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THE LIKELY IMPACT OF TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS (TRIPS) IN MOZAMBIQUE: THE
CASE OF ANTI-MALARIAL DRUGS.

Submitted by:

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Town, in partial fulfillment of the requirements for the Masters in Health
Economics Degree.

University of Cape Town

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DECLARATION

This research paper is my original work and has not been submitted for any academic
and/or examination purposes at any other university.

Signed by candidate

TANIA MATSINHE

This research paper has been submitted for examination with my approval as the
University Supervisor.

PROF. CLAS REHNBERG

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However, any errors or omissions that have arisen are my responsibility alone.

LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
AQ	Amodiaquine
ASEAN	Association of South-East Asian Nations
ASU	Artesunate
CL	Central Level
CQ	Chloroquine
CMMA	Center of Medicines and Medical Articles
DL	District Level
DPC	Department of Planning and Cooperation
ESRP	Economic and Social Rehabilitation Programme
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GNP	Gross National Product
HAL	Halofantrine
HIV	Human Immune-deficiency Virus
HRD	Human Resource Department
IFPMA	International Federation of Pharmaceutical Manufacturers
IMF	International Monetary Fund
IP	Intellectual Property
IPR	Intellectual Property Rights
ITO	International Trade Organization
LDCs	Less Developed Countries
MAD	Management and Administration Department
MoH	Ministry of Health
MQ	Mefloquine
MR	Marginal Revenue
NGOs	Non-Governmental Organizations
NHS	National Health Service
OECD	Organization for Economic Cooperation and Development
PDH	Provincial Department of Health
PMAC	Pharmaceutical Manufacturers Association of Canada
PL	Provincial Level
PPP	Purchasing Power Parity
Q	Quinine
R	Coartem
R&D	Research and Development
SADC	Southern African Development Committee
SP	Sulfadoxine-pyrimethamine
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Program
USA	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

ABSTRACT

Since 1994, there has been a lot of attention drawn on the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as the most important international instrument ever negotiated in this area. TRIPS establishes minimum universal standards in all areas of intellectual property and the intention is to implement these standards globally through a strong enforcement mechanism established in WTO. These standards affect pharmaceuticals, which many countries had previously excluded from patent protection in order to produce drugs at reduced prices and hence contribute to the improvement of public health. But now any Member State must comply with these minimum standards since failure to do so will result to the WTO dispute settlement system.

No extensive review of the practical implications of the TRIPS Agreement has taken place at the global and national levels. The main objective of this paper is to examine the likely impact of this agreement on anti-malarial drugs in Mozambique. Given the persistence of the malaria epidemic in the country and the resistance to the drugs being utilized for this disease there is an acknowledged need for a new drug to eradicate the problem. The problem is that this new drug is likely to be under patent and this country has relied on generic drugs for all its existence and being a Member of the WTO Agreement they now have to wait until patents on the required drugs have expired or be submissive to the more expensive original brand.

To accomplish this objective and to ascertain the end result of the above situation, past experiences were a major tool. By reviewing experiences of less developed countries in relation to patent protection and pharmaceuticals, some conclusions were made possible. In order to narrow down the conclusions drawn from these country experiences, a study was done in the Mozambican public sector by reviewing and analyzing the existing laws and regulations pertaining to pharmaceuticals and patent protection. This was done through questionnaires and interviews of the main stakeholders in this area. With this information the researcher was able to describe where Mozambique stands in relation to patents and how this might affect the

pharmaceutical industry as a Member of the WTO agreement in the long run. This study therefore, relies heavily on secondary data.

Major findings from this study indicate that:

- The TRIPS patent system can be expected to have a great impact on the health sector and may negatively affect drug prices; in terms of increased prices of drugs and the availability of essential medicines for diseases most persistent in developing countries.
- In the specific case of anti-malarial drugs should it be the case where drug companies agree to reduce prices for these drugs in Mozambique there is likely to be a reduction in Research and Development (R&D) on those drugs because they are not income generating drugs. Additionally, even if there is a reduction in the prices of anti-malarial drugs, this reduction will still be extremely marginal as compared to what the country paid for its current first line therapy.
- Additionally, there could be a greater concentration of drug production in industrial countries rather than a transfer of technology to, or foreign direct investment in developing countries.
- Tools like compulsory licenses and the expansion of generic manufacturing, as well as negotiations with original manufacturers can help bring down the price of drugs in poor countries.

Because of the nature of the problem, Mozambique unilaterally can only do so much. There is a need for SADC countries to negotiate collectively in order to increase bargaining power in order to reduce the likely negative impact of this agreement in these countries in general and in Mozambique in particular.

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BACKGROUND AND INTRODUCTION

1. 0 Introduction

International trade agreements have introduced big changes, not only in the area of trade, but through the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), as well as in the area of intellectual property. These are changes that call for important decisions both from the national level to the global level. As a result, even the stakeholders are changing, and public health officials have to play an even more important role in discussions on intellectual property rights.

Countries like Mozambique have been asked to apply their patent system at a moment when there is an increased concern about the impact of this system on the pharmaceutical area's drug prices, innovation and investment. The introduction of the TRIPS Agreement has brought a lot of debate as to whether developing countries will benefit or not from these drastic changes that they have to implement in their nations or whether this implementation will only be at the industrialized countries favor.

Developing countries have therefore been requested to implement a system that has some critical flaws and that is highly and continuously criticized. In Mozambique, like many other African countries, there is an increased need for new drugs to combat persistent diseases and the introduction of patents will certainly have an impact on the availability of these drugs both in terms of prices and in terms of accessibility.

This fact is one of the main reasons that motivated the researcher to take a more vivid look at where countries like Mozambique stand in terms of getting hold of the much needed medicines and how the patent system is likely to affect the availability of those drugs in the future. The main challenge for public authorities is to learn to manage this growing system. Some fear that globalization might just be another name for the empire of Northern capital and it is for this reason why this study is of critical importance.

This chapter gives the background of the study, starting with some information background of Mozambique. In section 1.1 we discuss the geographical background, section 1.2 discusses the political background, section 1.3 looks at the economic background. The background information is intended to give a guide to those readers who may not be familiar with the country.

The second section presents a detailed discussion of the Mozambican health sector, with section 1.4.1 looking at how the health sector is financed, and section 1.4.2 thoroughly looking at the health system structure and the problems faced in the health sector. Section 1.4.3 and 1.4.4 respectively look at the pharmaceutical sector and the health sector reform progress in the country.

Finally, the last sections define the problem statement, aims and objectives of the study, as well as the justification of the study. The chapter concludes with the scope and limitations of the study.

1.1 Geographical and socio-demographic Background

Mozambique, with an area of about 799.380 square kilometres is densely and unevenly populated. It is located on the southeastern coast of Africa. It borders on Tanzania to the north, Zambia, Malawi and Zimbabwe to the west and South Africa and Swaziland to the south. Maputo City, with a population of 1,039.6, is the capital of the country.

As far as the whole country is concerned, Mozambique has a population of 19,371,057. The estimates for this country explicitly take into account the effects of excess mortality due to AIDS; this can result in lower life expectancy, higher infant mortality and death rates, lower population and growth rates, and changes in the distribution of population by age and sex than would otherwise be expected. The 1997 Mozambican census reported a population of 16,099,246 with 45.7% accounting for the young population under 15 (National Institute of Statistics, 2000). The country has more women than men; 52% of the population are women and 48% are men.

Registration of births and deaths is quite limited in Mozambique but the available figures on these rates are not entirely reliable but just an approximation. The 2001

estimates show us a population growth rate of 1.3% per year with about 70% residing in rural areas and living below the poverty line, depending mainly on agriculture for their income. Mozambique has a high rate of infant mortality; per 1000 babies born alive, 146 die before reaching the age of one. The rate is higher in rural areas as compared to urban areas, 160 and 101 respectively.

Life expectancy at birth is about 36.45 years for the total population with females having less life expectancy (35.62 years) as compared to men (37.25 years). The death rate of about 24.21-deaths/1,000 population is mostly accounted for by the AIDS pandemic, with an HIV/AIDS adult prevalence rate of 13.22% in 1999, which was higher than the South African prevalence rate of 11% in 2000 (UNDP, 2000). According to the 1999 Health National Directorate there were about 1.2 million people living with HIV/AIDS at the time.

Of the population of 7 years and above, about 62% are economically active and 38% are inactive with a higher percentage of the economically active found in rural areas. Women dominated economic activity in rural areas. At national level most of the population works in the agriculture, forest, and fisheries sectors.

1.2 Political background

Mozambique has recovered from the thirty years of turbulence. The country has endured three wars: the liberation struggle against the Portuguese, the involvement in the Rhodesian war and the South African backed internal revolution. Besides war, the life of ordinary Mozambicans has been shaken by other dramatic events. The country moved from colonial rule and protected economy to an ambitious development experiment along socialist lines (Pavignani, 1997).

Almost five centuries as a Portuguese colony came to an end with independence in 1975. Large-scale emigration by whites, economic dependence on South Africa, a severe drought, and a prolonged civil war hindered the country's development. The ruling party formally abandoned Marxism in 1989, and a new constitution the following year provided for multiparty elections and a free market economy. A United Nations negotiated peace agreement with rebel forces ended the fighting in 1992 (Pavignani, 1997).

1.3 Economic overview

Before the peace accord in October 1992, Mozambique's economy was devastated by a prolonged civil war and socialist mismanagement. In 1994, it ranked as one of the poorest countries in the world. Since then, Mozambique has undertaken a series of economic reforms. In 1987 the Mozambican government launched an Economic and Social Rehabilitation Programme (ESRP), resulting in fundamental reforms of the system and the implantation of a market economy. The basic goal was to achieve financial stability at national and international level, and to reactivate the economy in a sustainable form, (Pavignani, 1997).

The role of the State in the economy has thus been gradually reduced, and more space created for the intervention of private economic agents. The aim was to boost the economy while simultaneously enabling the state to concentrate its resources on supplying basic goods and services and implementing strategic development programmes. Almost all aspects of the economy have been liberalized to some extent. More than 900 state enterprises have been privatised. A value-added tax, introduced in 1999, launched the government's comprehensive tax reform program.

There is still an increased concern about the need for reform and greater private sector involvement in the transportation, telecommunications, and energy sectors. Since 1996, inflation has been low and foreign exchange rates relatively stable. Even though from a small base, Mozambique's economy grew at an annual 10% rate in 1997-99, one of the highest growth rates in the world a lot still has to change. Growth slowed and inflation rose in 2000 due to devastating flooding in the early part of the year.

Mozambique's current GDP stands at US\$ 56,918 and GNP per capita is estimated at US\$ 3, 348. Over the past years the GDP growth rate has been growing at a 1.6% growth rate¹. Being an agrarian economy, agriculture accounts for about 27.93% of GDP, trade accounts for 21.91%, industry accounting for 8.5%, and other sectors accounting for 41.46%. The main export products are cashew nuts, prawns, lobsters, cotton and wood; with the main export market being Spain, South Africa, USA, Japan, Portugal, and Malawi, (Investment promotion centre 2002).

¹ In real terms.

The country depends on foreign assistance to balance the budget and to pay for a trade imbalance in which imports greatly outnumber exports. The trade situation should improve in the medium term, however, as trade and transportation links to South Africa and the rest of the region have been improved and sizeable foreign investments are beginning to materialize. Among these investments are metal production (aluminum, steel), natural gas, power generation, agriculture, fishing, timber, and transportation services. Mozambique has received a formal cancellation of a large portion of its external debt through an IMF initiative and is scheduled to receive additional relief. (National Institute of Statistics 2001).

With regard to sectoral economic policies, priority goes to agriculture, by which the majority of the population lives. In addition to rural extension, particularly geared towards improving post-harvest storage techniques and extending the period of guaranteed domestic food security, a major priority is developing a rural market. The aim is to create the structural and operational bases for expanding an active rural marketing network through infrastructure investment that will make private initiative in the marketing of cereals and other crops viable, thus getting them from the production areas to the consumer markets while at the same time guaranteeing supply of the inputs and consumer goods that peasants need.

1.4 Health sector in Mozambique

Despite the improvement in the living standards, the economic growth and the expansion of the registered healthcare services in the post-war period, the health of the population remains poor, illustrated by the high maternal and infant mortality rate, malnutrition, the extreme vulnerability to epidemics, such as malaria, cholera, meningitis and dysentery, and to the natural catastrophes. The transmittable diseases, related to either the tropical climate or the poor environmental hygiene or even to poverty, are the main causes of this situation.

The HIV/AIDS pandemic with 14% of the sexually active adult population considered to be infected is reaching catastrophic proportions. Reproduction related diseases, alcohol abuse and violence make the picture bleaker. The health of the population imposes frightening challenges to the to the health department, which has limited

capacity. Since the Independence, healthcare services have been provided mainly by the State, until 1992 as a monopoly and after that as a provider.

1.4.1 Financing the health sector

Government highly supports the finance of the health sector and in the period 1995-99 it increased by 155% in real terms². International assistance of about 80% on the other hand, declined to almost half the funds in 2001, which was a large blow for the country seeing as these contribute largely to medicine expenditures.

The quote of the global expense funded by the international community reduced, from 80% in 1996 to 50% in 2001. While the international support funded most of the investment, medication and medical equipment expenses, the government focuses on salaries and other current expenses. In 2001, the aggregate funding was US\$9 per capita (without taking private contributions into account as there are hard to estimate, but it is thought that they have a considerable size). From these US\$9, around US\$1.5 is spent on drugs, (MoH, 2001).

According to the Ministry of Health a substantial part of external assistance in Mozambique has been through projects, creating secondary effects such as equity problems and a destruction of the already weak accountability system. Up to this date the health sector in Mozambique, especially the pharmaceutical area is highly dependent on donor funding. The dependency of the pharmaceutical sector on donors deserves much consideration. In 1997 the import system of Mozambique was considered as one of the most efficient in Africa.

In the pharmaceutical sector, there are certain tendencies that have implications on their positive outcome. The expansion of hospitals, for instance, implies an increase in demand for drugs. Also, the deregulation of the national economy and the health sector combined with the expansion of private medicine and the increased demand for recent and popular drugs, threaten the survival of the pharmaceutical policy that has been successful, from the MoH's point of view, for years.

² The proportion of funds from the state destined to the health sector has gone up from 9% in 1996 to 13% in 1999.

1.4.2 Health system structure and problems³

The management of the National Health Service (NHS) is structured in three levels: Ministry of Health (MoH)- Central Level (CL), Provincial Level (PL) and District Level (DL). The MoH-CL has under its supervision various institutions; some of them are three central hospitals that have financial autonomy. The MoH allocates resources throughout the provinces, supervises and inspects activities, formulates strategies, creates norms, defines targets and conducts various operations, ranging from fumigation with insecticides to the continuous training of personnel. During the 90s the CL has been increasing notably the resources directly managed by them, to the point of doubling their staff. There is yet another department called the Provincial Department of Health (PDH), which is essentially an administrative body, modelled by the MoH responsible for all the activities related to health services in the province.

The PDH enjoys a considerable amount of management autonomy, being responsible for the allocation of resources throughout the province, management of personnel, supervision, etc. The PDH hires and exonerates low-level workers. The majority of the services provided in the districts, which are managed by the DL reach an average of 100,000 people (the extremes are 10,000 and 400,000). Most of the senior staff at the DL are not professional managers, but healthcare professionals.

The medication storage and distribution network follows the NHS structure, i.e. central, provincial and district deposits and sanitary unit pharmacies (SUP).

The sanitary network is structured into four levels:

³ This section draws largely from the Ministry of Health's pharmaceutical department's evaluation done recently in Mozambique.

Table 1.1: the sanitary network

Level	Category of sanitary unit	Approximate number of sanitary units	Approximate number of available beds	Type of service provided
I	Health care post	700	7.200	Primary care (preventive and curative)
	Health care centre	350		
II	Rural hospitals	30	3.200	First referral with basic surgical facilities
	General hospitals			
III	Provincial hospitals	7	1.800	Surgery, obstetrics, gynaecology, paediatrics, orthopaedics and dentistry
IV	Central hospitals	3	2.900	The most differentiated sanitary units, with multiple fields and sub-fields (especially in Maputo central hospitals which has half of the beds at this level)
	Psychiatric hospitals	2		

Source: Ministry of Health, Pharmaceutical department 2001

The composition of the sanitary network is in evolution, in the sense that small health care posts are being upgraded to small health care centres and some big health care centres are being upgraded to rural hospitals. All the hospitals in the public sector, as well as medium-sized and big health care centres, have pharmacies. The small health care centres and health care posts, due to their characteristics, do not have proper pharmacies. With a population of around 17.7 million to care for, the sanitary network is not enough to ensure the overall access to all the basic healthcare procedures (MoH 2001).

As far as human resource is concerned, the healthcare sector employs approximately 16,500 workers, from which around 60% are healthcare professionals. Top level and medium level staff are only 4% and 16% of the workforce, respectively. A few hundred technicians in engineering complement the national staff (MoH, 2001). The MoH and its provincial department are directly responsible for the education of elementary- low- mid-level staff in all the provinces.

