Declaration, but a country needs a functioning pharmaceutical industry to exploit this flexibility. This feature is lacking in many countries⁹. TRIPS can restrain the possibility of exporting cheap drugs produced by compulsory licensees to countries without pharmaceutical capabilities. This however depends on how the decision on Article 31(f) of TRIPS will work out. It will still be possible to parallel import cheaper patented drugs, but this may become just a theoretical option when much of the competition on the medicine market is history.

⁹ For a list of countries without pharmaceutical industry, or with only reproductive capabilities, see Annex 2 of the Doha Declaration (WTO, 2001).

Chapter 3

3. HIV/AIDS: The Prices and the Impacts

In this chapter I will discuss the impact of TRIPS on the prices of HIV/AIDS drugs. Secondly, I will discuss the macroeconomic consequences of the HIV/AIDS pandemic for developing countries. It is essential to establish that the high drug prices actually are a hindrance for access to drugs. Affordability of drugs is clearly not the only barrier. However, what remains clear is that for as long as drugs are out of reach for most people with HIV/AIDS, governments have little incentive to put systems in place to deal with efficient distribution and strict compliance with often complicated drug-taking regimes. Lastly, I will discuss South Africa's special economic and social situation, and how TRIPS might affect the access to antiretroviral drugs.

3.1. Why do not People get Treatment?

Between 5 or 6 million of the 42 million infected by HIV need antiretroviral therapy (ART), but only 300.000 use them, one third of them living in Brazil (WHO, 2002b, p.1). Why do not people have access to antiretroviral drugs, is it all about affordability, or is the health service infrastructure the greatest hindrance? Last, but certainly not least; how does TRIPS affect the prices?

3.1.1. The Prices

I will try to answer the last question first. The pharmaceutical industry asserts that the fact that few pharmaceutical products are patented, even in developing countries where patent protection is available, proves that the IPRs are not important concerning access to drugs. A recent study of 53 African countries found that of a theoretically possible 795 instances of patenting (they assume that all countries offer patenting, which they admit is not true) of 15 important antiretroviral drugs, only 172 (21.6%) actually exist. In 13 countries there were no

patents on these medicines at all. This led the researchers to conclude that patents “generally do not appear to be a substantial barrier to...treatment in Africa today” (Attaran & Gillespie-White, 2001, p.1891).

If we compare with the UNAIDS/WHO report made on patents (2000), the figures do not coincide. UNAIDS/WHO finds more patents than Attaran and Gillespie-White. Still the level of patenting is not very high. There are several reasons why the industry does not patent its products. In countries with small markets and limited technological capacity, the risk of infringement is low, and the expense of getting and protecting a patent may be higher than the potential benefits of the patent. Attaran and Gillespie-White find for instance few or no patents granted in Algeria, Libya, Tunisia, Morocco, Mauritius, Egypt and Djibouti. In the North-African countries the HIV/AIDS prevalence is low, and countries like Mauritius and Djibouti are simply too small to represent a threat to the pharmaceutical companies.

The prevalence of patents is very much higher in countries in which there is a substantial market, and technological capacity. In South Africa 13 of the 15 drugs are patented and there are 6-8 patents for these drugs in Botswana, Gambia, Ghana, Kenya, Malawi, Sudan, Swaziland, Uganda, Zambia and Zimbabwe, which together account for another 31% of HIV cases in sub-Saharan Africa. The patents that are granted also block the access to combination drugs that are often considered among the most appropriate for developing countries (Boelaert et al, 2002, p.840). The combination of the two antiretroviral drugs Zidovudine and Lamivudine is for instance patented in 37 countries. Eric Goemaere *et al* also argue that many of the non-patented drugs are therapeutically impractical in resource-poor settings (Goemaere et al., 2002, p.841).

Moreover, the mere possibility of patenting may keep the potential patent infringers away. Most LDCs do not have the capacity to produce drugs themselves, they have to rely on imports for their supplies. Strong IPRs in potential supplier countries may allow the patentee

to prevent supplies being exported to another country, particularly through controls on distribution channels. This is another reason why companies may selectively patent in countries such as South Africa because it is a potential supplier to its poorer neighbours (CIPR, 2002).

The prices of pharmaceuticals are the result of negotiations between governments and firms (Lanjouw & Jack, 2003) and of market structures. Comparison is difficult because of “the lack of standardisation among different companies on eligibility, terms and conditions, and pricing” (MSF, 2003, p. 5). The pharmaceutical companies offer poor countries various discounts taking different criteria, like LDC classification or HIV/AIDS prevalence, into account. Even if a country is offered discounts, all institutions within the country may not be offered the reduced prices. According to Jayashree Watal, there are few reliable estimates of differences in prices in medicines in developing countries, especially on account of patents alone (Watal, 2000b, p.3). A simple price comparison between countries does not take account of the number of other price-influencing aspects like tariffs and other forms of indirect taxation. It is important not to ignore that the national tax systems do not always operate in a way that supports public health.

Having said this, it is interesting to look at what actually happens when a generic drug enters the market. An efficient generic drug market requires two conditions: interchangeability between pharmaceutical products and price competition. According to Enrique C. Seoane Vázquez (2003) and MSF (MSF, 2003) generic drugs are the main source of competition in the pharmaceutical market. The development of a competitive generic market allows consumers to access interchangeable drugs at a lower price. MSF states that “the injection of generic competition into the global ARV market has catalysed a dramatic drop in drug prices. As a result, medical, academic, and political leaders are now beginning to

tackle other barriers to treatment”¹⁰ (MSF Access Website, FAQ). MSF states that the most efficient tactic to push prices down is a system of equity pricing. Equity pricing involves the stimulation of generic competition, differential pricing according to clearly defined policies, or voluntary licensing and an active use of compulsory licensing (MSF, 2003).