Despite the progress made, serious problems remain. The quality of initial and continuous instruction and of supervision is inadequate. Incentives and career prospects await radical reforms. Top-level personnel remain concentrated in the big cities, particularly in the capital. Human resource management keeps using bureaucratic assessments to evaluate performance. Losses due to HIV/AIDS, now in the hundreds of workers a year, will increase the propagation of the disease. Reforms in the public sector recently initiated by the government should reduce the impact of the problems mentioned above.

The coverage and consumption of services increased since 1993 as is depicted in the table below.

Table 1.2: activities and coverage of some selected services (most frequently used)

Activities	Total consumption 1993	Total consumption 2000	Growth	Consumption per person (2000)
External consultations	6.252.937	14.350	129%	0,8
Births in sanitary units	193.166	313.400	62%	40%
Vaccination	293.635	591.187	101%	93%
Health units	38.954.107	61.954.468	59%	3,6

Source: Ministry of Health, Pharmaceutical department 2001

This increase is due to a number of factors and these are: the refugee resettlement, the accessibility to previously inaccessible areas, the opening of new sanitary units, the improvement of healthcare services, the increase and redistribution of the resources available, the increased efficiency of the operations, and the progressive recovery of civil life (MoH, 2001).

There are still serious imbalances between and within the provinces. Niassa, Cabo Delgado, Nampula and Zambézia are the least favoured. The provinces in the Centre and in the South have much higher service consumption, with better quality relatively

to the rest of the country. This results in an uneven distribution of resources, with Maputo city receiving six times more resources per capita than Zambézia (the least favoured). As the volume of activities undertaken is directly correlated with the size of the sanitary network, huge investments are being aimed at the North and Zambézia. In each province, the national pattern repeats itself; more resources and higher levels of consumption are allocated to the capital, leaving the rural areas deprived of any service. However, the distance between privileged and deprived populations has been decreasing. On average, in 2000 the top quartile of privileged population consumed 4.7 times more services than the lower quartile of the underprivileged population, against a difference of 5.7 in 1997 (MoH, 2001).

Like in most African countries, the quality and service of healthcare remain low: long waits, short duration of appointments, illegal fees charged, and not motivated and incompetent personnel, wrong use of medication, lack of medication, torn equipment and lack of personnel with adequate education in the periphery.

1.4.3 The pharmaceutical sector

Until mid 1998, drugs in Mozambique were regulated by the dispositions contained in the enactment 229/70 which approved the regulation of the pharmaceutical professional exercise. From the organizational point of view this meant a structured pharmaceutical service with responsibilities in the pharmaceutical regulatory areas and provision of drugs in the context of a centrally planned economy. The responsibility of drug supply has been empowered under the enactment No.13/75 to the medical centre of medicines, which was responsible for the purchase and distribution of drugs to the public sector (MoH, 2002).

In 1975 the Ministry of Health established a technical commission of pharmacies, which was an organ of a consultive character with the responsibility of contributing to the definition and establishment of a national political pharmacy. One of the results obtained from the work of this commission was the publication in 1977 of the first edition of essential drugs, which contained 430 types of medicines, 20 diagnostic agents, and 14 rapid plasters. This changed though in 1977, through article 27/77 which introduced alterations in the juridical board of medicines that exist. These alterations interdicted the Centre of Medicines and Medical Articles (CMMA) from

acquiring drugs that were not part of the essential drug list and it made it compulsory to use international generic names on medical prescriptions. It also prohibited the advertisement of drugs (MoH, 2002). It is important to note that these alterations were taken in the context of a nationalised health sector.

When this happened, owners of some importing companies were not happy and most of them opted to abandon their companies. This brought about the creation of a limited company known as MEDIMOC in 1987. This company at first worked with private importers until 1988, having obtained excellent results in the reduction of unitary prices of importation. This resulted in MEDIMOC being attributed exclusivity from 1979 (MoH, 2002).

The combination of a centralised buying and the fact that it was the only importing company had a pervasive effect on the drug regulatory system; it actually changed the whole health system. The registration of drugs, given the lack of competition since there was only one importer, stopped being of importance in serving the quality drugs, while the pharmaceutical inspection started being neglected. By reasons linked to the evolution and capacity of the MoH, gradually MEDIMOC started assuming certain responsibilities, by their own initiative. This resulted in the adoption of the of CMMA's old functions with the intention of resolving MEDIMOC's problems (MoH, 2002).

1.4.4 Health sector reforms in progress

The debate about the healthcare sector began in the early 90s, resulting in many initiatives, frequently promoted by cooperation agencies. Amongst the various trends in progress, the following can be mentioned:

Box 1: Health sector reforms in progress in Mozambique

- The expansion of private practice, for profit and non-profit. The profit providers are experiencing a constant growth in the urban areas. The big public hospitals provide higher quality and more comfortable services, if a higher fee is paid. In the rural areas, there are a limited number of non-profit sanitary units, managed by religious organizations, but funded mainly by the government and by charity organizations. The NGOs provide complementary healthcare services, frequently supporting the public sector directly. The traditional doctors and nurses provide services to the communities.
- Return of the activities previously undertaken by NGOs in the public sector. The proportion of channelled resources through the NGOs has been reducing. The number of active NGOs in this sector has been falling due to the end of many projects connected to the war context. The national NGOs have been growing rapidly in number, although only a few achieved important sizes.
- Restructuring of certain specific areas, such as pharmaceutical, administrative, and sub-sectorial reforms.
- Decentralization of responsibilities, in benefit of more peripheral decision levels. The NHS management remains relatively centralized. Around 40% of the State's Budget is controlled by the Central hospitals. In certain areas, such as investment, the power of the central levels reaches higher levels. The authoritarian and centralist tradition is associated with the weaknesses of the periphery levels, the detection of which ends up reinforcing the first. While the control of certain tasks, such as the purchase of medication, shows clear advantages. Meanwhile, with the present situation persisting (favoured by the presence of non-professional managers in the sector), the Central hospital ends up linking the regulatory mandate with the executive one, resulting in role uncertainties and inevitable conflicts.
- Hiring services, from companies outside the public sector, such as MEDIMOC.

Source: MoH 2001

The reform process has not been a constant one; instead, it has been the result of many forces. Some areas have been more dynamic and showing a clearer vision of the direction to take. Certain options were abandoned.

1.5 Statement of the problem

The introduction of the TRIPS agreement has brought about certain concerns and debates in the pharmaceutical area. There are two main concerns in developing countries: one is that they will be unable to afford patented drugs because the latter's prices will be too high and two is that the less expensive generic drugs will not be available, due to the fact that these will have to await expiration of patented drugs before being put in the market. If the public sector does not have the capacity to access and distribute generic and affordable drugs, this will further increase inequalities in health and health care. Only those who can afford more expensive drugs will access these from their alternative sources, leaving the poor with inadequate or no health care at all (EQUINET and SADC Health Sector, 2000).

According to the World Health Organization, some 300 to 500 million people around the world suffer from the effects of malaria and around one million succumb to it every year, most of them children. Sub-Saharan Africa has been worst hit, with 90 per cent of Africa's malaria cases registered there. African countries spend 40 per cent of their health budgets on combating malaria, and WHO figures indicate Africa's gross

domestic product would have been 100 billion dollars higher if malaria had been successfully contained in the past.

Malaria pandemic in Mozambique is on the increase and the distressing part is that the resistance to chloroquine is increasing in high levels and the Mozambican government has acknowledged this problem. There is therefore a consensus on the need for new drugs but the latter will imply more costs incurred by the government mainly because the new drugs are likely to be under patents. Hence, even if new drugs were developed against these scourges there is a need to ensure that these are available to all the patients in Mozambique, especially those heavily dependent on the public sector for provision.

The dilemma is that Mozambique has no local production of anti-malarial drugs hence all the medicine they require for malaria is imported from abroad, making these not readily available. TRIPS requires patent protection for all products and processes, with a minimum duration of 20 years from the original date of filing. This requirement might cause dire consequences for the accessibility of anti-malarial drugs since it might delay the availability of generic drugs in the country. The government needs therefore to scrutinise the existing options that they could undertake to modify their laws and regulations within the agreement so as to ensure that the problem of malaria is effectively solved. Whether this is possible or not is debatable.

1.6 Aims and Objectives of the study

In order to help policy makers this study will provide findings and conclusions required to alert them to the implications of TRIPS in Mozambique through the analysis of existing laws and regulations and the experience of neighbouring countries with regard to pharmaceuticals. It will further investigate the viability of these regulations given the competing interests of key stakeholders in the pharmaceutical policy arena.

The research specifically aims at accomplishing the following objectives:

- (i) To describe the current laws and regulations in the pharmaceutical industry in Mozambique and the changes made for the adjustment of the IPRs legislation.

- (ii) Examine the likely implication of TRIPS for anti-malarial drugs in Mozambique.
- (iii) Look at less developed countries' experiences with TRIPS, and how the strengthening of patent protection affected their pharmaceutical industries.

1.7 Justification of the study

Malaria is highly endemic in Mozambique, resulting in high mortality rates, most of which are children under 5 (18% of deaths). Accounting for 70% of all paediatric admissions, malaria is also a major cause of anaemia, low birth weight and miscarriages, (Roll Back Malaria profile, 2000). For these reasons malaria is considered a public health problem in Mozambique. The emergence and spread of anti-malarial first line therapy resistance has limited the achievement of an effective control of malaria in this country.

Recent studies estimated the level of resistance of *P. falciparum* to chloroquine (first line and cheapest drug) to be around 30-40 percent in sentinel sites situated in the most populated urban areas (Roll Back Malaria Report 2000). This is seriously increasing mortality rates in the country. There is a need to switch to other drugs. The problem though is that these drugs will be considerably more expensive than the current first line treatment, given that they are usually newer drugs and still under patent.

Results from this study will be of particular importance to the Mozambican Ministry of Health, who are currently struggling with this major health problem in the country. Political commitment in the health sector is very strong shown by the level of participation and activities done to combat malaria. The country's National Malaria Control Programme conducts an annual indoor spraying programme in almost all low lying land concentrations of poor quality housing but despite the effort this only covers about 10% of the population. This points back to the fact that what is considered to be of utmost importance are efficient drugs. Government being the main provider would be interested in analysing the impact of TRIPS on drugs and find ways to adjust their regulations so as to accommodate the provisions of this agreement without impinging the whole national health system.

This research will provide information to the relevant stakeholders about where Mozambique stands when it comes to TRIPS hence allowing them to critically assess which way is best for being able to get the new drugs recommended for malaria to be accessible to all sectors of the population. Through the analysis of current policies and the past experiences with TRIPS this paper will allow the ministry of health an awareness of the possible consequences to the oncoming potential impact of this agreement.

1.8 Scope and Limitations of the study

Like any other study, there are limitations to the collection of data. Because of time and access to data, the study is limited to the public sector only, also because it would take a much broader study to look at both the private and public sector in the whole country; mainly because the private sector is dispersed around the whole country, which is out of reach to such a small study. It is important to note though that the fact that the private sector is not included is unlikely to have such an implication on both the results and the recommendations of the study as the same laws apply to both sectors, that is, in relation to intellectual property and/or patents.

But it is still acknowledged that the private sector, unlike its counterpart, imports more patented drugs than generics but the implication of TRIPS in the country as a whole will still be felt in both the private and the public sector because the new laws to be implemented apply to the whole country. The study site is the capital of Mozambique, which is where all the data related to the public sector, is located.

Given the size of Mozambique and various provinces, each with their cultural differences, the study may not have an accurate representation of the country especially when it comes to what other importing companies prefer when it comes to importing anti-malarial drugs to sell in private pharmacies. Also, Mozambique has a critical shortage of important data and this is a serious limitation that makes it very difficult to produce a comprehensive picture of the situation in Mozambique and what is likely to happen when TRIPS is implemented. It is therefore important to note that the analysis of this research is based on the minimal information that is available.

Chapter 2

LITERATURE REVIEW

2.0 Introduction

“If nature has made one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of everyone, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He, who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That an idea should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density at any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be subject of property.”

-Thomas Jefferson (1980)

This thesis is largely concerned with how the ownership of a product impacts those that do not own that product or those that did not take part in the production of that product and these products are called property rights. Property rights are the rights individuals appropriate over their own labour in the goods and services they possess (North, 1994). Economic rules define property rights, as the bundle of rights over the use and the income to be derived from property and the ability to alienate an asset or a resource. The chapter will analyze why we have patent protection and how the enforcement of such a protection is likely to impact on developing countries.

2.1 The foundations of patent protection

Back in the yesteryears, certain segments of European commerce became centralized and exclusively controlled by various groups. These monopolies were nothing like the modern exclusive rights awarded for inventive developments. The right to control various sectors of the market became a royal privilege, granted by the monarch in return for various benefits. These early patent monopolies were not concerned with invention but rather with commerce. The monarch would grant the privilege to practice a certain art or manufacturing process to a foreigner who brought new technical skills into the jurisdiction. The patentee frequently would be required to

train a number of citizens. The term of the patent was almost always for a certain term of years. By the time of Elizabeth, this practice had become a burden on free competition; this effect was heightened by the gradual transition from a feudal to a mercantile economy (Miller, 1983).

Thus, in 1623, the Statute of Monopolies effectively ended the monopolies affecting free trade and competition. The common law reaction against monopolies was received in the New World and gradually the American colonies became more fiercely opposed to monopolies than their English counterparts. The colonists started recognizing that the offer of an exclusive patent to someone who invented something new and useful would encourage inventiveness. By the time of the Revolution, almost all of the colonies had granted patents. At the Constitutional Convention, in 1787, a measure was proposed to incorporate the ability to secure, for limited times, patents and copyrights. The first patent law was enacted in 1790 and thereafter only three major revisions were made, in 1793, 1836, and 1952. The present Patent Act, enacted in 1952, is completely codified in Title 35 of the United States Code (Miller, *ibid.*).

2.2 Intellectual Property Rights

Intellectual property rights (IPR) are rights given to an individual's creativity. This right was established in order to acknowledge the creation of human mind by promoting the publication of ideas and inventions so as to make them available to others who will improve them in the future. Another rationale for the proliferation of these rights is to provide an economic incentive for people to be creative and invent things by making sure that the creator of an idea can benefit financially from his/her invention. The idea of intellectual property rights is to reward the inventor of ideas by granting him/her a temporary monopoly power in exchange for making his/her idea available to society. There are different types of IPs but this paper is interested in the most well known one, which are patents (for different inventions with industrial application).

A patent is a grant of monopoly power by the state to an inventor who is therein given the exclusive right to commercially exploit her or his invention for a limited period of time. The patent provides an incentive to invent and innovate. To obtain a patent one has to go through some procedures starting by filing an application and getting it

approved by the patent office; their validity only takes place when issued and only in the country where they have been issued. For validity in other countries there is a need to file an international application under the Patent Cooperation Treaty. An invention can only be patentable under these criteria: originality (novelty), inventiveness and industrial applicability or utility.

In exchange for a temporary monopoly on its use, a patent necessitates the creator to disclose his invention. It is through this short-term monopoly power that the inventor will earn his/her profit in case of trade of the invention or in case a third party is given a license to use the invention. According to Heinemann (1999) without intellectual property protection, technical innovation would be a public good; no one could be excluded from it; common use by an unrestricted number of people would be possible (Zach, 1999). The incident of free rider would retrench the incentives to invest in innovation activities. Intellectual property converts public goods into private ones hence excluding third parties from accessing it and increasing incentives for innovation activities. This is a way of encouraging innovation and rewarding someone's creativity. The profits gained from this patent are not automatic, just like any other goods and services that can have a lack of profit if the demand for them is low.

The owner of a patented product uses his position to control a market to the disadvantage of competitors and consumers. He can prevent potential competitors from developing products similar to his own, and he can charge higher prices for the product. Such a monopoly can undoubtedly lead to unfair advantage from intellectual property right holders and this can only have one consequence, *abuse*. In Loughlan's words, the ordinary, rational, profit-maximizing, private firm will only invest in research and development when that form of investment can be calculated to yield an economic return, on a risk adjusted basis, at least as attractive as that which alternative forms of investment can offer (Loughlan, 1998). The patent system, with its promise of monopoly and its inhibition of free riders, helps to make investment in R&D economically attractive. In other words, patent law exists to prevent the market failure, which would result from failure to inhibit imitation of innovation.

The basic reason for intellectual property is that a man should own what he produces, that is, what he brings into being. According to Bainbridge (1999) encouragement, inducement and reward are the main factors underlying the patent system. The public interest, although jeopardized by the grant of a monopoly, is said to be secured by increased industrial activity, developing new technologies and disclosure of new and useful inventions. Under the TRIPS agreement the public is claimed to be protected through their safeguard, i.e. compulsory licensing, to control any significant abuse of the patent monopoly, but whether or not that helps for developing countries is still questionable. But again if patent protection were to be abolished tomorrow, inventive activity would not cease altogether but that will never be the case because the contrary has happened, they have been strengthened. The next section justifies IPRs implicitly.

2.3 Justifying Intellectual Property Rights

It is generally assumed that technological advance depends on the development of science. Causation is sometimes believed to lead from the growth of knowledge in science over technological growth to economic growth. The main justification for IPRs is the fact that human beings should be rewarded for the fruits of their labour as a right they naturally own. But there is an argument against this justification in Thumm (2000) that suggests that intellectual products are not in themselves original, in the sense that they build on other existing intellectual work. John Locke argues that there should be gratitude for ownership of additional input added but not total ownership. Another argument by Thumm against intellectual property rights is that intellectual property should not provide ownership at the full market value via IPRs. This value is said to depend on too many different factors (product marketing, patent conditions, market constitution and others), which are not related to the direct creation of the intellectual product.