Fink (2000) and Watal (2000a) have estimated the impacts of patents in India. They found impacts between 12-242%, depending on which assumptions the calculations were based on. Figure 3.1 illustrates how much the price of the antiretroviral drug Fluconazole changed after the introduction of generic competition in 1998 (Love, 2002a).

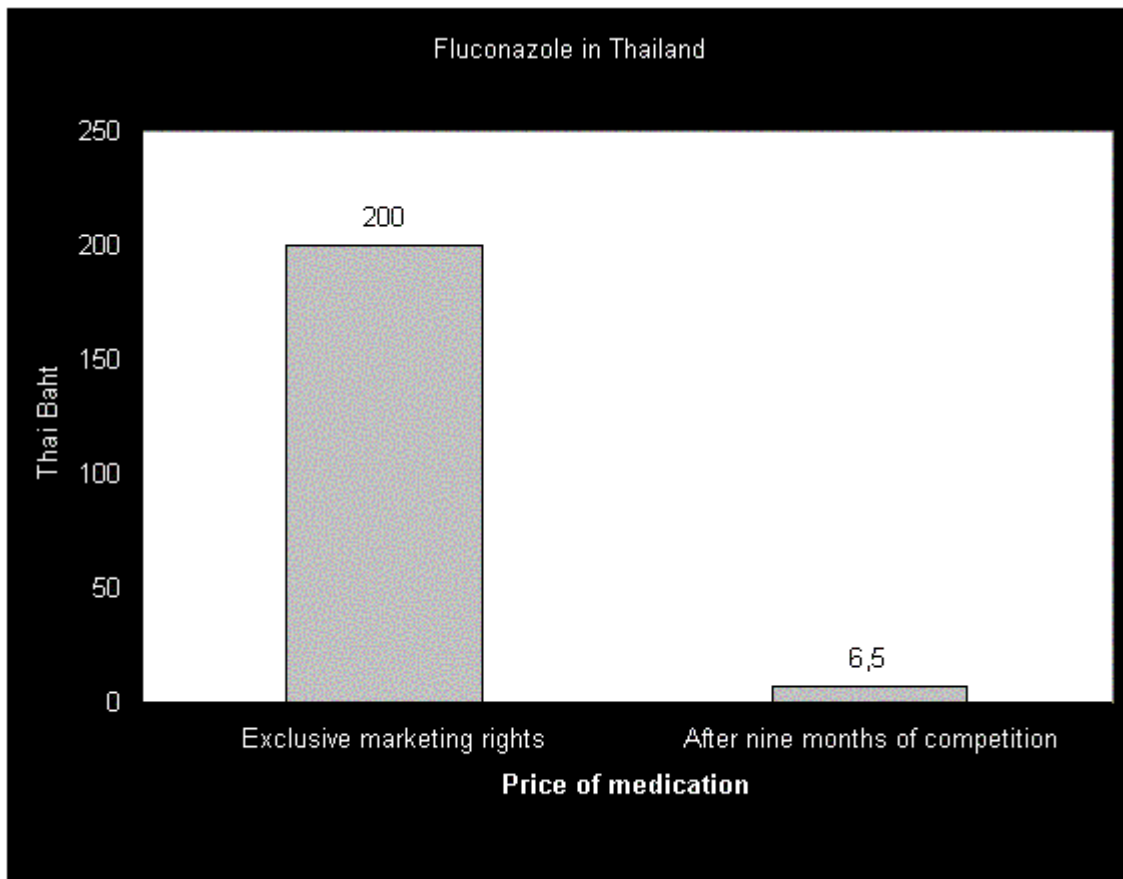


Figure 3.1 The changes in prices for Fluconazole in Thailand, following the introduction of competition in 1998. (Love, 2002a)

¹⁰ For updated price information on antiretroviral drugs, see MSF, 2003.

Evidence shows that drug prices rise with per capita income, fall with per capita consumption volume, fall with price controls and rise with patent protection (Schut & Van Bergijk, 1986). An investigation made by Jean O. Lanjouw (1998) showed that the prices of four patented drugs in the United Kingdom were between 26 and 57 times higher in the United States than in India. According to Lanjouw, these differences were mainly due to the fact that India had not patented drugs since 1972. The Indian pharmaceutical industry flourished and brought cheap generic medications to the Indian market. Such a degree of competition affected the prices of the patented products.

Following Maskus, Indian drug prices will rise when the IPRs get stronger, but how much they will rise is dependent on several factors. Market structure before and after stronger IPRs is essential, factors like the number of firms competing with right holders and the ease of market entry and exit do vary. The demand elasticity is also a key variable determining market power. Maskus concludes that “the larger the share of the drugs market that is patented, the higher will be the price impact” (Maskus, 2000, p. 163) I think we can conclude that patenting does affect prices, and that implementing TRIPS *probably* will raise the drug prices, but we have to keep in mind that other factors also affect them.

3.1.2. Do Prices Block Access?

So, is it the price that blocks the access to drugs? It needs to be stated that it is primarily poverty itself that must take the blame for the poor access to essential medicines. Poverty means that the poor cannot purchase medication and that their governments cannot build up a proper health system with the resources needed to cope with the HIV/AIDS pandemic. It is important to recognise that HIV/AIDS also leads to poverty. This means that addressing the problem may be a good starting point for fighting poverty. HIV/AIDS is an inherent part of

the poverty problem and fighting poverty without HIV/AIDS treatment programmes will be like trying to fill up a bath tub without plugging the run-off.