Another justification for IPRs is drawn from the need of a scientific and technological progress. Without IPR individuals, organisations etc would not have any incentive at all to invest in research and development. This is because there would be free riders that would be willing to copy intellectual property in the absence of the inventor. Patent pirates in some developing countries freely copy (pirate) innovative medicines that are under patent in the United States and other countries without compensating patent holders. The Congressional Research Service estimates that U.S. companies

lose \$1 to piracy for every \$3 worth of products shipped overseas. U.S. pharmaceutical firms are projected to invest over \$26 billion in R&D in 2000 alone, but the U.S. International Trade Commission found that global patent piracy reduces annual R&D investment by \$720-\$900 million annually (PhRMA, 1998).

Technological knowledge does not go without market failures. One of these is the large amount of costs incurred by the investor and the indivisibility of research expenditures. The other market failure is the investment risk that one faces due to technological uncertainty and investment for research and development. The other rationale for market failure is the problem of non-excludability i.e. inventors of knowledge cannot prevent others from using it. There is no rivalry in this product. Economically, there are no marginal costs of providing intellectual objects to an additional user. Under free market conditions these features result in an excessive use of intellectual property and hence a loss of incentive for research and development investments. This is where government is required to play her role in the form of intellectual property rights. This is what brings a dual debate about the impact of IPRs on the free flow of ideas. Whereas on the one hand they limit the availability and use of intellectual products, they, on the other hand, limit the future production and availability of these products.

Without IPRs innovators will be reluctant to invest and spend money on researching how to develop new products and by making others pay for the usage of intellectual products could also mean no business for inventors. There has to be a way of rewarding inventors without jeopardizing the public interest. In Gervais's words "the question of optimal intellectual property right protection is one of finding the correct equilibrium between the innovation spurring and knowledge deterring effects in the performance of IPR" (Gervais, 1998).

There are many arguments against IPRs and this comes from the fact that innovators can abuse the monopoly power granted to them in the form of patents and this they can do in many ways, such as dominating the market and creating barriers to entry against competitors. But we should also take the point of view of the innovator whereby firms and or individuals imitating the inventor become more efficient in making innovations than the original innovator, for instance, by developing a more

market appropriate product version. By so doing, the second mover will have saved hugely on research and development costs.

The following section takes it from the point of view of macroeconomics and microeconomics. These sections draw largely from Thumms work on justifying intellectual property rights from the economic point of view.

2.4 Microeconomic theory of IPRs

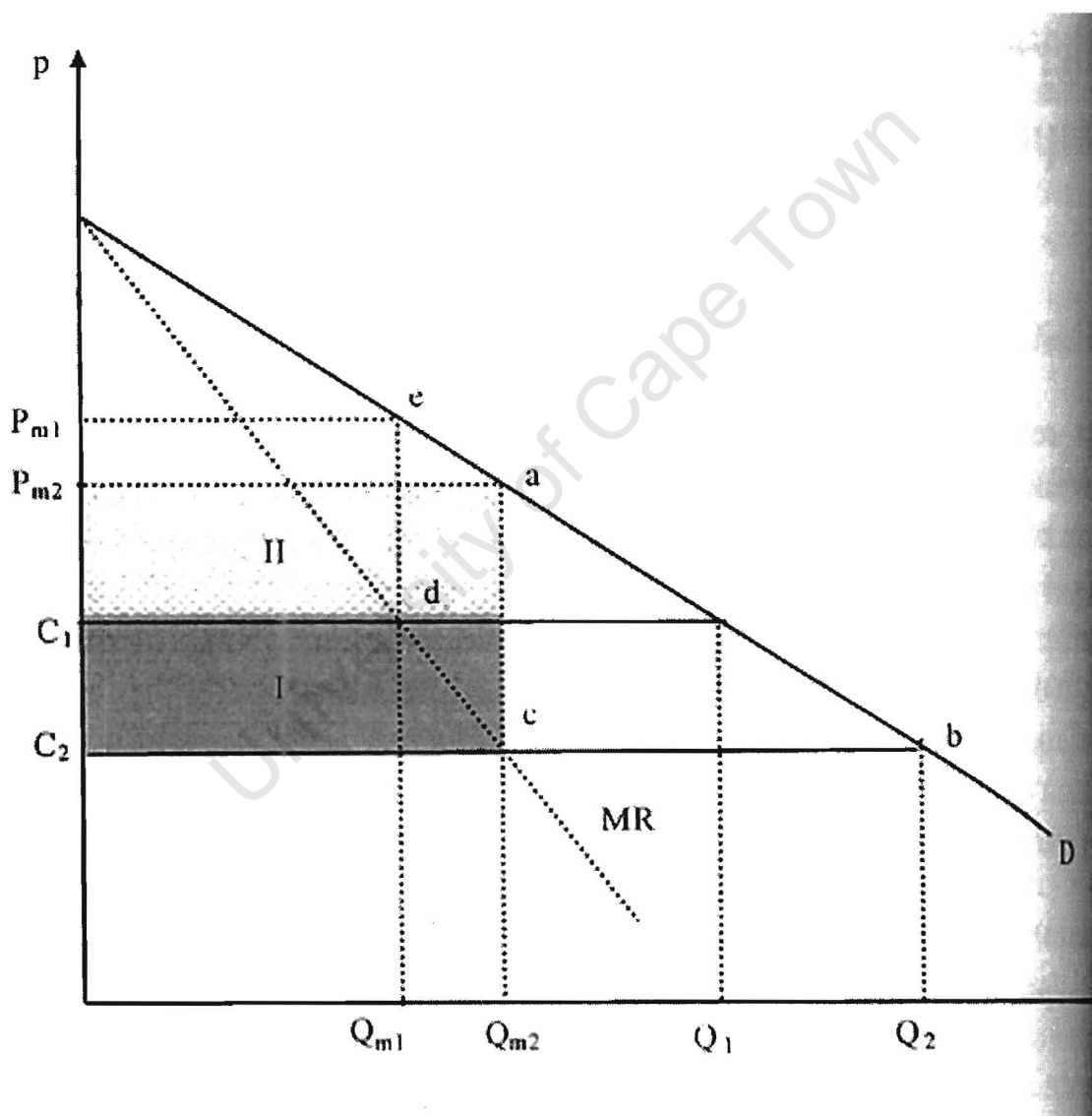
Many economic theories, such as neo-classics, new growth theory and evolutionary theory consider innovation as one, if not the main source, of economic growth. The reasoning behind IPRs is driven from the fact that the public good character of technological knowledge requires artificial incentives for innovators in the form of temporary monopoly rights on innovations (Thumm, 2000). According to economic theory IPRs increase expected profits for the innovator and gives him/her the incentive⁴ to invest more in research and development in order to increase the effect of innovation. The classical welfare analysis of IPRs refers to monopoly theory and considers the general welfare effect negative because there is a dead weight loss, which is caused by the way monopolists, price their products. The intellectual property right holder sells less quantity of the innovative good for a higher price, implementing a dead weight loss compared to the competitive market situation.

According to Tirole (1988), innovation reduces the marginal cost curve of production in graph 2.1 from $C1$ to $C2$ within an already existing market. In a competitive market situation quantities $Q1$ and $Q2$ would be produced. When invention is protected one would expect prices to increase because the inventor is now setting monopolistic prices at a higher level, where the production costs are equal to its marginal revenue. If we look at figure 1 this scenario is reflected by prices $Pm1$ which is at its highest level ($Pm1 > C1$) where the production costs $C1$ are equal to MR.

The additional surpluses (area I and II) are the monopoly's profit and stand for the monopolist's incentive to innovate. Nonetheless, monopolistic profits are only

⁴ Human beings are believed to need some form of motivation and/or incentive to do things, for instance they go to work because at the end of the month they will get a financial or self satisfaction and that is what inspires them to wake up every morning to go to work.

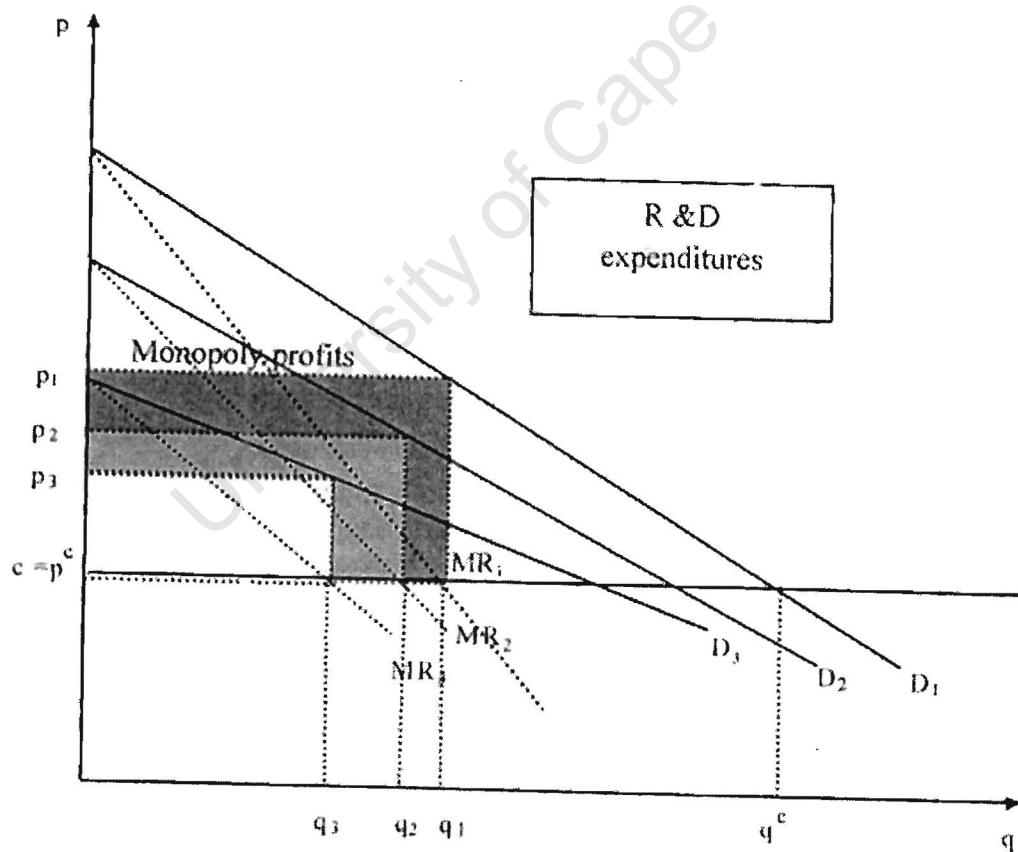
possible by reducing the production level in comparison to the competitive situation ($Q_{m1} < Q_1$). According to Schumpeter, monopoly power is conducive to innovation, and thus welfare losses are the price we have to pay for innovative activity. But it is important to note that an already established monopolist has a lower additional profit from innovating than its competitor who is a newcomer on the market. Competitors still gain the entire new monopoly profit from innovation, whereas the monopolist only replaces himself. The incentive to innovate of an already established innovator is therefore lower.



Graph 2.1: welfare effects of monopolist pricing of a single invention

The main question is what would happen without intellectual property rights. Some assume that without the additional barriers constituted by IPR against competitors and

their achievement of the innovators' technological knowledge the scenario would be different. Graph 2.2 shows us how different. Competitors, as one would expect, would freely enter the market and come up with an own production, which would take away some demand from the original innovator. New competitors do not bear the costs of research and achieve supra-normal profits. This will attract further potential imitators to enter the market. Any additional supplier lowers down the original demand curve of the innovator from D_1 to D_n . Consequently, the innovator's profit decreases, shown by the decreasing shadowed areas, and finally total profit's quantity is lower than the research and development costs. If we take this reasoning into consideration the rational innovator would decide not to invest in R&D and the total benefit from innovation is lost for society. The incentive to innovate is driven by the surplus gained from innovation. Without barriers to entry entrepreneurs theoretically enter the market as long as the profits are not zero.



Graph 2.2: new product pricing without patent protection

Conclusively, Intellectual Property Rights create an artificial market barrier for competitors and therefore ensures that profits are not driven down to zero. Competition is essential to ensure that the innovation process continues. It encourages economic growth by disallowing that innovators establish in the long term as monopolists and it is an assurance that innovation will always be overcome by relatively newer innovation. Monopolistic industries are better equipped for innovation than competitive ones in so far as they can prevent imitation better and therefore capture more profit for innovation. A monopolist is also more able to finance high research and development costs, (Thumm, *ibid*).

It is for this reason that it is doubted that monopolies are really a natural ground for R & D and that there actually exists causation from a strong market position towards innovation. The main problem of the monopolist is that he/she basically has the lower incentive to innovate in terms of expected surplus from innovation, (Zeuthen, *ibid*). But, this does not take away the argument that the innovator needs a strong market position in order to cover his R&D expenditures. Therefore the granting of intellectual property rights is a prerequisite for the creation of an innovative society. On the other hand we see that granting monopolistic rights in form of intellectual property rights is not a first best solution because they do not achieve the socially best amount of invention and thus fail as a political instrument in promoting the most favourable amount of invention.

2.5 Macroeconomic Theory of Intellectual Property Rights

There has been a worldwide debate about the pros and cons of IPRs and this has been emphasised after the proliferation of international agreements related to Intellectual Property Rights. There is a conflict of interests between industrialised first world and developing third world countries. As Loughlan (1998) puts it “the complexity of international intellectual property rights, should be considered within a dynamic model that includes trade effects, the role of foreign direct investment, the allocation of research and development and catching up possibilities”.

One of the easiest ways of analysing this type of situation would be to look at it from the point of view of a two country situation, i.e. a rich and innovative country against a poor and technologically dependent one. If the latter country relies on imitating, the

innovators, who export their technology, will lose their market shares in the imitating countries. This would lead to a fall in monopolistic prices for the innovators, hence losing their producer surplus leading to a lack of incentive to invest.

On the other hand consumers will be enjoying low product prices from both types of countries and hence get a free ride on the technologically advanced country. But the critical issue that should not be overlooked is the fact that these imitators need the innovators for the production of their goods, hence if we demolish the latter's incentive to invent the free-ride might only be temporal because there will be no product to imitate from, since inventors will have lost the incentive to research. This factor shows us the importance of time in the sense that in the short run free riders have something to gain but in the long run they run out of gains and this might impact their whole system of existence. In this context it is important to note that short run investments through imitation jeopardise long-term investments in R&D.

In cases whereby there is an extended patent protection, i.e. whereby protection of the technologically advanced country's innovation is also guaranteed in the poor non-innovative country, the monopolists (innovators) achieve monopoly profits from both countries. In this situation the monopolists face lower research costs and therefore have a higher incentive to invest in innovation. Consumers from both countries will therein benefit from this additional innovation. They do not go without paying for that though, since they have to pay higher monopolistic prices.

What we have to realise here is that the welfare gains for the innovative country comes not only from its consumers but also from consumers of the poor country. The net welfare effect therefore depends on the additional consumer loss in the country that does not have the capacity to innovate because of higher prices in relation to the benefits from new innovation in both countries. The relative market sizes in both countries play a major role in determining the net effect of the gains and losses. If this were the case it would be ideal to find out what would happen if African countries joined forces to fight against international agreements and industrialised countries. But the question is how large is the market size of African countries to determine the net effect of the gains and losses of such agreements. It is unlikely that it could be large enough, at least as compared to industrialised countries when it comes to issues

of technology and innovation. With regards to international agreements on intellectual property rights and its incorporation of developing countries it is debatable whether or not patent protection is not redistributing welfare away from developing countries.

The first economists to analyse the problem of intellectual property rights in a poor-rich country framework, were Chin and Grossman (1988). These came about with a conclusion that poor, non-creative (innovative) countries are most likely to achieve higher national welfare when they neglect to protect patents. But this only applies to situations where innovation is not productive such that poorer countries would not gain from innovation. But it is unlikely that a particular country would not gain from innovation especially in the case of pharmaceuticals whereby old and new diseases depend on innovation to be eradicated.

Grossman argues that the world as a whole gains when poor countries do not enforce IPR protection i.e. when innovation is booming. It is for the fact that rich innovative countries always benefit from having their IPR protected that the main focus should be on how to make efficient bargaining between both countries, without making the poor countries worse off. According to Diwan and Rodrick (1991) poor countries can only benefit from free riding if there is no detrimental effect of imitating innovative activities. It is also crucial to note though that poor and rich countries have different technological needs and demands and that both countries need something from each other.

Rich countries know that in order to achieve maximum profits the poor countries must have an interest in their products so that they are able to spread their fixed costs over a large range by selling their products in poor countries' markets. So, rich countries do have a motivation to market their products to poor countries hence, the stronger the protection in the innovative countries, the higher the expansion of a wide variety of discovered technology. As a result, poor countries' protection (given the fact that they have an interest in getting their own technological needs from the rich) encourages innovation of their technological needs from the rich innovative countries.