Lately the price of the life-extending antiretroviral drugs have fallen, “thanks to the work of hundreds of individuals and activists in non governmental organisations (NGOs), governments, UN agencies and the private sector ... and we are now in a position to consider scaling up access in resource limited settings” (WHO, 2002c, p.6). However, still the minimum annual costs of antiretroviral therapies far exceed the annual health expenditure per capita of most developing countries. Current per capita health expenditures in low income developing countries average \$23 annually and the cheapest generic antiretroviral triple therapies cost \$208 (CMH, 2001, p.56).

The last three years global expenditure on AIDS has increased from \$300 million annually to nearly \$3 billion annually (WHO, 2002b, p.2), resulting in e.g. 70.000 more people on ART last year. When such donor financing is available, drug prices certainly affect the share of these funds that is spent on drugs, hence influencing the number of people getting ART. There is also considerable evidence that the consumption of medicines *is* sensitive to price. A global econometric study estimated that switching from a patent regime to a no patent regime in a cross-section of developing countries would have increased the access to ART by 30% between 1995 and 1999, albeit from the very low existing level (Borrell & Watal, 2002). The study suggests that the negative impacts of patents on access vary much over time and across income levels. The corresponding numbers for South Africa were an increase of access to drugs by more than 100%. It is important to note that the study only referred to unsubsidised drug sales; donations of drugs or subsidised medicines did not count. The inclusion of these figures may lead to even more significant numbers. A study in Uganda estimated that a price reduction on antiretroviral triple therapy from \$6000 annually to \$600 annually would increase the demand for treatment from 1000 to 50000 patients if associated

with relatively modest investments in treatment infrastructure of \$4-6 million (McKinsey & Company, 2000).

3.1.3. Health Infrastructure

To avoid drug-resistance HIV strains, ART must be properly monitored. In the past, patients were bound to take many pills at fixed hours every day. WHO's guidelines on simplified standardised regimens and laboratory monitoring have greatly reduced the complexity of treatment, making ART more available (WHO, 2002c). The Indian drug manufacturer Cipla has put a three-drug cocktail in one pill to be taken twice day on the market. Soon the company will launch the first once-a-day cocktail that will make treatment much easier in poor countries (Bosley, 2003a). Several pilot projects have showed the possibility of ART in resource-poor settings, for instance MSF's work in Khayelitsha in the Western Cape, South Africa (MSF, 2003).

At the AIDS conference in Barcelona in July 2002, dr. Joep Lange, president of the International AIDS Society noted that "If we can get cold Coca Cola and beer to every remote corner of Africa, it should not be impossible to do the same with drugs" (WHO, 2002b, p.8).

Dr. Peter Piot, executive Director of UNAIDS, stated that

Treatment is technically feasible in every part of the world. Even the lack of infrastructure is not an excuse – I don't know a single place in the world where the real reason AIDS treatment is unavailable is that the health infrastructure has exhausted its capacity to deliver it. It's not knowledge that's the barrier. It's political will

(WHO, 2002b, p. 9).

WHO concludes that

Drug access for the millions who need it will be improved not only by guidance on the rational selection and use of ARV drugs, but also by improved affordability and sustainability of drug financing and by accessible, appropriate and competent health services

(WHO, 2002c, p. 9).

MSF declare that

In many developing countries, particularly in urban centers, the necessary infrastructure exists to provide antiretroviral therapy today. Small pilot programmes in Uganda, Côte d'Ivoire, and Senegal, and widescale treatment programmes in Brazil and other Latin American countries, have demonstrated that it is possible. ... Infrastructure challenges are not a valid excuse to continue denying medical treatment to those in need

(MSF Access Website, FAQ).

3.2. The Economic Impact of HIV/AIDS

The HIV/AIDS epidemic is not homogeneous; sub-Saharan Africa suffers the worst, with HIV prevalence rising at increasing speed. The relationship between HIV/AIDS and economic development is complex, mainly because of reverse causality. Does HIV/AIDS lead to poverty or does poverty lead to HIV/AIDS, or does it go both ways? HIV prevalence can be used to foresee the number of future illnesses, deaths and orphans but can not predict with same degree of preciseness what the effects of increased morbidity and mortality will be for business and national economies in the medium and long term.

I have mentioned earlier that, according to Adeboye, the development model based on imitation of technology has proved hard for the sub-Saharan countries, because they have difficulties in providing “the basic traditional services of governance- law and order, basic infrastructure, education, health and a competent bureaucracy“ (Adeboye, 1997 p.215). Other basic features in this model are *inter alia* the level of general education, human development in targeted industries and sectors and a high managerial and technical competence of the bureaucracy. It is important to grasp that the HIV/AIDS pandemic may affect all these *basic* features in the national innovation system.

Many studies on the economic consequences have been carried out, with very variable results. UNAIDS have chosen six indicators of the economic impact of AIDS on basis of “their transparency, robustness and usefulness” (UNAIDS, 2000, p.1). These indicators include the macro economic level, the household level, education, health, agriculture and

business. Where the HIV prevalence is low, the impacts are experienced mostly in households and in the health sector. The higher the prevalence, the more severe the consequences are, on all levels. In 2000 UNAIDS emphasized that there is too little systematic, substantial evidence concerning the economic impacts on HIV/AIDS (p.10). They stated that HIV/AIDS quickly becomes more than “only” a health problem; “once HIV prevalence increases beyond 5%, there are few parts of society unaffected” (p.11).

3.2.1. Macroeconomic Impact

Economists use several models to calculate the reductions in overall economic growth rates. Most researchers use “with” and “without AIDS” scenarios, and in general they apply regression analysis to estimate the impact of HIV/AIDS, see table 3.1. Bonnel uses cross-country data that show that HIV/AIDS reduced Africa’s per capita income by 0.7 percentage points annually from 1990-1997 (Bonnel, 2000b, p.17), but countries with an adult HIV prevalence of over 10% experienced a 1.0-1.6 percentage points reduction in growth of GDP per capita.