Thumms argues that any model explaining the analysis of intellectual property rights should mention the detrimental effect of imitating on the innovation rate. A complete

welfare analysis, he argues, describes a dynamic equilibrium between the rise in global consumer surplus and the rise of producer surplus imitators, the fall of producer surplus in innovating countries and the changes in the rate of innovation. The dynamic welfare analysis of intellectual property rights is best explained by Krugman's (1979) model of endogenous growth that deals with innovation and imitation within North and South framework. It is first assumed that the rate of innovation is taken as an endogenous variable, old goods are common property and can be produced in both North and South, whereas new goods are only produced in the North. The level at which new goods will be produced depends on the already available stock of technology. This model does not consider any possibility of the South catching up with technological advances from the North.

If $n^S = t * n^N$,

n being the total number of products available in North and South ($n = n^N + n^S$) and $1/t$ being time before South learns how to manufacture a new product.

The growth rate of Northern products n^N depends on the total number of products n , the innovation rate r and the proportion t^N that is copied by the South.

Therein, $n^N = r * n - t * n^N$.

These equations determine the availability of products in both regions and they show us that both regions depend on the rate of innovation r . From these equations we can tell that a high rate of innovation is in the interest of both North and South. There is a need therefore to ensure that innovators maintain the incentive to innovate and whether or not intellectual property right is the way to go is debatable.

Romer (1990) who highly believes in human capital argues that what is necessary for growth is not the protection of intellectual property but the amount of human capital for innovation. He says, "New designs automatically provide a monopolistic position in the market and thus inherently contain the incentive to innovate". Some see imitation as a natural means of giving out/distributing knowledge and as a source of convergence between creative and imitating regions i.e. North and South. For the

latter it is cheaper to imitate but only if the number of copiable products keeps increasing or remains the same because trying to identify uncopied products can be as expensive as research costs.

Barro and Sala-iMartin believe that the rate of copying decreases over time and growth rates in both countries converge in the long run towards a steady state. But this would mean the South does catch up technologically and there is a convergence towards a steady state after a long time of copying from the North, but the question would be how realistic this is. The main feature in this model is the composition of the cost imitation V_2 :

$$V_2 = V_2 (N^f / N^n)$$

The cost of imitation depends on the number of goods that have been discovered but there can only be so many goods left uncopied. Barro et al, conclude that imitation leaves no room to motivate innovation and they agree that intellectual property rights might be the best way to compensate this lack of incentive. Some authors argue that no inter-country technology diffusion takes place without patent protection and if there is denial of such protection innovators will opt for secrecy and the latter will not help in the distribution of knowledge. In Grossman and Helpman's words international intellectual property right is the guarantee of full knowledge diffusion and free trade in ideas. Currie, Levine et al. (1996) support this argument. They emphasise that the knowledge transfer between countries increases given intellectual property rights and this supposedly accelerates the development of less innovative countries.

Thumm (2000) questions this development in the South, given the fact that there is a lack of knowledge capital stock. Helpman (1993) discovered that intellectual property rights shift production and terms of trade from the South towards the North, making the latter the sole winner from strengthening intellectual property rights. His paper shows that the overall welfare effect of international intellectual property rights largely depends on the level of imitation, trade relations with regards to the affected products and the presence of foreign direct investment. His conclusion was that the South never gains from tight intellectual property rights.

Conclusively, less innovative countries depend on foreign direct investment and foreign technology from innovative countries. Hence if they do not want to be left out by international technological and economic developments and if they want to hold out against competing countries in the race for foreign direct investment they have to make their markets attractive, which among other things means a standardised intellectual property right protection. It is difficult to distinguish between the macro and microeconomic levels when analysing international intellectual property rights. There are obvious differences between innovating and imitating countries and these include needs, preferences and interests. It is because of these differences that the debate about intellectual property rights is endless and leads to the search for different options by the South as they seek ways to have access to the North's products at a cheaper rate than the actual hence the increase in price discrimination and parallel importation. This leads us to the next section, which goes into more detail about the latter subjects.

2.6 Parallel imports and international price discrimination

Parallel imports are genuine products, and not counterfeits, imported by unauthorized resellers. A common situation is where one firm owns the national trademarks in several countries, each trademark conferring the exclusive distribution right in that country, but another party obtains the product in one country and diverts it to another country without the authorization of the trademark holder, (Malueg et al., 1994). Policies that support parallel imports do so because they believe that the latter is driven by international price discrimination.

The price discrimination view supports parallel importation because the scope of price discrimination is larger internationally (disparities in demand elasticities across countries are likely to be greater than across regions within countries, mainly because of the larger differences in per capita incomes between countries than regionally within countries). Mackie-Mason (1988) says uniform price monopolists would only serve the high demand market (seeing as we are facing markets with different known demands) but under discrimination would add the second market and not raise price in the first. Legal parallel imports flowing in one direction does not prove discrimination, it merely reflects differences in demand attributable to different levels of free ridable distributor investments in two countries.

An advantage of allowing some international price discrimination is that additional countries will likely be served. If parallel imports are prevented, at least between certain groups of countries, firms could offer lower prices to lower demand countries without fearing that the products would resurface in high price markets. Uniform pricing will certainly have a negative impact in developing countries, which are likely to go unserved. Malueg found, in his study, that when demand is largely scattered, welfare is higher under discrimination. Discrimination, however, affects not only total welfare but also distribution between countries. But manufactures of products prone to parallel imports are from richer, more technologically advanced countries.

Allowing complete international price discrimination, in favor of least developed countries, will not reduce the national welfare of industrialized countries, especially in the case of pharmaceuticals. According to Schut (1986) pharmaceutical's prices vary internationally because of the different per capita incomes. Poor countries often pay higher prices than rich ones and these reversals are claimed to be caused by varying government policies in LDCs and also from choices by suppliers to target their products to the rich rather than the mass market in LDCs. Suppliers are said to do this because LDCs do not allow them to control parallel imports. So price discrimination does not necessarily favor LDCs.

2.7 International pharmaceutical market

Patents are of vast importance in the pharmaceutical sector. Actually, the existence of the TRIPs Agreement is due to the pressure from the big pharmaceutical companies on the United States government, which in turn insisted that this issue should be on the agenda of the Uruguay Round negotiations. Pharmaceutical products rely on patent protection, which gives drug makers a temporal monopoly power over the marketing of a new chemical unit. This is because for pharmaceutical products it takes a long time to develop a new chemical unit, but when a drug is eventually developed and displayed in the market it becomes easier for a generic manufacturer to produce a copy. If we had generic manufacturers waiting to make copies of new drugs there would certainly be no incentive for innovators to invest in new drugs.

Patent protection therefore gives drug developers that incentive to invest in new drugs and in exchange supply the public with the drug when the patent has expired;

consequently opening the door for generic manufacturers to enter the market. This incentive required by the drug developers also comes into cause because of the costs they incur developing a new chemical unit. There is a high fixed cost of research and development of drugs hence in the context of a competitive market with marginal cost pricing, the drug developer would make a loss because average costs are always above marginal costs given that marginal costs of producing each unit is close to zero. Drug developers try therefore to spread fixed costs over more and more units so as to reduce average costs such that a firm would not invest in the development of a new drug unless they can price it above marginal cost. As the economist put it “developing drugs is expensive. If companies are to keep trying, they must expect to make enough profit to meet the cost of developing not only the drugs that work, but also the ones that do not” (The Economist, 2001).

International pharmaceutical markets are well known for the exercise of price discrimination, which has a costly implication on developing countries. The high prices charged by pharmaceuticals do not necessarily reflect the production costs incurred by manufacturers of pharmaceutical products. According to Schut et al, (1986: 1141) the common features of the pharmaceutical market are, abnormal profits, absence of significant price competition, high concentration in production, exceptional expenditure on promotion as well as price discrepancies for identical products.

It is because of these features that pharmaceutical markets are said to exercise extreme market power and charging whatever price the market will bear. This is a problem for developing countries like Mozambique because developing countries, as a group spend about 1% of the Gross Domestic Product (GDP) on pharmaceuticals, hence a monopolistic mark up has high opportunity costs implications caused by a loss of foreign exchange and investment opportunities forgone. Although there have been quests for the reduction of such unbearable costs for developing countries, these have been to no avail mostly because studies that have been done to support these quests have only looked at a few drugs and a limited number of countries.

2.8 Patents and pharmaceuticals

Pharmaceuticals raise crucial debates about the legitimacy of patents and the patent system. Loughlan (ibid) quotes the example Ceredase, a pharmaceutical introduced in the market in 1991 in the U.S as the only effective drug therapy for Gaucher's disease.⁵ The price of Ceredase was such as to make one year of treatment costing over \$100 000. It is the patent on Ceredase, which brought about that price, not the cost of its production, even when a rational economic return to the producer was built into the concept of cost of production. Because of the legally enforced monopoly the owners of the patent on Ceredase charged what they liked. This touching example should make us aware of the fact that we are not dealing with any commodity here but life saving drugs. Yes, it is agreeable that without the patent protection the drugs would probably never exist, hence bringing up questions like, "without the promise of a patent why develop the drug at all, why incur non-recoupable costs, why take such risks of having new competitors in the market (free riders) who could simply manufacture and market the drug at a lower price".

All these questions make sense but the patent monopoly on the drug also allows a price and product output structure which results in many people, who could live longer lives with the help of the drug if it were priced reasonably, as would be the case of a competitive market, living in some pain or dying young. Developing countries argue that the level of intellectual protection demanded of a country should correspond with its level of economic development. In Australia for instance, more than 90% of the patents approved are granted to foreign patent holders (Loughlan, ibid). This figure tells us that the greater part of patents are used to protect foreign suppliers from imitations either from domestic or overseas sources hence giving foreign patentees leeway to charge monopoly prices in Australia without fearing competition by imitators. Without the patent system Australians would be able to reverse engineer inventions and supply them cheaper in their country.

India for instance abolished patents for pharmaceuticals in 1970 and have been able, through reverse engineering of pharmaceuticals invented somewhere else, to create a successful industry manufacturing compounds chemically equivalent to patented

⁵ Gaucher's disease is a condition which leads to an underproduction in the body of a particular enzyme which breaks down glycolipids, which can cause severe pain and sometimes death in younger patients.

pharmaceuticals in other countries and their drug prices have been among the cheapest in the world. Actually, prices for a drug sold in India for the same drug sold in the U.S vary from 900 to 3010 percent times lower in India and this has an immeasurable contribution to public health. Such an abolishment of patents has its consequences for signatory countries of the TRIPS agreement such as a general trade sanction being taken against the particular country and this could even lead to an exclusion from the World Trade Organization and being excluded from the WTO means not being recognized in other countries.

Patents theorists argue that patents impose a major social loss by the way they induce increased monopoly prices but that loss is endured because patents create an incentive for invention and technological advance. But if society grants patents for inventions for which it would have had anyway (because other sorts of incentives to invent have been at work), then society endures the deadweight loss with no corresponding benefit and there therein a net social loss. The patents regime should therefore be designed in such a way that as to minimize social loss in all possible ways.

Given the fact that developing countries demand different products as compared to developed countries there should be a way that the TRIPS agreement caters for these differences in a way that ensures a win-win situation. For instance, whereas developed countries demand not only drugs but also health care equipment, such as scans, developing countries are unlikely to demand equipment over drugs. This is because the marginal benefit of having equipment in developing countries is lower than that of a drug because the latter solves the problem instead of identifying it. This is not to say health care equipment is not demanded in developing countries but when making a comparison with their counterpart the demand is incomparably higher. Hence once again, as has been mentioned, the TRIPS Agreement should take these differences into consideration before suggesting that the same patent protection applied in an industrialised country should be applied in a less developed country.

Chapter 3

METHODOLOGY AND CONCEPTUAL FRAMEWORK

3.0 Introduction

This study is mainly based on secondary data and relies on findings from past studies in the area of intellectual property, given the objectives of the study and the availability of data this was found to be most appropriate. The methodology used in this study depends on the availability of information with regards to research done in this area and the latter is quite limited hence the reason why this paper opted to bring together past experiences on the area which would help come with a conclusion to what is likely to happen in Mozambique (a country that has no experience with regards to patents on pharmaceuticals). Relevant research has therefore been analyzed.

In Mozambique interviews were conducted so as to have an analysis of the history of pharmaceutical laws and regulations, as well as what has happened with regards to patents in the country. With this information we were able to identify the country's weaknesses and hence come with some conclusions as to what will happen to this vulnerable country once patents have been strengthened. What should be noted though is that this study only covers the public sector hence there is no complete coverage of data information but even so it is still possible to come to some generalized conclusions in the country.

This chapter describes the process of data collection that was used for this study.

The chapter will describe the instruments used for the data collection, sources and types of data collected. It will also look at the conceptual framework used for the study, both theoretical and diagrammatical.

3.1 Framework of analysis

Mozambique, like many other African countries suffers from the lack of updated and meaningful data. The objective of this study is to review the potential impact of Trade Related Intellectual Property Rights (TRIPS) on the pharmaceutical industry in Mozambique, giving special attention to anti-malarial drugs.

The methodology used to prepare this case study consisted of a situation analysis based on a literature review of relevant research and information analysis. Although there has been no extensive review of the practical implications of the TRIPS agreement on the pharmaceutical industry, there have been many studies on smaller parts of the larger issue. Some of these studies specific to less developed countries were used for this assessment, including key studies on experiences in drug prices. The objective of it all is to find out what these countries have experienced, in relation to pharmaceuticals, after the introduction of intellectual property rights. With this information it becomes possible to analyze what is likely to happen in Mozambique with the implementation of the TRIPS Agreement.

3.2 Conceptual framework

There is a large debate about the WTO/TRIPS agreement, especially in relation to pharmaceuticals. Some authors argue that the strengthening of patent protection will have negative effects in less developed countries, especially with regards to pharmaceutical prices. The latter is predicted to increase as intellectual property is enforced. Others argue that intellectual property will promote and transfer technology, FDI, research and development. Countries without protection for these rights will not benefit from more advanced nations that are likely to transfer what less advantaged nations have, it is argued.

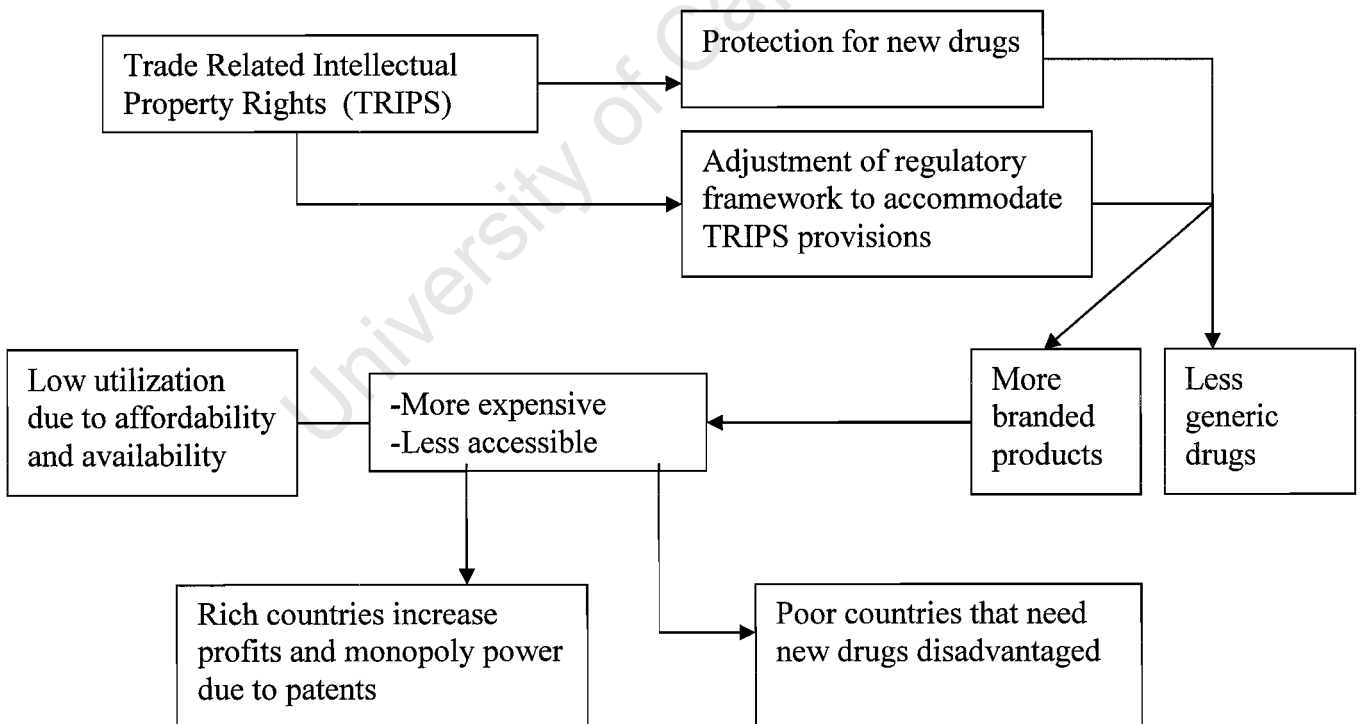
The relevance of these arguments in this study is the fact that being a WTO member, Mozambique and other developing countries have to adhere to 18 specific provisions annexed to the Agreement establishing the WTO. They cannot chose to take part in some of the agreements (probably those that favor them) and not take part in others. The most significant of these provisions to the health sector is the agreement on Trade Related Aspects of Intellectual Property Rights.