Other researchers emphasise that these studies are too optimistic, because they do not take into account how HIV/AIDS undermines human capacity, reduces productivity, and damages organisations and institutions. They stress that the effects of the pandemic tend to be non-linear. A class of economic models that estimates differential effects of HIV/AIDS across sectors predicts greater impact on growth rates and more variation between sectors. Jeffrey Lewis and Channing Arendt (2000) have estimated that the size of the South African economy will be reduced with 17% by 2010, the GDP per capita reduction will be more than

7% and the consumption per capita about 12% lower than without HIV/AIDS.

Study	Countries	Period of most recently used data	Results (comparison w/ non-HIV/AIDS scenario)
Dixon et al (2001)	41 countries (1960-98)	Late '90s	Growth rates reduced by 2-4%, large variations across countries, in line with prevalence of HIV
World Bank (2001)	Swaziland	Early '90s	Average rate of growth of GDP in 1991-2015 will be 1.5% lower a year
World Bank (2001)	Namibia	Early '90s	Average rate of growth of GDP in 1991-2015 will be 1.1% lower a year
World Bank (2000)	Lesotho	Late '80s	Average rate of growth of GDP in 1986-2015 will be 0.8% lower a year
Bonnel (2000)	About 50 countries (1990-97)	Mid- '90s	Rate of growth of GDP per capita reduced by 0.7% a year in the 1990s
Quattek et al (2000)	South Africa	Mid- '90s	Average rate of GDP growth over next 15 years will be 0.3-0.4% lower a year
BIDPA (2000)	Botswana	Late '90s	Average rate of growth of GDP in 2000-2010 reduced by 1.5% a year
Bloom et al (1995)	51 Countries (1980-92)	Early '90s	Insignificant effect on income growth
Cuddington et al (1994)	Malawi	Early '90s	Average rate of growth of GDP in 1985-2010 reduced by up to 0.3%
Cuddington (1993)	Tanzania	Early '90s	Per capita GDP in 1985-2010 up to 10% smaller
Over (1992)	30 sub-Saharan countries	Early '90s	Rate of growth of GDP per capita in 1990-2025 reduced by 0.15% (0.6% in 10 most affected countries)

Table 3.1 Summary of studies of the macroeconomic impact of HIV/AIDS in Africa (Dixon, McDonald, Roberts, 2001, p.233)

3.2.2. Household Level Impact

AIDS tends to strike young adults in the prime of their productive years. AIDS-related deaths are likely to occur in the 25 to 50 age group (Quattek & Fourie, 2000, p.5), increasing the burden on the elderly and the very young. On household level, studies suggest that occurrence of HIV/AIDS redistributes private consumption; people use more money on medical care, drugs and funerals, hence reducing investment and savings. Most poor consumers have to pay for drugs directly. WHO (2001) estimated that in 28 countries half of the health costs are paid by directly by individuals. Studies show that the income of AIDS-ridden households can be less than half that of the average household (UNAIDS, 2002b, p.12).

There is a lot of country specific empirical evidence stating the impact of HIV/AIDS on the household, see UNAIDS (2000a). With lower savings, the rate of investment falls, reinforcing the decline in economic growth. Some authors using a Malthusian framework¹¹ argue that the per capita income actually may rise because unemployed people fill the vacancies resulting from AIDS, see e.g. Over (1992). Markus Haacker (2002) however argues that the demand for unskilled workers also will diminish as a result of the disease.

3.2.3. Educational Impact

Regarding education, recent research indicates that the reduction of incentives to study due to shorter expected longevity plays a key role (Ferreira & Passoa, 2003). Simulations predict that the worst affected sub-Saharan countries on average will be a quarter poorer than they would be without AIDS, due to the human capital reduction and the decline in savings and investments. They point to the fact that life expectancy has fallen dramatically. In South Africa, Zambia, Zimbabwe and Swaziland life expectancy decreased by more than 10 years from 1985 to 1999 (p.3). Average life expectancy in sub-Saharan Africa is now 47 years, UNAIDS (2002a) has estimated that it would have been 62 years without AIDS. In South Africa, life expectancy for the period 2000-2005 is estimated to be 18 years less than without AIDS (UNAIDS, 2002b, p.9). Ferreira and Passoa argue that this reduction decreases productive life span, and that people as a consequence tend to leave school earlier, so that the average education level decreases.

An additional problem is absenteeism and high mortality among teachers and other school staff suffering from HIV/AIDS (Kelly, 1999). Survey evidence also shows that many households cannot afford their children's education because of HIV/AIDS, and that many children are not attending school as a direct consequence of the death of one of their parents

¹¹ In the early model of Malthus the relationship between growth and per capita income was negative. The Black Plague for instance led to higher real incomes for a smaller population.

(UNAIDS, 2000, p.9). In some African countries, school enrolment is reported to go down by 20-36% due to AIDS and its subsequent consequences (UNAIDS, 2002b, p.11). An epidemic may also reduce the school budgets, because of an AIDS-related decrease in private and public funding.

Less funding, sick teachers and pupils and a general unhealthy environment in the schools must affect the quality of the training and education. In total, this directly affects output because human capital is a factor of production. The level of education is also a vulnerable and important part of the national innovation system. The decrease in the general education level will throw the HIV/AIDS pandemic to new heights; UNAIDS states that “There is evidence that greater educational achievements correlate strongly to reduced risky behaviour in places where the epidemic is well entrenched” (ibid).

3.2.4. The Health Sector

The health sector is hard hit by HIV/AIDS, both concerning the supply and the demand. Concerning supply, ill doctors, nurses and other staff stay home from work, and the group suffers from high mortality. The demand for health service has grown enormously in countries with a high prevalence of HIV/AIDS, and HIV/AIDS patients occupy a rising share of the beds. Another worry is how HIV/AIDS-related costs eat up the health budgets, leaving less for other concerns. In 2001 African governments committed themselves to increase their health budgets to 15% of government revenue.

3.2.5. Firm, Organisation and Bureaucracy Level Impact

If we look at the firm level, HIV/AIDS directly reduces labour productivity. Workers suffering from AIDS are absent from work, or when they do come, they tend to perform less. The firms also face increased health care costs and burial fees. In addition, HIV/AIDS erodes

human capacity in firms and may be a hindrance to so called “capacity deepening” (McPherson, 2001). Capacity deepening may be defined as increasing productivity by building upon existing skills. When trained personnel die the company loses valuable knowledge and know-how and it experiences that work schedules are disrupted. As a result on-the-job-training may decrease and the firm must meet the cost of training new personnel. The incentive to support training is also brought down, because a high prevalence of HIV among workers reduces the chance of subsequent revenues.

Some studies of sub-Saharan firms show that the burden that a firm acquires each year as a result of new infections among employees ranges from 3 to 11 percent of annual salaries in 1999 and 2 to 8 percent in 2010 (Bark-Ruggles & others, 2001). The differences between the firms depends on production structures and human resource policies, including differences in retirement, death and disability benefits, level of medical care paid for by the firm, baseline labour productivity and the contractual status for unskilled workers. For companies that have not reduced death and disability benefits, these benefits comprise the largest share of the total cost; for the others, on-the-job productivity loss is the largest component. This implies that some of the firms take the burden of HIV/AIDS, whilst others shift the burden to public society.

Many of the problems concerning firms also apply for organisations, the institutions and governmental policy making. Bonnel launches a hypothesis that HIV/AIDS has macro economic effects because it worsens fiscal deficits and reduces the management capacity of governments, hence affecting economic growth (Bonnel, 2000, p.4). Because of inadequate information on HIV/AIDS in the early period, also a generation of highly educated people, very valuable for the organisations and civil services, is being lost. This may also adversely influence the government’s ability to enforce effective regulations and legal framework. It is very clear that the HIV/AIDS pandemic will affect the national innovation system, when

interpreting NIS both in a narrow and a broad way. The role of institutions and policy making is very central, and HIV/AIDS affects the institutions directly by eroding their human capacity and secondly by binding up more money, giving the institutions less economical freedom. Bonnel states that “the main conclusion is ... that HIV/AIDS reduces the capacity of governments to implement efficient economic management and adversely affects the enabling environment which is important for private sector development” (p. 8). A high managerial and technical competence of the bureaucracy is one of the basic features in a well functioning national innovation system.

Several survey evidence and case studies show the impacts of HIV/AIDS on NGOs and community based organisations (CBOs). In a recent South African survey 76% of the CBO representatives participating reported that HIV/AIDS had impact on their organisations. The impacts ranged from absenteeism and turnover to declining community participations and stigma problems (Manning, 2002, p.8).

3.2.6. Conclusions

The Commission on Human Rights stated in 2003 that “that the spread of HIV/AIDS can have a uniquely devastating impact on all sectors and levels of society” (UN, 2003). I can conclude with stating that there is a need for keeping people alive to reduce the loss of human capacity, to ease the pressure on the health budgets, the organisations, the firms and the educational sector. The scale of the epidemic in South Africa and other sub-Saharan countries means that one cannot focus exclusively on prevention programs. Access to medicines is in this context, both for treating the HIV infection and the other infections associated with HIV/AIDS, of major importance. Access to antiretroviral drugs can dramatically reduce morbidity and mortality and improve quality of live.

3.3. South Africa as a Special Case

South Africa is in several respects a special case. 5 of the 40 million people suffering from HIV/AIDS live in South Africa. At the same time, the country is relatively rich (US \$2,900 per capita 2001), but it has among the highest income disparities in the world. Thirteen percent of the population (about 5.4 million people) lives in “first world” conditions, fifty-three percent of the population (about 22 million people) live in “third world” conditions (World Bank website). South Africa has one of the highest HIV/AIDS infection rates in the world. By the end of 2001 the estimated adult prevalence rate was 20.1%. The South African health infrastructure is relatively good, but apartheid structures still dominate; 80% of the South Africans rely on a public sector that lacks funding, the rest enjoys a very good private health sector (Achmat, 1999). Currently (September 2003), less than two percent of the people living with HIV/AIDS in South Africa are receiving antiretroviral treatment.

3.3.1. Intellectual Property in South Africa

TRIPS came into force in 1995, and South Africa had a transition period of only one year to apply its provisions. South Africa has been known for its high drug prices, partly due to the provisions of TRIPS, but also as a result of a tradition of rather strong IPRs. High distribution chain costs are also blamed for the high prices (Kettler & Collins, 2002). In 2000 and 2001, multinational pharmaceutical companies offered some AIDS drugs to lower prices in Africa. Many health groups saw this as a result of competitions from generic companies. Currently (September 2003), GlaxoSmithKlein has patents in South Africa that prevents the Indian generic drug producer Cipla from entering the market and the prices are still high. The dual combination AIDS-drug Combivir costs \$2.50 a day, \$927 a year, compared to the Malawian cost of \$1.70, \$620 a year. In India Cipla sells a generic version of Combivir for \$292 a year

(Bosley, 2003b). A problem in the drug market in South Africa is the lack of transparency. The market functions as much as a result of the bargaining power of firms and other groups, as a function of supply and demand.