Depending on the way in which national legislation is designed and implemented, TRIPS may significantly delay the introduction of new generic drugs and the interest Mozambique has on the latter is vast. The study is looking at what is likely to happen, due to the introduction of TRIPS, to the prices of antimalarial drugs in Mozambique. The fact that there have been a few studies done in this area, mainly because the implementation of the TRIPS agreement has only just began, has urged the researcher

to review other studies and country experiences and use them for the overall analysis of this study.

Subramaniam (1995) found, in his multi-country study (India, Indonesia, Pakistan, the Phillipines and Thailand), that welfare and price effects of the WTO agreement were negative. Price increases estimated for patented drugs ranged from 5-67%. But again a single country study in Thailand, done by Supakankuti et al. more recently in 2001, reveals no price change due to the patent protection Act that was amended to accommodate the TRIPS agreement. But the authors of the latter study still argue that some economic disadvantages are expected for the Thai pharmaceutical industry and that so far the TRIPS agreement has not provided any evidence of technology transfer and foreign direct investment as was stipulated in one of the main objectives of TRIPS. This can be shown diagrammatically.

3.3 Diagrammatic framework



3.4 Sources of data

The main actors studied were the Ministry of Health, especially their import/export company (MEDIMOC) that deals with the supply of medicines in the country⁶. The other important stakeholder is the Ministry of Commerce and Industry, which provided information about the TRIPS Agreement; that is, information about what the country has done so far in response to TRIPS requirements so as to ensure that the national legislation complies with the provisions stipulated in the agreement and also some stakeholder's opinions about the future of TRIPS in Mozambique.

The National Institute of Industry, which represents the Ministry of Commerce and Industry, provided all the data needed in relation to intellectual property rights and patents in the country. The data needed in relation to intellectual property was with regards to patent protection in the country, what laws exist and what laws existed in relation to intellectual property, as well as the progress of amending those laws to accommodate international agreements. This information is needed in order to tackle the first objective.

The National Institute of Books and Discs, which falls under the Ministry of Culture provided some information on patents as well. Stakeholder's opinions through interviews, both from the Ministry of Health, Culture and Commerce helped the researcher answer and understand some of the critical issues around this topic.

Literature review resources include the Health economics resource center, the University of Cape Town, electronic databases, including journals. The Mozambican Ministry of Health documents, such as health policy documents, National health reports and bulletins were also used. For the cross-country comparison, recent articles on country experiences with intellectual property rights and pharmaceuticals were vastly used.

On the basis of the work done and previous studies it was possible to arrive at a general overview. This will allow conclusions to be drawn and suggestions for dealing with the impact of the TRIPS Agreement on the country's pharmaceutical

⁶ Supply of medicines for public sector provision.

industry. Given the mentioned objectives in chapter one, the following table summarizes the order in which data was collected.

Table 3.1: summary of data collection

Research question	Variables	Indicators	Location of data collection
1. Review current laws and regulations in the pharmaceutical industry	Current laws and regulations in the pharmaceutical industry	Drug registration policy, legislative and regulatory procedures.	Ministry of Health. Department of the pharmaceutical industry
2. What are the changes made for the adjustment of Intellectual property rights legislation	Provisions of TRIPS agreement incorporated into national legislation	National changes/alterations accommodating TRIPSs agreement	Ministry of Commerce and Industry. National Institute of Industry
3. What is the likely implication of TRIPS for anti-malarial drug prices in Mozambique	Prices of anti-malarial drugs, total government expenditure on anti-malarial drugs.	Prices of anti-malarial drugs, Costs of antimalarial drugs, Finance of pharmaceuticals.	Ministry of Health. Department of pharmaceutical industry. Medimoc (drug import company)
4. What has happened with other LDCs' pharmaceutical prices after reinforcing patent protection	Price changes after strengthening patent protection. Negative/positive effects in relation to pharmaceuticals	Price changes, Problems encountered, Benefits observed	Databases, relevant literature, libraries (University of Cape Town, Mozambican national library)

The instruments used for the collection of primary data were structured interviews and for secondary data the researcher reviewed relevant literature. With regards to the interviews, both closed and opened ended questionnaires were used as an instrument.

The first objective is analysed in chapter six, whereby the laws and regulations in the pharmaceutical industry are described. The changes made for the adjustment of the intellectual property rights legislation to accommodate TRIPS will also be looked at with a vivid description of the national IPRs legislation in the country. This is done in order to critically view what laws exist in the country and see whether or not there is a gap between the national laws and the TRIPS required laws.

The second objective, which looks at the likely impact of TRIPS for anti-malarial drugs, based on scenarios that show what happens when we have generics and patented drugs, is also analysed in chapter six. Lastly, the third objective is analysed in chapter five. The results of other countries' experiences will be of vast importance to the conclusion of this research because we can not conclude much about Mozambique seeing as they have not experienced much on patent protection hence the analysis of other countries will help answer the research question.

University of Cape Town

Chapter 4

INTERNATIONAL AGREEMENTS

4.0 Introduction

The importance of this chapter is to show us where it all began, in terms of international agreements because it did not start with WTO. This chapter takes us a step back to trade and how things changed in the area of trade and intellectual property after the introduction of Trade Related Aspects of Intellectual Property. These changes are of utmost importance because important decisions are removed from the national level to the global level. At the national level, it has made policy makers much more aware of the increased international implications of their policy actions. Policies that might appear sustainable within a national context may appear less so in an international one.

The rest of the chapter defines TRIPS and describes the provisions entailed in this agreement and relates its basic features within the context of the developed countries and developing countries as well as its limitations. Finally the provisions within the agreement that are meant to facilitate implementation in developing countries are very well defined.

4.1 The Genesis of GATT and the Emergence of the TRIPS Agreement

The TRIPS Agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organisation (WIPO), was certainly the most significant milestone in the development of intellectual property in that century. Looking back at the history of intellectual property it is easier to understand how it all began. The system governing world monetary movements was established at Bretton Woods in July 1944. It constituted the first half of the economics sector of the new world organisation that was under construction at the time, and which later became the United Nations. Trade was to receive its own world body, the ITO. The latter was launched in 1946 for the purpose of promoting the expansion of trade and production, exchange and consumption of goods (Subramanian, 1990).

After a second Conference was convened in August 1947 a draft Contract was submitted to governments and the results of discussions on this draft were combined in the text of GATT, which was signed at Geneva on October 30, 1947 by representatives of 25 governments. Provisional applications of GATT began as of January 1, 1948. The full United Nations Conference on Trade and Employment was then held at Havana, which formed the ITO Agreement, but this never came into force as the United States Congress rejected it (Subramanian, 1990).

In the aftermath of the Second World War, 23 nations signed the General Agreement on Tariffs and Trade, a treaty that aimed at an increased freedom international trade through unending negotiations. The Uruguay Round, also known as the eighth round, had duration of 8 years having commenced in 1986 and ending in 1994. The latter ended with the proliferation of the World Trade Organisation (WTO) on the 1st of January 1995, which until the 1st of January 2002 had 144 member states.

The World Trade Organisation is the international organisation dealing with the rules of trade between nations. Within this organisation there are certain agreements, which are negotiated and signed by WTO members. These agreements include goods (the General Agreement on Tariffs and Trade or GATT), services (the General Agreement on Trade in services or GATS) and intellectual property (the Agreement on Trade Related Aspects of Intellectual Property Rights or TRIPs). The latter is the one agreement that this paper is interested in.

4.2 Defining TRIPS

Trade Related Aspects of Intellectual Property is only one of the 26 agreements found in the WTO convention. The TRIPS agreement incorporates both intellectual (copyright and neighbouring rights) and industrial property (trademarks, patents, geographical indicators, industrial designs, and trade secrets). The TRIPS agreement prescribes a minimum standard of intellectual property protection for WTO members. For industrialised countries, intellectual property rights are of vast importance because their competitive boundary lies in R&D in high technological areas. Without this kind of protection it would not be easy for the firms in these countries to be guaranteed an adequate return on their investment into new technology (Correa, 2000).

Less developed countries or rather, countries without the capacity to innovate, on the other hand, before TRIPS, relied on reproducing what innovators developed. This is the reason why these countries were not in favour of such protection since they perceived it as harmful to their development, given the fact that without being able to imitate invented products they would not have adequate access to products from developed countries. Towards the end of this chapter more will be said about the practical examples that have originated from the mentioned harm caused by this protection.

One of the articles in the agreement (33 to be precise) state that protection offered for a patented product only expires after 20 years. This may lead to an increase in the duration of the patent owner's monopoly in many Member states that do not have competition. In the pharmaceutical area the most likely result of this provision would be that drug prices might increase just like any other monopoly product, for a longer period of time. Another consequence of this provision is that manufactures of generic products will have to wait for 20 years before they can produce the particular drug and sell it at a more reasonable price (Correa, 2000).

Article 7 of this agreement lays down a general principle that the protection and implementation of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Everyone concerned (producers and users of technological knowledge) should benefit from this. This article essentially establishes a balanced framework for TRIPS whereby the rights of owners of IPRs are balanced against the needs of users or consumers. Article 8 allows WTO members to take appropriate measures, consistent with other provisions of TRIPS, to enhance public or national interest including measures to prevent abuse or resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology. This provision makes more sense for developing countries where members can adopt measures necessary to protect public health.

Intellectual property rights are exhausted once the goods or services, which incorporate these rights, are launched on the market. This implies that once a patented, trademarked, or copyrighted article has been soled by the IPR owner, the continued sale or distribution of this article cannot be controlled by him anymore.

This process is called the exhaustion of rights and is accepted in all countries, depending on their national authorities (Correa, 2000).

Article 6 of the TRIPs agreement on exhaustion does not prohibit the freedom of WTO members on the question of exhaustion of IPRs as long as national treatment and most favoured nation are accorded. Some view these terms as the key option for developing countries to satisfy the adverse impact of strengthened intellectual property protection, and also to reduce the unfair duplication of the rights of IPR holders. We will see more of this impact in the next few sections, especially where drugs are concerned.

4.3 Trade and Intellectual Property Rights (North-South)

Trade requires a certain guarantee for the proprietary of traded goods hence the performance of trade depends, at least partly, on property rights. Intellectual property rights fulfil the function of enhancing domestic innovation and attracting multinational companies. But the problem is that developed and less developed countries see this view in two different ways and because of this difference the flow of international trade and investment becomes constrained. According to Schott, (2000) the close relationship between trade and foreign direct investment makes it difficult to distinguish their individual dependency on intellectual property rights. With weak patent protection, companies could, for instance, shift from exports to foreign direct investment in order to retain control over technological information. Stronger patent laws attract greater bilateral trade across all nations.

Maskus and Penurbati (1995) assume that trade is a positive function that arises out of the intellectual property right system. This basically tells us that without intellectual property rights countries would not have the incentive to trade. According to Correa, the TRIPS agreement was not only conceived as an instrument to combat imitation of invented products. "The agreement was also regarded as a component of a policy of technological protectionism aimed at consolidating an international division of labour whereby Northern countries generate innovations and Southern countries constitute the market for the resulting products and services" (Correa, 2000). This new international rule ensures that there is a universal standard of protection, most fit for industrialized countries.

The TRIPS agreement does leave some space for national authorities to control their own countries but with so many restrictions available in it this space leaves much to be desired. This is an irony because industrialised countries also criticise TRIPS, arguing that it does not constitute an international system of protection given that they leave the implementation of rights to the Member states. The TRIPS agreement does not give special attention to the fact that the North and the South have significant economic and technological differences and capabilities; it ignores the fact that these countries demand different products.

Developing countries' share in world R&D expenses is insignificant hence their dependency on innovations made in the North (Correa, *ibid*). The patent statistics shows that 95% of 1,650,800 patents granted in the United States between the years 1977-1996 were given on applicants from 10 industrialised countries. This left developing countries accounting for less than 2% at the time⁷. The fact that developing countries have such a small share in the trade of medium and high tech goods shows us that the new international rule on intellectual property rights is in favour of industrialised countries. This leaves a big question as to what the aim of increased patent protection is; is it really to the advantage of the world or is it a way of the industrialised countries reinforcing their power over the world.

Despite the origins and main objectives behind the TRIPS agreement, as mentioned earlier, this agreement still has elements that may allow a certain balance in its implementation. According to the agreement, its main goal is to reduce conflicts and impediments to international trade.

In Watal's words (2001), "all intellectual property rights can be broadly held to grant a right to exclude others from certain unauthorised acts with respect to the subject matter of protection". These rights are granted under national law to avoid unfair competition whilst at the same time encouraging innovation and other creative activities. In the context of the TRIPS Agreement, IPRs that directly reflect the objective of encouraging creative or inventive activity include patents, copyright related rights, industrial designs and layout designs. These IPRs are meant to grant

⁷ Kumar, 1977, pp. 5-9 in Correa 2000, pp.5

market power through legal exclusivity, although limited in time and scope. Because of the way society views these rights (i.e. they recognise that public interest or welfare may suffer with the grant of this monopoly power) they do not go without exceptions. But even though there are exceptions these cannot be such that the objective or rewarding creativity is defeated.

The next section looks at measures that have and can be taken to alleviate developing countries from the likely consequences of the TRIPS Agreement.

4.4 Transitional period arrangements

According to the TRIPS agreement parties shall take all necessary steps to ensure that conformity of their laws, regulations and practices within the provisions of this Annex in a period of X years is put into force. Developing countries, which face special problems in the preparation and implementation of intellectual property laws, dispose of an additional period not exceeding Y years. WTO Members have to implement the TRIPS Agreement as a part of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, signed at Marrakesh on April 15, 1994. In Gervais's words, the Agreement creates obligations not only to change laws but also to implement reasonable changes to intellectual property laws or judicial procedures (Gervais, D. 1998).

With the view to achieve full and successful adjustment and compliance with levels of protection and enforcement set forth in this agreement; least developed parties are not expected to apply such standard for a period of a total years. The WTO generally accepts the United Nations list of least developed countries. Under the provisions of Article 66(1), least developed WTO Members benefit from a transitional period until January 1, 2006 to apply the TRIPS Agreement (other Articles 3, 4 and 5), with possible extensions by the TRIPS Council. The Article justifies the need for this transitional period: "the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints and their need for flexibility to create a viable technological base".

The next sections will look at whether or not the granting of compulsory licenses or the admission of parallel imports by some developing countries threaten the long term viability of drug R&D. This is not likely to happen because developed countries'

markets already provide a significant amount of resources for R&D, and the pharmaceutical firms have had large sales in many developing countries, even in the absence of patent protection. In Brazil and Mexico for instance the large pharmaceutical firms already controlled the largest part of the markets before the introduction of product patent protection in the 1990s (Correa, 2002). Additionally, the contribution to R&D that could be made by some developing countries is insignificant in global terms. For instance, in Africa, one of the regions where the problems of access to drugs are more severe only accounts for around 1.3% of world pharmaceutical sales (Correa, 2001). The next section will give a more detailed view on compulsory licenses and parallel imports.

4.5 Compulsory licensing

A compulsory license is an approval granted by the government without the authorization of the patent holder. Under the TRIPS agreement, countries have the right to issue such licenses regulated in accordance with the agreement (Article 31). There are different grounds under which to issue compulsory licenses such as public health, emergency situations, epidemics, protecting the environment and others. It all depends on the national law to decide which are the grounds. In Germany for instance, the law states that compulsory licensing is permitted for reasons of public interest.

TRIPS has set five specific conditions under which compulsory licensing can be granted. These conditions are:

- 1) Refusal to deal
- 2) Emergency and extreme urgency
- 3) Anti-competitive practices
- 4) Non-commercial use
- 5) Dependent patents

Although the TRIPS Agreement has set these five specific conditions for the grant of compulsory license, it does not prohibit the Members' rights to create compulsory licenses on other grounds not clearly stated in the Agreement such as public interest. The only case that is denied freedom relates to semi-conductor technology, which is only subject to compulsory licenses for public non-commercial use and remedy anti-competitive practices.

Licenses to remedy anti-competitive practices require some form of compensation payment to the patent holder. According to Correa, most countries provide for different modalities of compulsory licenses; the US Government is one example, which has made extensive use of compulsory licenses for governmental use, which has led to complaints from the European Union. Although the agreement does not limit the grounds for the allowance of compulsory licences, those that want the latter granted must respect the following conditions:

- a) Case-by-case evaluation and decision
- b) Prior request to the patentee for a voluntary licence
- c) Determination of scope and duration of the compulsory licence
- d) Non-exclusivity
- e) Non-assignability
- f) Preferably for the domestic market
- g) Remuneration
- h) Possibility of requesting the revision of decisions and the revocation of the licence

There is enough room left for interpretation at the national level of the criteria to determine when remuneration is to be deemed adequate, but it should take into account the economic value of the authorization. In the case of a compulsory licence to provide drugs to a population that would otherwise be unable to afford those drugs, it could be argued that the patent holder lost nothing. It must be determined in each individual case, taking into consideration the circumstances of the licensee and of the market where it operates, as well as the purpose of the licence.