In 1997, the South African government passed the Medicines and Related Substance Control Amendment Act. In February 1998, the Pharmaceutical Manufacturers Association of South Africa (PMA) and 39 pharmaceutical companies began legal proceedings against the government to block the law, asserting that several of its provisions were in violation of the South African Constitution and of TRIPS. Partly because of the threat of trade retaliation from the US government, the South African government agreed not to implement the legislation until the court case was decided. The main issue was Amendment 15(c) to South Africa's Medicines and Related Substances Act that would allow compulsory licensing and parallel imports of medicines in South Africa.

On April 19, 2001, the pharmaceuticals companies, under an extremely high amount of international pressure, dropped their case. However, two years later, the government has not yet used the possibilities provided for in Amendment 15(c). The answer to why this has not happened is a complex one.

There has been some international experience with the use of the flexibilities provided for in TRIPS. Brazil had to implement the agreement by 1. January 2000. Pushed by a strong activist movement, the government of Brazil started to locally manufacture ARVs that were not patented. Generic production by state companies, combined with bulk purchases of imported ARVs, decreased drug costs by 79% between 1996 and 2000. Many of these drugs are the subject of patent protection in other countries. Because Brazil did not allow patents to issue on pharmaceuticals prior to its accession to TRIPS, these drugs are not subject to Brazilian patent rights. When faced with high prices of new patented drugs the Brazilian government threatened to override patents by issuing a compulsory license unless drug

companies lowered their prices. This strategy has dramatically reduced the prices of patented drugs. Many observers believe the Brazilian program to be highly successful and should serve as a model for other nations (Thomas, 2001).

The Brazilian government has sponsored an anti-HIV/AIDS campaign that, among other components, includes a drug distribution program. At the moment, government facilities manufacture seven anti-HIV/AIDS medications, including antiretroviral combination therapies, and distribute them to HIV/AIDS patients free of charge. Almost all people in Brazil have access to treatment, and mortality from AIDS has dropped by more than half between 1996 and 1999. In addition to prolonging patients' lives, ARV treatment has also saved the government \$472 million in hospitalisations and treatment of infections related to HIV/AIDS from 1997-1999.

In July 2002, the South African government established a joint Health/Treasury team to examine treatment options to supplement comprehensive care for HIV/AIDS in the public health sector. In August 2003, the report was finished with interesting results, leading the Cabinet to instruct the Department of Health to develop an operational plan within one month to provide ARVs in the public sector. The report estimated the costs of universal access to antiretroviral therapy including necessary non-ARV care, like for instance nutrition. The 100% ARV coverage scenario would defer 1.721.000 deaths between 2003 and 2010, at a cost of 26.238 Rand per death. This scenario could save an additional 5 million years of life more than the non-ARV treatment. The number of orphaned children would be reduced by 860.000. The estimations took the current prices of treatment in account, but emphasised that there is still room for improvement from the current prices. To get better prices, the report recommended the establishment of a national price negotiations team and “strategy to assertively negotiate reduced prices for ARVs and other essential drugs”, to “strongly encourage the granting of voluntary licences by patent holders for local manufacture” and in the medium

term to “consider the using of the provisions of Article 31 of TRIPS to move forward with compulsory licensing” (Joint Health and Treasury Task Team, 2003, p. 20). It seems as if the South African government will finally try to use the flexibilities in TRIPS, as one of the instruments to get lower drug prices. The question is of course if this will be enough when the Indian competition disappears in 2005.

Chapter 4

4. A Human Rights Prospective on Access to Drugs

In this chapter I will briefly outline the international human rights framework and I will see how the right to life, health, development and medical treatment is relevant in an access to drugs discussion. I will also discuss if and how TRIPS restricts a country's possibilities to protect and promote human rights. In 2000 the UN High Commissioner stated that "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights" (UN, 2000b). It is important to see that both the TRIPS text in itself *and* the implementation, and hence the *effects* of the agreement must be "assessed for compatibility with a human rights approach" (UN, 2001a, para. 15).

4.1. The International Human Rights Framework

The Universal Declaration of Human Rights adopted by the UN General Assembly in 1948 is the most authoritative statement of human rights (Chapman, 2002). The Universal Declaration recognises traditional civil and political rights, but goes a step further by recognising economic and social rights. There is an international consensus that the different types of rights are of equal status and are interconnected; "All human rights are universal, indivisible and interdependent and interrelated" (UN, 1993, para. 5). The Universal Declaration is, strictly seen, not legally binding, but many experts consider it to be "internationally accepted common law" (Chapman, 2002, p.863). The International Covenant on Economic, Social and Cultural Rights (ICESCR) and The International Covenant on Civil and Political Rights (ICCPR) from 1966 are human rights instrument refining the rights stated in the Universal Declaration. Countries that ratify or accede to these human rights instruments become states parties legally bound by their requirements. The ICESCR has 145 states parties, excluding the

US and South Africa, which have signed but not ratified this treaty (p. 864). Regional instruments, like the African Charter on Human and Peoples' Rights, also enshrine State obligations relevant to HIV/AIDS.

4.1.1. The Implementation of Human Rights Legislation

States and governments are responsible for the implementation of the human rights legislation. The responsibility is threefold; first, the government must *respect* the rights. This means that they cannot violate a right legally or politically. Secondly, they must *protect* the rights through legislation or other means to prevent others from violating the rights. Thirdly, they must *fulfil* the rights by ensuring that individuals and communities can enjoy their rights (ibid). General Comment 14 (paras. 34-37) includes a list of what these specific duties entail.