The possibility of revocation of the licence, if too strictly applied, may defeat the whole system of compulsory licensing, since the more effective a compulsory licence is, the sooner the licensee may lose his rights (Correa, 1994). But as it has been said, each case is treated differently, for instance, if a compulsory licence is issued to remedy anti-competitive practices, many of the conditions do not apply, such as the requirement to first try to obtain a voluntary licence. Also the fact that a decision to issue a compulsory licence must be subject to review does not necessarily imply

judicial review; TRIPS only requires that the review is independent, so countries may opt for an administrative review, which is faster.

One may say that compulsory licensing is a way of controlling the abuse of monopoly power by the patent holder. When the latter thinks of abusing his rights he may think twice about it with the fear that he will face compulsory licensing for his product. This in some way may prevent malpractice and misuse of monopoly rights, hence making it a necessary element in any intellectual property rights law. But the only way this system can be effective is only if the grounds set within it are as transparent as possible.

4.6 Parallel importation

Parallel importation refers to the importation, without permission of the patent owner, into a country of a product from a third country, where this product has been marketed by the patent holder or in another legitimate way. It is mostly used when the price in the third country is considerably lower than the price the patent holder charges in the country concerned. Under the TRIPS Agreement, parallel import is allowed whereby countries are given the freedom to determine their own policy in respect to parallel imports. As stated in Article 1, the method of implementing the TRIPS provisions can be freely determined within the own legal system and practice of each country. Article 6 leaves each country with the room to incorporate the principle of international exhaustion of rights in its national legislation. This means any Member can determine the extent to which the principle of exhaustion of rights is applied in its own control, without breaking any obligation under the Agreement.

Although there is an argument that parallel imports in developing countries will increase the level of non-genuine products, it is very clear that this policy has a positive effect on developing countries. In markets such as the pharmaceutical market whereby there is an extensive exercise of price discrimination (where prices for the same product can vary considerably between countries) parallel imports may play a major role in preventing preferential prices for developing countries. In the pharmaceutical area, by allowing the importation of a patented medicine from a country where it is sold cheaper than in the importing country, access to the product may benefit a larger number of patients. The acceptance of parallel imports may

therein be regarded as one of the measures, consistent with the TRIPS Agreement, that Member countries are explicitly authorized to take to protect public health (Article 8.1 of the TRIPS Agreement).

Some argue strongly against parallel trade in products protected by IPRs, especially pharmaceuticals. In the case of patents it is argued that the terms allowing the exclusive right of importation, as well as the terms prohibiting any discrimination on grounds of whether the product is imported or domestically produced, leads to an obligation to restrict parallel imports. But Article 6 does not take away the right of patent owners to prevent importation by third parties. Supporters of this view argue that in the case of pharmaceuticals, parallel trade would decrease incentives for innovation (Watal, 2000). Also, if parallel import increases, there would be less of price discrimination.

Most developed countries are against parallel trade in patented products; actually most of them continue to follow policies of national exhaustion, disallowing parallel imports. Developing countries on the other hand highly support parallel importation because they always questioned whether or not this would help them achieve their objective of gaining access to newer and more effective (patented) medicines at sensible prices. This is one of the objectives that led South Africa to amend its Medicines Act to allow for parallel imports of medicines. After strong oppositions and pressure from the US and European based pharmaceutical companies, the South African government amended its policies and an agreement was reached that South Africa would respect TRIPS.

The Thai patent law gives way to importation of patented products if the patentee has approved to the manufacture or sale of the product elsewhere. But Watal argues against international exhaustion policies aimed to benefit consumers in certain developing countries through lower prices due to price competition. He says that consumers in those other developing countries from which parallel imports are established may lack the product subjected to parallel exports.

4.7 Conclusion

Conclusively, from what we have seen in this chapter the present times have been hailed as the information age where knowledge constitutes power and a competitive edge over competitors. It is therefore in the interest of technology owners that knowledge is not easily taken away and they have therefore, pressed for the introduction of TRIPS as another barrier to access, and as one of the means of controlling knowledge. Attempts to tighten the enforcement of intellectual property rights in international conventions by industrialized countries had been unsuccessful due to the deadlock in negotiations between industrialized and developing countries with differing views, in the Paris Convention.

But the introduction of the TRIPS agreement, which ended up allowing the strengthening of patent protection and according to this chapter as far as the pharmaceutical sector is concerned, is likely to lead to an increase in drug prices just like any other monopoly product. Some authors argue that without IPRs countries would have no incentive to trade. But others stress the fact that developing countries have such a small share in the trade of medium and high tech goods, showing us that the new international rule on IPRs is in favour of industrialized countries.

Although there are certain measures, such as compulsory licenses, allowed for developing countries to alleviate the potential consequences of the TRIPS Agreement, developed countries are not so much in favor of these measures. But as has been shown in the previous sections, the grant of a compulsory license has no detrimental effect to the patent holder. Both compulsory licenses and parallel importation have a positive effect on developing countries because they allow access to products that would otherwise be unavailable to patients if they had to access them in a different way.

COMPARATIVE ANALYSIS: CROSS COUNTRY COMPARISON

5.0 Introduction

This chapter looks at different country experiences with regards to TRIPS. As it has been mentioned earlier, it is hard to come to a generalized conclusion to this study given the fact that different countries experience different consequences in this regard but it is essential to have a look at what other countries have gone through either after implementing TRIPS or after strengthening their patent protection.

It will not be easy if possible, to have evidence about the implication of TRIPS because TRIPS standards have only just been enforced in many developing countries. But even so, given the large coverage of the TRIPS agreement and the differences existing among developing countries, it becomes difficult to make a quantitative assessment of its likely impact. This is because the levels of economic and technological development of these countries are different. What can be looked at is the experience of countries that have adopted pharmaceutical patents in the past ten years, which is highly relevant in this context.

Industrialised countries support the argument that patent protection in all fields of technology, as annexed in the TRIPS Article 27, would have three main effects in developing countries and these are: promote foreign direct investment (FDI), increase the diffusion of technology and the promotion of local research and development (R&D). Given these expectations with regards to the introduction of patents, it is possible to look at how these have implicated on these objectives. With this it does not mean that we do not acknowledge the fact that IPRs is only a part of the elements that may influence FDI, innovation and technology transfer.

5.1 Effect on FDI, technology transfer and R&D

Changes in IPRs are most likely to have a significant impact in countries that are more technologically advanced. According to Correa, the effect of reinforced IPRs is not only likely to be felt in terms of market prices of protected products, but also with regard to the conditions for access to foreign technology, as well as the viability of

productive activities based on imitation. In such countries the effects of changes in IPRs will go beyond trade, and involve access to technology and the patterns of industrial development (Correa, 2000:24).

The pharmaceutical industry is among the most R&D intensive industries. The impact on R&D expenditures in pharmaceuticals, both domestic and global has been looked at in different studies and Argentina found no reason to expect an increase in domestic R&D in pharmaceuticals. According to Nogues (1991) the main reason is that the development of new chemical entities is outside the reach of local companies in any developing country, since there are no firms in these countries big enough to finance the high costs of pharmaceutical R&D.

According to Scherer (1995) less developed countries could be better off if the extra profits conveyed to drug firms led to the development of more new drugs and hence to a multiplication of consumers' surplus. Scherer found that in Italy since patents were granted in 1978 drug product patenting exhibited a strong upward trend before the change in the patent regime. With regards to trends in foreign trade after patents were introduced, Scherer identified a fast deterioration of the trade balance, which turned negative.

This brings about two important queries and these are (a) what is the extent to which the income generated by patents in the developing world is actually invested to develop the medicines needed by the poor; and (b) what is the extent to which the granting of patents in developing countries, under conditions substantially similar to those applicable in developed countries, is essential to provide incentives for industry's global R&D activities (Lanjouw, 2001).

In some Latin American countries, such as, Chili and Colombia, the introduction of patents in pharmaceuticals in 1990/1991 has not led to any increase in FDI in the pharmaceutical sector. Foreign companies have taken hold of local companies but new investment has not taken place. An ASEAN workshop on the TRIPs Agreement done in 2000 found that a high number of formulation plants have been shut down. With this we can conclude that the introduction of the patents in these countries has not resulted in an increase in FDI because many companies have opted to import other

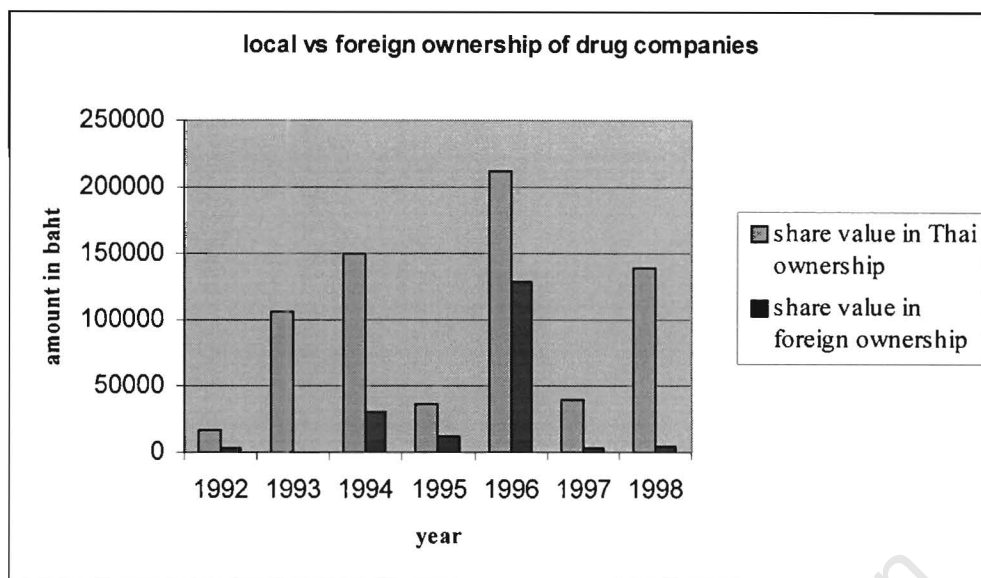
than producing locally. This has meant an increase in trade deficit caused by the substitution of local production by direct import.

The same pretty much applies to technology transfer and pharmaceutical R&D in these countries, which has not been positive at all. The authors of the ASEAN workshop say, “license agreements usually mean that the patent holder provides the active ingredient, not the technology for the production of the active ingredient, and the licensee is usually just formulating” (2000). These countries have not experienced an increase in pharmaceutical R&D and we have to acknowledge the fact that if R&D is to increase it has to come from developing countries which is ironical since there is a lack of human capital. It has been clearly pointed out by different authors that there is hardly any hope that R&D for diseases relevant to developing countries will augment in industrialised countries.

A study done by the WHO collaborating Centre for Health Economics assessed the impact of the introduction of pharmaceutical product and process patents in Thailand and found some similarities with the countries mentioned above. After the enactment of the 1992 patent act, there has been no significant increase in technology transfer that could lead to R&D of new pharmaceutical products in Thailand; in fact, there has been more reliance from imports of drugs as compared to local products. Foreign companies have more to gain from change in patent law than local companies, “the share of originator products as percentage of the total pharmaceutical market increased, on average by 4% per year” (WHO 2000). FDI has also been stagnant since 1992.

The following graph shows what has happened in Thailand with regards to technology transfer and FDI.

Graph 5.1: Distribution of total direct investment in pharmaceuticals-Thailand, 1992-98



Source: *Bulletin of the WHO, 2001*

As has been said and as is shown in the above graph, there has not been much technology transfer to or FDI in the Thai pharmaceutical industry since 1992. As we can see in the graph, between 1997 and 98 there has been no transfer of FDI at all. Between these years the total share value in Thai ownership was 79.4% and 20.7% in foreign ownership. From 1992 to 96 alone we see a total share value of 74.9% in Thai ownership, leaving 25.1% on foreign ownership. The industry is still rather small compared with other production sectors. The data on Thai pharmaceutical companies registered from 1984 to 1998 indicated that there were more Thai than foreign shareholders, reflecting the fact that little FDI is flowing into the industry.

This could reflect a trend in the pharmaceutical industry's foreign direct investment, in the sense that as costs of R&D increase there is a tendency for drug companies to merge and join forces hence further reducing the transfer of FDI's. The more and more large companies merge the bigger they get so as to disperse their investment risks, maybe because they fear being vulnerable. The consequence of this event will certainly be negative on developing countries because the bigger the firms become the less likely they are to transfer FDI to developing countries.

The Thai and other countries' evidence show us that the promises (i.e. having affirmed that enhanced and global protection of IPRs would promote technology and

investment flows to developing countries, therein fostering their participation in trade and economic development) made by developed countries are far from taking place. As shown by the above countries, imports of drugs from developed countries are on the increase. As Correa (2000) puts it, “the negotiation on TRIPs was presented by developed countries as a necessary condition to promote innovation and to stimulate technology and capital flows to developing countries with the assumption that both countries will benefit alike from IPRs. It remains unproven however, that reinforced protection of IPRs worldwide shall increase the flows of capital and technology to developing countries”.

5.2 Effect on drug prices

Pharmaceutical patents by design and function increase the price of medicines to consumers. According to Abbott (2000) patents enable pharmaceutical manufacturers to sustain prices higher than their marginal costs of production by discouraging the emergence of competitors. The United States and the OECD pharmaceutical industry have argued that price is only one factor in determining access to medicines in developing countries, and infrastructure and professional support must also be addressed. Yet this is hardly an argument against measures that would lower the price of patented pharmaceuticals.

For a developing country, the grant of pharmaceutical patent protection almost certainly means increasing payments to U.S, European or Japan based pharmaceutical companies. As a general proposition, the U.S will be by far the largest beneficiary of the patent provisions of the TRIPs agreement. As a consequence of TRIPs implementation, there will be large rent transfers from the developing countries to wealthier developed countries.

In Italy, the establishment of patent protection took place in 1978. This country was previously not doing so badly in the production and exportation of pharmaceutical products. After the introduction of patents drug prices increased dramatically in this country by almost 200% and this led to an increase in the net imports of pharmaceutical products. Their incredible trade surplus in pharmaceutical products decreased to become a trade deficit.

In the case of HIV drugs for instance, the drug d4T, one of the components of a dual therapy to slow the progression of the AIDS virus, which Bristol- Myers Squibb sells under the brand name Zerit, saw an increase in price. The drug was synthesized by Michigan Cancer Foundation in 1966 with the utilization of public funds, and its use to treat AIDS was discovered by Yale University, which holds a patent. Despite the public funding for R&D, Zerit is reported to sell at a price considerably higher than the product available from generic producers (Rosenberg, 2001).

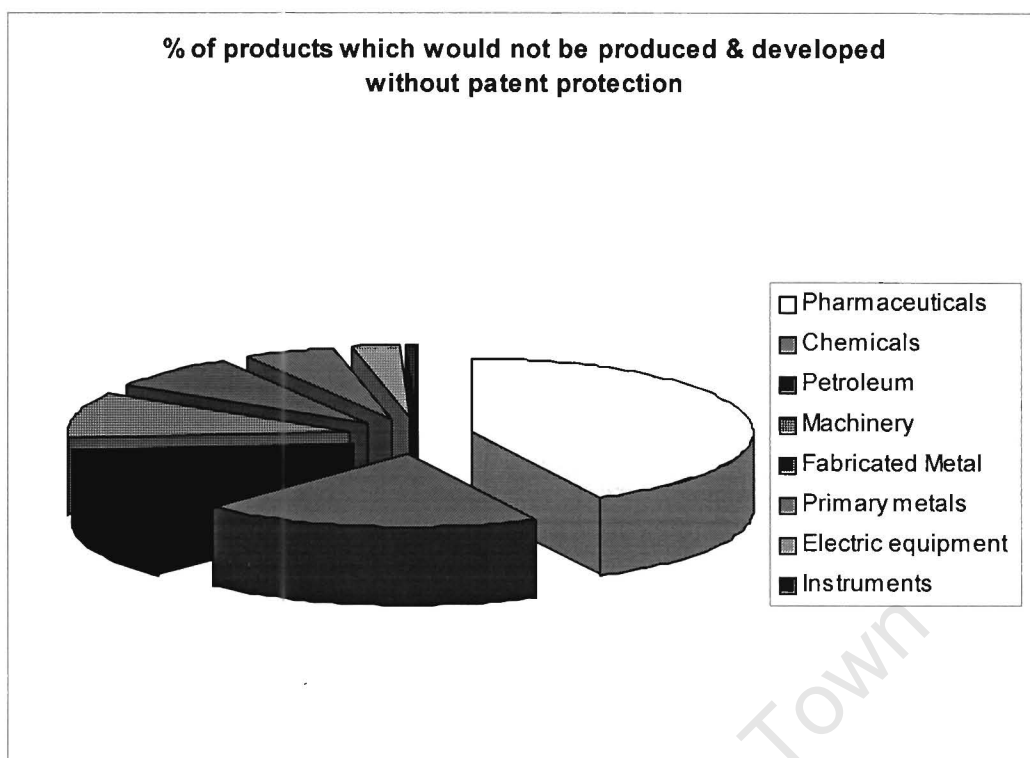
5.3 Benefits of Intellectual Property Protection to Developing countries

Progress in intellectual property protection has occurred because countries all over the world have recognized that such protection encourages investment, innovation, and economic growth. Strong intellectual property protection not only benefits research-based pharmaceutical companies and the patients they serve; it also helps developing nations by enhancing the conditions for investment, encouraging the development of local industry, and enabling more goods to be produced.

In the international innovative pharmaceutical industry's perspective (IFPMA) new medicines and access to these medicines, which are of utmost importance in the fight against communicable and non-communicable diseases, are dependent on strong patent protection and other intellectual property protection. They argue that the patent system represents a compromise between competing short-term and long-term economic and social interests. It allows the private pharmaceutical industry to operate and make a contribution to a socially driven public health sector by providing it with cost-effective new technologies.

While the commercial sector discovers and develops nearly all new drugs and vaccines, this is done within certain risks; the patent system therefore provides the incentive necessary to investigate and invest millions of dollars in R&D. The following table shows us the importance of patent protection for development of innovative products in various industries.

Diagram 5.2: importance of patent protection for development of innovative products in various industries



Source: patents and innovation: an empirical study by Mansfield, Management Science, 1986

As is shown in the diagram, the dependence of pharmaceutical discovery and development on adequate intellectual property rights is the highest among various sectors. The diagram shows us that the first rank is held by the pharmaceutical industry.

A 1994 World Bank study found that "the strength or weakness of a country's system of intellectual property protection seems to have a substantial effect, particularly in high-technology industries, on the kinds of technology transferred by many U.S. firms to that country (Mansfield, 1994). According to the study, 86-100 percent of leading U.S., German, and Japanese chemical and drug companies reported that a country's system of intellectual property protection has a major impact on their decision to invest—or not to invest—in research and development facilities in that country.

This conclusion is supported by empirical examples. Italy, for instance, instituted a strong patent protection for pharmaceuticals in 1978. In that year, there were only 123 billion lira invested in local pharmaceutical R&D. Ten years later, that investment had more than quadrupled, and is still growing (Farindustria Indicatori Farmaceutici,

1994). But as has been mentioned before, the Italian drug industry has faced an increase in prices of drugs since the introduction of patents, hence what we see in this case are double results.

Korea adopted pharmaceutical-patent protection in the late 1980s. Since that time, local pharmaceutical companies have increased their share of the Korean pharmaceutical market. Mexico adopted a strong patent law in 1991. Since then, U.S. R&D investment in pharmaceuticals in Mexico has more than doubled. Canada, after strengthening intellectual property protection, experienced dramatic growth in R&D investment. In 1979, 2.7 percent of pharmaceutical sales were invested in R&D. That figure had increased to 15.7 percent by 1997, according to the Pharmaceutical Manufacturers Association of Canada (PMAC).

Between 1987 and 1997, pharmaceutical research spending in Canada rose by more than 700 percent, and new R&D investment exceeded \$4.6 billion. The PMAC estimates that almost 3,500 new jobs have been created as a result of the strengthening of pharmaceutical-patent protection (Pharmaceutical Manufacturers Association of Canada, Annual Review, 1998-1999).

Brazil enacted strong intellectual property protection for pharmaceuticals in May 1996. Since it became clear that Brazil would protect pharmaceutical patents, multinational pharmaceutical companies have announced investments worth hundreds of millions of dollars in the country, creating jobs, stimulating the economy, and improving health by making state-of-the-art medicines available (The Buenos Aires Herald, June 18, 1996).

Some developing nations have argued that they cannot afford patent protection for pharmaceuticals because their people need inexpensive medicines. Experience has proven, however, that lack of patent protection not only deprives people in such countries of state-of-the-art medicines, but also impedes the competition that can lower drug prices.

A 1990 study by the Latin American Economics Foundation stated that "the non-patentability of pharmaceutical products, that was in its beginning a device designed

to safeguard public health, has presently turned into an instrument to protect local industry." In countries that provide pharmaceutical patent protection, consumers benefit from the lower prices brought about when patents expire and generic competitors enter the market. For example, the ulcer drug Tagamet (cimetidine) lost U.S. patent protection in 1994. Within weeks, generic copies were introduced at prices 30 to 60 percent lower than that of the original product.

By contrast, in countries without pharmaceutical patent protection, there is little price competition. What competition exists is based on the strength of sales forces, the date of introduction of the products, brand loyalty, and other factors of little benefit to consumers. In fact, a survey by the Latin American Economics Foundation of prices in Argentina found that copied drugs in that country are, on average, priced higher than an originator's product. In such cases, the consumer pays twice. First, the consumer often pays a higher price—relative to income, prices of the original product, and even prices in the United States. Second, the price the consumer pays does not contribute to pharmaceutical research for future medical breakthroughs. In the U.S., for example, about 20.8 percent of the revenue of research-based companies is reinvested in R&D. Strong intellectual property protection is absolutely essential for pharmaceutical companies to invest in research—which leads to the discovery and development of more cures and better treatments for patients all over the world.

But this is still debatable, because there is evidence from both sides of the coin that intellectual property rights are good/bad for the pharmaceutical industry. It could be that those countries benefiting most from these rights are already well developed countries and the same cannot be said for less developed countries or countries without technological advantages. Most developing countries, for instance have no patent protection rights at all and this scenario does not help us understand how these countries are supposed to benefit from patent protection if all their existence they have not been using them.

5.4 International price discrimination

A cross-country analysis, done by Schut et al (ibid) based on prices of packages of pharmaceutical products to test that the pharmaceutical industry practices international price discrimination came up with interesting results. Firstly, the

monopolistic power of these industries leads to a behaviour in which competitive forces have no major role in the determination of prices such that competition is mainly pursued by means of innovation and product differentiation, supported by trademarks.

Being one of the most innovative industries, the pharmaceutical industry goes through extreme uncertainty on the supply side of the market and hence looks for protection against this event through thorough use of patents (to protect the innovation) and trademarks (to protect the product against me-too duplicates). What adds to this problem is the fact that the drug market has a very low price elasticity of demand due to the fact that it is a commodity mostly purchased out of necessity. According to this study there are not only large differences between the quotations of different companies but the same companies have prices that vary by 400 per cent from one country to another. Differences in price result because manufacturers apply typical profit maximizing strategies based on the price sensitivity of buyers; those buyers less sensitive to price pay more.

The fact that there is a high degree of product differentiation and the fact that the pharmaceutical industry are most of time unwilling to publish comprehensive information about their actual transaction prices, makes it unquestionable to find information about prices of pharmaceutical products scattered, especially when developing countries are concerned.

There is recognition that it is a difficult task to compare domestic prices of different countries by simply converting them at market exchange rates into a common currency unit, especially for developing countries that are characterized by fluctuating currencies. This certainly produces biased results seeing as exchange rates do not necessarily reflect the relative purchasing power of the currencies. After all, the market exchange rate applies to internationally traded goods hence comparisons may be misleading. According to Barnett (1980:481) in Ghana if imported drugs were valued at a rate of exchange, which valued the relative resource cost of producing goods domestically and abroad, the drug bill in domestic currency would certainly be very much higher than that shown in the Ministry's account.

Because of these problems Schut et al used the purchasing power parity (PPP) of each country (of the 32 they studied) for the category drugs and Medical preparations to construct price indices with respect to the U.S as base country. What they took note of is the fact that if a large number of countries are included in multilateral comparisons, an effort to produce a common list of drugs will result in too short a list or in pricing items that are not representative for all countries. So, for this reason the price indices shown in their findings were regarded as indicative instead of an accurate measure of the relative price differences among countries.

Their findings show that government policies to control prices are the most successful in lowering the price level of pharmaceuticals. Implementation of direct price control measures implies, on average, a more than 20% decrease in drug prices. It also shows that although excluding pharmaceutical products from patent protection also influences the price level of drugs in a downward direction by about 10%, their effect is less convincing.

Chudnosvsky (1983) and Lall et al (1977) support this argument by agreeing that the lack of patent protection or weak patent protection has not seriously affected the way transnational co-operations operate in developing countries. They argue that patents are an important instrument to reinforce the market power of leading firms but they are not the main source of that power. Chudnosky adds that a slight change in patent legislation is not enough to change the structure of the pharmaceutical industry in developing countries or to reduce the prices of pharmaceutical products and imports. He votes for a combined policy of excluding patent protection and promoting the use of generics so as to reduce the price level of drugs. Sri Lanka proved that a comprehensive drug policy can reduce the price level of drugs (Patel, 1983).

International price discrimination sometimes results in lower prices for poorer countries but the fact that drug prices vary randomly, depending on the existence and level of success of a national drug policy, means much higher prices than necessary for many poor countries with close to no possibilities to establish a successful drug policy. Although the drug prices in developing countries are often lower than in developed countries, the real costs of these products are still higher. According to Schut, the real costs of drugs in Malawi are more than 12 times higher than in the U.S

and Sri Lanka experiences about 60% higher real costs. But this is likely to be because of the different levels of economic conditions in the countries facing such differences in price.

The fact that total expenditure on pharmaceuticals increases more than double times from year to year should alert developing countries of the likely consequence of severe constraints on the development of other essentially needed health services. Price controls are therefore of vital importance for developing countries, especially those that regulate the price level of drugs. Some authors suggest that the solution would be an exclusion of some drugs, depending on local needs, from patent protection, but with the TRIPS agreement this is unlikely.

5.5 Generic drugs vs patented drugs

The market share of generic drugs has been rising. The Hatch-Waxman Act encouraged the entry of generic drugs by establishing an abbreviated approval process for generic versions of all nonantibiotic drugs. In addition, the act reversed a 1984 court ruling and allowed generic manufacturers to begin the tests required for FDA approval before the patent on the innovator drug they were copying had expired. These changes increased the probability that a generic copy would become available after patent expiration and reduced the average delay between patent expiration and generic entry from more than three years to less than three months.

The increase in generic sales since 1984 has brought down average prices for drugs that are no longer under patent protection. But these lower prices do not result from reductions in the price of the original drug when it begins to face competition from generic drugs but because consumers now have a choice to substitute one drug for another. This means more competition for generic manufacturers since they sell identical products. The increased use of generic drugs has lowered total spending on brand name drugs (according to Smith, the purchase of generic drugs reduces the cost of brand name, at retail prices, by roughly \$8-10 billion in 1994). The added competition created by generic drugs keeps the manufacturer of the breakthrough drug from raising its price as quickly as would otherwise be the case.

But this is not to say innovator drugs manufacturers loose out on profit because of the introduction of generics because the initial high prices they charge allows them to recover their investment in a drug's discovery and development. Studies have found that on average discovering and developing a drug takes about 12 years and costs about \$200 million per successful product in terms of the 1990-dollar rate (Grabowski et al. 1994). This amount of money includes the cost of drugs that never make it to the market and also accounts for the cost of capital, that is, the cost of waiting for a return until the drug is introduced.

The after tax profits over the life of a typical innovator drug changes. The first 12 years show a negative cash flow while the drug is being developed, undergoing testing, and awaiting approval. But when the drug is marketed over the next 20 years it earns back a return on the investment in its R&D. According to two studies, that profit stream has an average present value of \$220-230 million, after deducting manufacturing, advertising, distribution and other non-R&D-related costs, which more than compensates for the \$200 million in average capitalized costs of drug development. These studies estimate that for innovator drugs introduced in the early 1980s, after tax profits exceed development costs by \$22-36 million, on average, (Grabowski et al. *ibid.*)

At the end of day manufacturers of breakthrough drugs are not at any critical loss when counterfeits are introduced because the growth of the latter does not offset the sales that the breakthrough drug loses to its new competitors. And besides, the introduction of a counterfeit does not imply that the price of brand name drugs drops immediately after the former is placed in the market, it takes time and within that time the manufacturers of the brand name are still making excessive profits. Competition from generics does not therefore result in a loss for innovators but results in firms' earning close to a normal rate of return to their R&D investment, on average. The difference is that instead of earning abnormal profits, firms now earn normal profits and that is the problem.

5.6 Conclusion

Conclusively, one of the arguments from developed countries, in favour of patent protection, was that global protection of intellectual property rights would promote

technology and investment flows to developing countries, therein promoting their participation in trade and economic development. Developed countries also offered the multilateral way as a means to reduce trade tensions and avoid the use of independent punishment, probably with the recognition that unilateral retaliation is not in favour of a positive trade environment. But evidence does not show us these promises materialising but what we see is the new multilateral disciplines increasing exports from developed countries, while the well-being of the majority of the population are becoming more visible in developing countries.

We should never forget that the negotiation on TRIPS was presented by developed countries as a necessary condition to promote innovation and to stimulate technology and capital flows to developing countries. Like Correa says, the TRIPS agreement represented a great victory for the large pharmaceutical companies. This was a major breakthrough for them because it was the first time an international agreement obliged to grant patents on pharmaceutical products, under which trade sanctions may be applied against non-complying countries. The assumption was that both countries would benefit equally from IPRs. But all these benefits remain unproven. Basically, the argument suggests that the failure to grant appropriate IPRs protection, including in developing countries, would reduce the future flows of funds for R&D and lead to a deadly fall in the innovation performance by the industry.

What is evident from this chapter is that the consequences that take place due to the TRIPS Agreement vary from country, making it even harder to come a generalised conclusion. There is a difference between what happens in low and middle-income countries. The majority of the African states for instance, follow the common-law system, although some follow the French and Portuguese (as is the case for Mozambique) civil system. The methodology of IPR enforcement procedures will naturally reflect the problems that are inherent in these neo-colonial legal systems and their perception of this whole concept of intellectual property. These regions and/or countries have different institutional capacities to implement these laws hence the difference in the results that we see in this paper. Some of them are slightly advanced technologically and this means a different set of results and some are premature, technologically, hence a different set of consequences.

But as we can see from this chapter it is not only country differences but there are also conflicting results within countries. Italy is an example of a country that has shown conflicting results from the enactment of their patent laws. If we look at it from the point of view of the effects of TRIPS on FDI, technology transfer, R&D and drug prices, we can see that there are some positive effects on one side and negative effects on others. We saw from that country experience that although there was a positive impact on FDI, shown by an increase in foreign investments after the introduction of a strong patent protection, the Italian drug industry, their market as well as consumers faced an increase in prices of drugs. Double results are therefore expected from different countries and/or regions, and this makes it difficult to come up with a unified result and conclusion.

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Chapter 6

FINDINGS: THE CASE OF MOZAMBIQUE

6.0 Introduction

This chapter reports the findings of the study with regards to the specified objectives in chapter 1. The first objective will be discussed in this chapter, whereby we critically describe the laws and regulations of the pharmaceutical sector in Mozambique. The second objective, which examines the likely implications of TRIPS for anti-malarial drugs in the country, is also described in this chapter. The findings from this chapter together with the findings in chapter 5, that is the different country experiences, will help us come to a systematic conclusion to this research paper. It is important to note though that this conclusion cannot be generalized as we have seen in the previous chapters that there is no unified conclusion to the consequence of TRIPS.

As the research is looking at the potential impact of TRIPS for Mozambique's anti-malarial drugs, it is important to give a detailed overview of the malaria situation in the country, as well as an overview of anti-malarial drugs as this will help us integrate both situations, in terms of the relation between the increased drug resistance and the need for new drugs. Other sections will look at how the financing of the pharmaceutical sector takes place in the country and describe the market prices of anti-malarial drugs in the country; just so to add the importance of the need for funds in the country and how that can impact on the country's situation in the sense that they cannot afford significantly more expensive drugs that may arise as a consequence of being part of the WTO/TRIPS Agreement.

The rest of the chapters simply show the immaturity of the Mozambican drug registration policy as well as their stand with regards to patents; this is to stress that the country still has a long way with regards to being ready for enforcing strong patent protection. We will start by describing the patent situation in the country.

6.1 Patents and WTO/TRIPS in Mozambique

In 1966 there was a Portuguese colonial law on intellectual property and Mozambique was integrated in this law in 1971 (the colonial era) until independence in 1975. But

even after independence, the fact that there was no law on property to adhere to meant that whenever the need arose the only law that could be used was the Portuguese law. Even when used, these laws only benefited the Portuguese. It was not until 2001 that Mozambique implemented a law on intellectual property, which is actually called industrial property law and within it is incorporated intellectual property rights and patents.

Responsibility for Intellectual property matters is divided between two departments, one responsible for patents and other industrial matters and the other responsible for copyrights. The country's first law on industrial property protection came into force only in 1999 and was finally implemented in 2001. Enforcement on the current intellectual property laws is minimal.

The industrial property code of Mozambique was enacted under the decree no. 18/99 of 4 May. There are a number of objectives for introducing this law. One of them was to create conditions favorable to technological development in the country and get access to new industrial, commercial and service related techniques, in order to stimulate national and foreign investment through the protection of industrial property. They also recognize the fact that industrial property rights are instruments for transferring knowledge and new technology and to promote inventive activity in the country.

There are fewer requests for patent protection in Mozambique, most people demand trademarks and even so, those that are registered belong foreigners who come to the country and request protection. Some of them go via Geneva to protect their products and then come to Mozambique with patented products, especially in the industrial area. Some are of the view that patent protection is not very beneficial for less developed countries, especially in the pharmaceutical area therefore governments should not strengthen protection but should limit rights to protection. In Mozambique patents are protected solely to attract investors because other than that there are not many inventions in the country that would sincerely benefit from patent protection.