The ICESCR states that states parties must take steps “to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means” (UN, 1966a, Article 2.1.). The UN Committee on Economic, Social and Cultural Rights is an expert body reviewing how the members do concerning the obligations stated by the ICESCR. The Human Rights Committee is the corresponding body for the ICCPR. Despite these controlling organs, there is a general lack of effective human rights enforcement mechanisms. The institutions that oversee and help the implementation of the human rights law “only have sufficient power and resources to undertake the normative development of human rights” (Chapman, 2002, p. 866). Still, critical reports about abuses of human rights are a sanction possibility, if a relatively weak one. In theory, UN has powerful sanction possibilities, but UN’s relative power is tied to the relative power of other treaties and organisations, for instance WTO. The WTO has more effective enforcement mechanisms than the UN. In a potential or actual conflict between the obligations bound to the two organisations the outcome may be given.

4.1.2. The Right to Health

The human right to health is recognised in many international instruments. Article 25.1 of the Universal Declaration states that “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”. In Article 12.1 of the ICESCR, states parties recognise “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”, while Article 12.2 lists a number of “steps to be taken by the States parties ... to achieve the full realization of this right”. These steps include “the prevention, treatment and control of epidemic, endemic, occupational and other diseases” and “the creation of conditions which would assure to all medical service and medical attention in the event of sickness”. The ICCPR recognises the right to life (Article 6). The Human Rights Committee supervises the fulfilment of this Covenant, and has defined the role of the state to include undertaking measures to eliminate epidemics. In May 2000 the Committee on Economic, Social and Cultural Rights adopted General Comment 14 providing guidance on the implementation of the right to the highest attainable standard of health. It states that “to ensure the right access to health facilities, goods and services on a non-discriminatory basis” is a core obligation for any state party (para. 43).

The General Comment highlights four important principals; availability, accessibility, acceptability and quality (UN, 2000a, para. 12). Availability deals with the public health supply. Accessibility emphasises that everyone should have access to health services without discrimination, affordability is one dimension. Acceptability states that the health services should be supplied in an ethically and culturally appropriate way. The principle of quality emphasises that the health services provided should be of good quality.

Additionally, the right to health is recognised, *inter alia*, in Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in Articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in Article 24 of the Convention on the Rights of the Child of 1989. Several regional human rights instruments also recognise the right to health, for example the African Charter on Human and Peoples' Rights of 1981 (art. 16). Similarly, the right to health has been proclaimed by the Commission on Human Rights as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

4.2. South African Legislation

South Africa has signed the International Covenant of Economic, Social and Cultural Rights (ICESCR), but has yet to ratify it. It has also recognised socio economic rights in its Constitution, including the right to access to health care (Ngwena, 2000, p.27). Section 27 of the Constitution is modelled on provisions of the ICESCR (Pillay, 2003). It states that

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

(The South African Constitution, 1994)

These rights are somehow as vague as the ICESCR, not defining the quantity or quality of health care services. Section 27 is weaker than the ICESCR; it requires use of only “available” rather than “the maximum of its available” resources. However, Charles Ngwena (2000) emphasises that the formulation is realistic, stating that a strict definition of quantity

and quality would create false expectations. Section 39 of the Constitution obliges a court, tribunal or other forums to consider international law when interpreting the Bill of Rights. Karrison Pillay argues that this means that despite the fact that South Africa has not ratified the ICESCR, the interpretation of health rights is nevertheless relevant to the interpretation of health rights within the South African constitutional context (Pillay, 2003, p.63).

The fact that the South African Constitution is relatively new implies that there still are relatively large parts of it that have not been tried in court. This opportunity to create precedence has been used by several individuals and organisations. In 2002 the Treatment Access Campaign (TAC) won the case against the South African government concerning the right to access to mother-to-child-transmission drugs. The Constitutional Court emphasised that Sections 27(1) and (2) of the Constitution

require the government to devise and implement within its available resources a comprehensive and co-ordinated programme to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV

(Constitutional Court of South Africa, 2002).

It will probably be much more difficult to get a court decision obliging the government to use its available resources to realise the rights of patients HIV/AIDS, other than the pregnant women and their newborn. A court resolution like that would of course bind up much money and could be interpreted as a threat to the independency of the executive power towards the judiciary power and the principle of the separation of powers

4.3. TRIPS, HIV/AIDS and Human Rights

4.3.1. IPRs and Human Rights

Article 7 of TRIPS recognises the links between the agreement and the promotion and protection of human rights by stating that

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology... in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

(WTO, 1996)

The UN Sub-Commission on the Promotion and Protection of Human Rights notes that recognising these links is not the same as “saying that the TRIPS Agreement takes a human rights approach to intellectual property protection” (UN, 2001a, para. 21). The Sub-Commission points to some difficult aspects of TRIPS; first of all, the driving force of TRIPS is very different from the human rights approach. This means that that the implied concerns about rights in the agreement generally are expressed “in terms of exceptions to the rule rather than to the guiding principles” (para. 22). Secondly, TRIPS is relatively detailed about the content of intellectual property *rights*, but the *responsibilities* of the patent holders are rather vaguely described (para. 23).

4.3.2. The Right to Enjoy the Benefits of Scientific Progress

Article 15.1 (b) of the ICESCR and the corresponding Article 27 of the Universal Declaration state the right to enjoy the benefits of scientific progress and its applications. This means that an IPR regime must facilitate and promote the individual and collective participation in scientific progress. On the other hand, Article 15.1 (c) recognises the R&D trade-off described in chapter 1; it states everyone’s right to benefit from any scientific, literary or artistic production “of which he is the author”. The question is where to put the emphasis. A human rights approach however implies that this balance should be struck with the prime purpose of promoting and protecting human rights. In November 2001 the Committee on Economic, Social and Cultural Rights adopted a statement on human rights and intellectual property (UN, 2001b). The Committee stated that all national and supranational IPR regimes must respect and abide by the human rights law; highlighting that “the realms of trade,

finance and investments are in no way exempt from human rights principles” (UN, 2001b, para. 3). The Committee emphasised that the protection provided for authors in Article 15.1 (c) not “necessarily coincide with what is termed intellectual property rights under ... international agreements” (para. 6). It is also important to see how IPRs and human rights differ. IPRs can be held by corporations, they can be licensed, withdrawn and expire. In contrast, human rights are universal and inalienable (UN, 2001a, para. 14, UN, 2001b, para. 6). The Committee defines the human rights as *fundamental*, in contrast to IPRs that are *instrumental* (UN, 2001b, para. 6). The statement emphasises the need for balancing the protection of private and public interests in knowledge; “private interests should not be unduly advantaged and the public interest in enjoying broad access to new knowledge should be given due consideration” (para. 17).

4.3.3. The Right to Health and Medical Treatment

The right to health includes obligations on promoting research, especially research concerning a group of diseases including HIV/AIDS (UN, 2000b, para. 36). The states are also bound to ensure access to affordable treatment. According to General Comment 14, core obligations, applicable to all states parties irrespective of their level of development, include providing essential drugs “defined by the WHO’s Action Programme on Essential Drugs” (UN, 2000a, para. 43). Currently (December 2002) 12 different antiretroviral drugs were on the Essential Drugs list (WHO, 2002). The core obligations also include to “take measures to prevent, treat and control epidemic and endemic diseases” (UN, 2000, para. 44 (c)). The Committee also emphasises that making “relevant technologies” available is an inherent part of the control of diseases required for in Article 12.2 (c) of the ICESCR. The Commission on Human Rights stated that “access to medication in the context of pandemics such as HIV/AIDS... is one fundamental element for achieving progressively the full realization of the right of everyone

to the enjoyment of the highest attainable standard of physical and mental health” (UN, 2003, art. 1). General Comment 14 also emphasises that the State parties must adopt and implement a national public health strategy and action plan, addressing the health concerns of the whole population (para. 43). According to Pillay, the South African government’s “inability to deal effectively with the HIV/AIDS crisis has been extremely disappointing and a severe constraint on the realisation of health rights” (Pillay, 2003, p. 68). Hopefully will the South African treatment plan that is to be presented in 2003 change this picture.

4.3.4. The Economy of TRIPS and the Right to Development

The UN Sub-Commission on the Promotion and Protection of Human Rights expressed in 2001 concern on how TRIPS may affect the members autonomy and their abilities to promote and protect human rights, including the right to development (UN, 2001a, para. 24).

In 2001 the Committee on Economic, Social and Cultural Rights emphasised that

any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health...especially, or any other right set out in the Covenant, are inconsistent with the legally binding obligations of the State party

(UN, 2001b, para.12).

The Committee especially emphasised the fact that countries at different levels of development have dissimilar technological needs and that as a result countries may have different foci in their technology policy. Some may focus on protection and restriction of intellectual property, but for others the “key issue is facilitating access”. The Committee’s conclusion is that “international rules concerning intellectual property should not necessarily be uniform”. It also recommends the adoption and implementation of international mechanisms for intellectual property protection that accord special and differential treatment for developing countries (UN, 2001b, para. 15) The Committee also emphasised that in

adopting IPRs regimes, “States ... must give particular attention ... to the adequate protection of the human rights of disadvantaged and marginalized individuals and groups” (UN, 2001b, para. 8).

4.4. Conclusions

The Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution at its August 2000 session, stating that

Since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health ... and the right to self-determination, there are apparent conflicts between the intellectual property regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other

(UN, 2000b, para. 2)

The Sub-Commission also reminded the governments of “the primacy of human rights obligations over economic policies and agreements” (para. 3).

It is quite clear that various human rights may be threatened by the effects of TRIPS. This is most obvious concerning the right to health, including the right to medical treatment, the right to enjoy the benefits of scientific progress and indirectly, the right to development. South African legislation is in line with the international human rights framework. All in all, the implementation and the effects in the long run will show if this intellectual property regime really is in conflict with the international human rights law.

Conclusion

In 2003, Médecins sans Frontière stated that “The patenting of essential goods such as medicines and foods was for a long time though to be self-evidently against the public interest” (MSF, 2003, p.5). If we look at the development of international intellectual property law, this is not the case anymore.

In the first chapter of this thesis, I presented and discussed how a free diffusion of new technology may create a situation where the incentives for future research and development are strangled. The patent system, of which the Agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) is a part, tries to strike a balance between the static and the dynamic dimension of technology, creating a situation that will gain the world the most. This thesis has investigated if TRIPS really balances these two foci.

It is quite clear that the patent system has rather severe effects, the creation of monopoly markets being the most important. The fact that almost *all* new products can be patented, including medications¹², and that *all* members of WTO have to implement the *same* agreement, implies that it is difficult to adjust the provisions to local conditions and needs. This does not have to be fatal if the strengthening of intellectual property rights is positively related to economic growth. In the second chapter this link is investigated. The chapter concludes that this relation is uncertain, especially for developing countries, but that the way TRIPS is implemented will be of major importance.

In the third chapter, I conclude that prices is an important factor concerning access to HIV/AIDS medications and that these prices partly are results of patent protection. HIV/AIDS severely impacts on the foundations of society, damaging the basic structures needed for development. The fact that people do not get treatment will not ease this situation.

¹² An exception made for the LDCs until 2016.

In a human rights perspective, the effects of TRIPS are worrying. The human rights system has expressed these concerns, emphasising the primacy of human rights obligations over trade agreements and the need for differential treatment for developing countries.

When the Uruguay Round of WTO trade negotiations was launched in 1986, more than 50 countries were not granting patents on pharmaceuticals. There probably was a reason for this. Unless TRIPS is implemented in a way that gives room for local solutions to local problems, the agreement will most likely not benefit people living in countries that are not on the technological frontier.

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