Mozambique signed with the final Act of the Uruguay Round and the Marrakesh agreement establishing the WTO on 15 April 1994, and became member of the WTO

on 26 August 1995. Under the single undertaking, all WTO multilateral agreements were to become binding on Mozambique. Mozambique grants at least most-favored-nation treatment to all its trading partners. As a developing country it benefits from a transition period to implement a number of its commitments under various WTO agreements. Mozambique has pursuant to Article 20.1 notified the delayed application of the agreement on customs valuation.

Mozambique's commitment in the WTO falls short of its trade reforms. Mozambique certainly needs to more vivid wisdom about WTO rules and regulations. Mozambican officials continue the process of preparing legislation and regulations consistent with various WTO regulations. Technical assistance is viewed to be essential for the country to come into full compliance with its WTO obligations. In general, people feel that the price paid by Mozambique to join the multilateral trading system is too high; they believe that it might be better for Mozambique to look for benefits within the framework of regional integration schemes, especially SADC. TRIPS's efforts to modernize domestic legislation are needed, as Mozambique's current intellectual property laws date back to the Portuguese administration.

The possibility that the TRIPS agreement could lead to a concentration of drug production in industrialized rather than technology transfer to, or FDI in developing countries is likely in Mozambique, especially because this country is at a premature stage with drug manufacturing and its laws on patents.

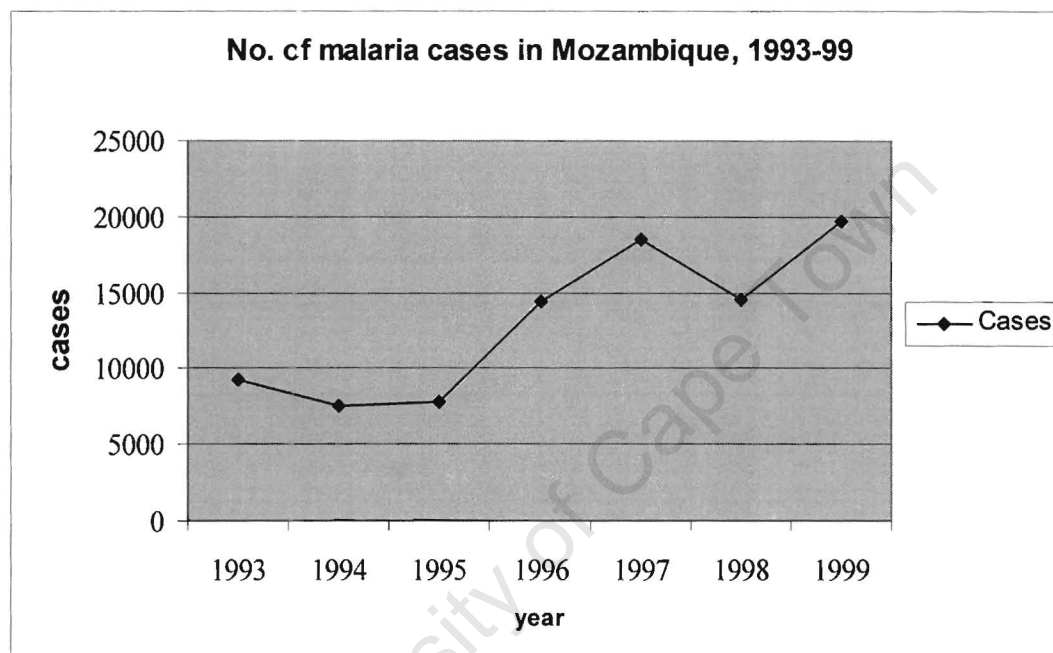
6.2 Malaria in Mozambique

Malaria is a major cause of mortality in Southern Africa. Obtaining reliable data on malaria mortality is very difficult. Misdiagnosis and unrecorded deaths can mean surveillance data can give a misleading picture. However, by using all cause population-based mortality rates and hospital data on the proportion of deaths attributed to malaria, it is possible to calculate broad malaria mortality estimates. Using this method, it is estimated that between 200,000 and 300,000 malaria deaths occur annually in Southern Africa (Demographic Health Survey, 1997).

Qualitative reports as well as surveillance data indicate that malaria deaths are rising in Mozambique. If this is the case, it is due to a combination of factors including late-

treatment seeking behaviour, quality of care, inadequate transport and communication for referral systems to function properly, growing drug resistance and, possibly, HIV. The number of malaria cases reported in hospitals has been on the increase for the past years. The following graph shows us how cases of malaria have not stopped since 1993.

Graph 6.1: Number of malaria cases reported from 1993-98.



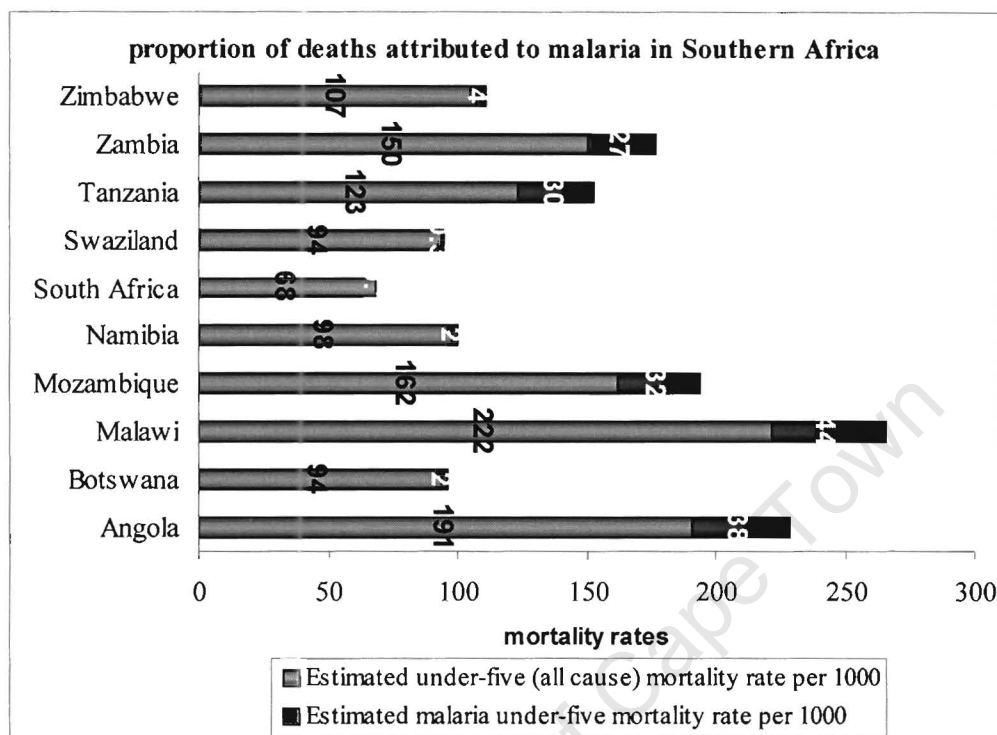
Source: MoH, 1998

It is important to note that this is the hospital annual data and hence it does not reflect the real picture of the situation because, as has been said before it is very hard to obtain the exact figure representing the actual situation; but the trend would only change marginally. The reason behind this is because many people, especially in rural areas do not report their condition, opting to either go for traditional medication or using other measures other than going to the hospital.

The most important risk groups are under-five year olds, pregnant women and travellers who normally reside in unstable or malaria-free areas. Malaria and malaria epidemic is a major public health problem experienced in Mozambique and other countries within the Southern African region. Despite being preventable and curable it

is one of the largest killers in Africa. The following graph illustrates the rate of deaths caused by malaria in Southern Africa.

Graph 6.2: Proportion of deaths attributed to malaria in Southern Africa.



Source: Demographic Health Survey, 1997

These rates are rather high for a disease that has treatment and is preventable. And as has been said before, the under fives are the most vulnerable to this disease. From this graph, the most vulnerable countries are Angola, Malawi, Mozambique and Tanzania, which have a much higher percentage of deaths per 1000 children being caused by malaria. Almost 20% of Mozambique's under- five deaths are attributed to malaria, and this is pretty high for a curable disease.

This evidence shows us that there is a need for drugs that will completely eradicate the malaria epidemic and if anything the TRIPS Agreement should have a positive impact on the availability of these drugs that can help combat this problem. Should there be any slight evidence that this agreement is likely to cause more harm than good for the country then there should not be any two ways about making the decisions of whether or not to comply with the provisions enclosed in the agreement.

There is too much at stake; people's lives, hence this should not be a matter of a test that can be passed or failed.

6.2.1 Anti-malarial drugs in Mozambique

This section will look at the main anti-malarial drugs used in the public sector (Chloroquine and Quinine) in Mozambique, focusing on the resistance to these drugs. Chloroquine is the first line drug treatment in the country.

Antimalarial drug resistance is on the increase and according to the WHO (2000) the latter is the "ability of a parasite strain to survive and/or multiply despite the administration and absorption of a drug given in doses equal to or higher than those usually recommended, but within the limit of tolerance of the subject". The increase in chloroquine resistance in East Africa in general and Mozambique in particular has increased the malaria mortality rates. In Senegal, West Africa, there has been a significant rise in malaria mortality in children under 5 years of age, which highly coincides with the emergence of chloroquine resistance in the area. There has also been an observation of a severe malaria increase as well as chloroquine resistance increase in Malawi and the Democratic Republic of Congo (WHO 2000).

What we must take into consideration though is that Mozambique should not only look at it as resistance to chloroquine but also look at the situation from a broader perspective. It is important to consider the context within which we find this resistance and ask ourselves whether or not there is no possibility that the drugs are not being used adequately or the environment within which we find higher rates of mortality are not surrounded by malnutrition and unpurified water that could worsen the disease at that point in time. This is not to say there is no resistance to chloroquine but it is to encourage the Ministry of Health and other collaborators to resolve the whole problem (which is drug resistance and the environment within which most occurrences take place).

The history of resistance started in 1957. Strains of *P.falciparum* resistant to chloroquine were initially suspected in Thailand way back in 1957 and found in patients in Colombia and Thailand in 1960. Since then, there has been a huge spread of resistance to chloroquine and the situation has only been perverse in South Asia,

South East Asia, Oceania, the Amazon Basin and other Coastal areas of South America. Only in 1979 did Africa start encountering the same problem and this was first documented in Tanzania in 1979 and has become like a plague since then. The World Health Organisation found that in most East African countries and in Ethiopia more than 50% of patients experience a recurrence of parasitaemia with symptoms by the 14th day after treatment. Central and Southern Africa only face moderate levels of resistance and even lower levels are faced in West Africa.

Quinine on the other hand has seen a decreasing sensitivity and this has been shown in areas of South-East Asia where it has been extensively used as the first-line treatment for malaria and in some parts of South America. In Mozambique quinine is mostly used as an injectable for inpatients. Most of this resistance, especially in quinine, could be due to impatience from the patients and when this occurs they tend not to complete the treatment. Strains of *P.falciparum* from Africa are generally highly sensitive to quinine.

By the end of the year 2000, nine countries had changed their antimalarial treatment policies and these are: Botswana, Ethiopia, Kenya, Malawi, South Africa, Uganda, United Republic of Tanzania, Zambia, and Zimbabwe. Burundi, Eritrea, Ghana, Mozambique and Rwanda have started the process of change.

The reason why this study focuses so much in the issue of drug resistance is mainly because the researcher wants to highlight the fact that there is a connection between drug resistance and the need for new drugs. Because Mozambique and the other countries mentioned above, have a high drug resistance in anti-malarial drugs this means that they will at some point need newer drugs to eradicate the problem. As a matter of fact, Mozambique is already looking for the best substitute for its first line therapy (which is chloroquine) and this substitute is likely to be a drug that is under patent since most new drugs are still under patents.

Anti-malarial drugs have become a basic need in Mozambique but if the costs of these drugs are too exorbitant, the problem of both malaria and drug resistance are not likely to be solved. It is because of these high prices that Mozambique prefers to use generic rather than brand-name products. There is an interesting question that comes

to mind when looking at how much drug resistance there is in African countries, and that is, could this mean there has been no research for more effective anti-malarial drugs for the past decades. It looks like this is the case, hence taking us to the conclusion that industrialised countries have no interest in investing their R&D for drugs needed in developing countries but now why so much interest in having the latter countries introduce protection on pharmaceutical products.

Nonetheless, as Mozambique and other African countries embark on the task of analysing alternative drugs for malaria they should critically be aware of the fact that there are regional differences in patterns of antimalarial drug resistance in countries. Policy options therefore should reflect these differences. The decision to change therefore should depend on country circumstances. It is highly acknowledged that the options available to countries for improved anti-malarial treatment policies are limited, especially in regions of highest resource constraints such as Mozambique.

In many instances, the lack of resources has resulted in countries continuing the use of drugs whose effectiveness is limited by drug resistance. This situation brings us to the next section, which will look at the financial situation in Mozambique as far as the pharmaceutical sector is concerned.

6.3 Financing the pharmaceutical sector

According to the MoH (1995) one of the main problems that affect the logistic of medicines in the public sector is the imprecision of the availability of financial resources in foreign currency. This imprecision is due to the extreme dependence on donors, which are not normally known before hand. There are different types of donors in the country and these come at different times of the fiscal year, which does not allow the establishment of a normal cycle of funds.

It has been very difficult to obtain foreign currency to facilitate the importation of drugs in Mozambique. The increased debt and the economic crises in the country resulted in the total dependence of external financing for the importation of drugs. The MoH had no means of financing and distributing drugs. This resulted in a disorganized availability of medication in the sense that donors would provide drug in different quantities and in their own time regardless of the need at the particular

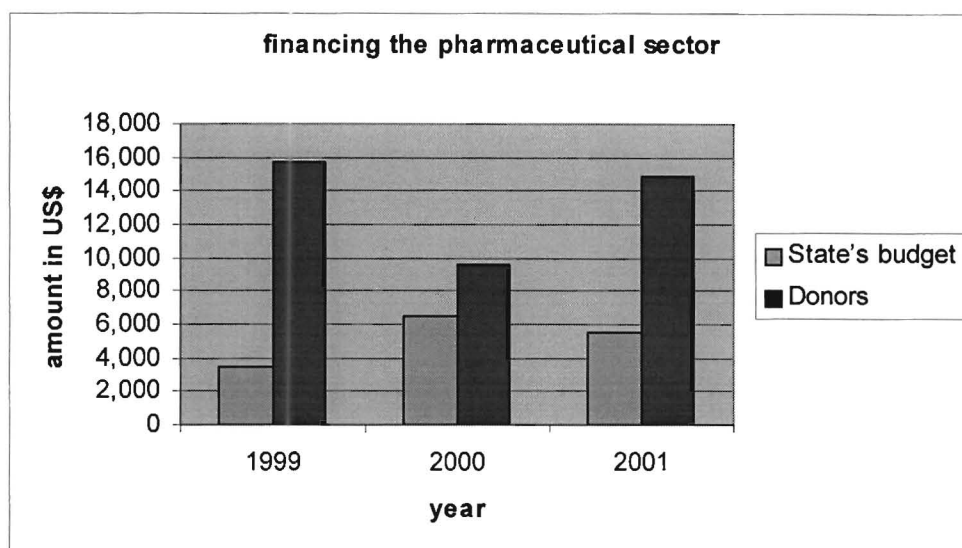
moment. Things started changing gradually when bilateral donors eventually left the responsibility of procurement decision making on the required drugs in the hands of the MoH; their responsibility was to be the donors.

At this moment the only thing that became uncertain was the amount of fund that would come through and when it would come through, that is, in what period it would be available. This case scenario prejudiced mainly the level of primary health care in the sense that there was a limited supply of drugs because there was no money, at least not from the MoH, to import them. The only drugs that were available were only accessible by those that lived in the central areas of Mozambique, leaving the disadvantaged rural dwellers unattained.

In 1995 the MoH together with a number of donors, namely the Swiss Cooperation, Holland and Norwegian embassy, had an intensive discussion about how alternative mechanisms could be found to best finance the pharmaceutical sector. In 1997 there was more uniformity in the ways finances were given and the MoH also had to be responsible in telling the donors in advance about the required drugs. Regardless of this effort from 1996 to 1998 there was still a considerable delay in the availability and utilization of funds, some of these occurrences took place because the MoH did not comply with some of the conditions that came with the finance. The increased dependence on donors is shown in the graph below.

The importance of this graph is to show us that the source of funds in Mozambique is not a stable one hence the pharmaceutical sector cannot be stable because not only does it rely on imported drugs but also relies on unstable sources of finance. The expected amount of funds from the State's budget in 2001 varies in accordance to the particular exchange rate used for the importation. This fluctuation is best shown in the graph.

Graph 6.3 financing the pharmaceutical sector



A very important note from the above graph is the fact that the Mozambican government depends on donors for more than 50% of their funds. In 1999 donors provided 81.8% of the total financing for the pharmaceutical sector and in 2001 they financed 72.9%. In 2000 although we can see a drop in funds it is still above 50% (59.7% to be precise). This shows us the dependency on external financing from the Mozambican part.

The following table shows us the extent of total expenditure on the pharmaceutical sector, which depends on the finances received in a particular year.

Table 6.3: extent of total expenditure on the pharmaceutical sector for the past 3 years

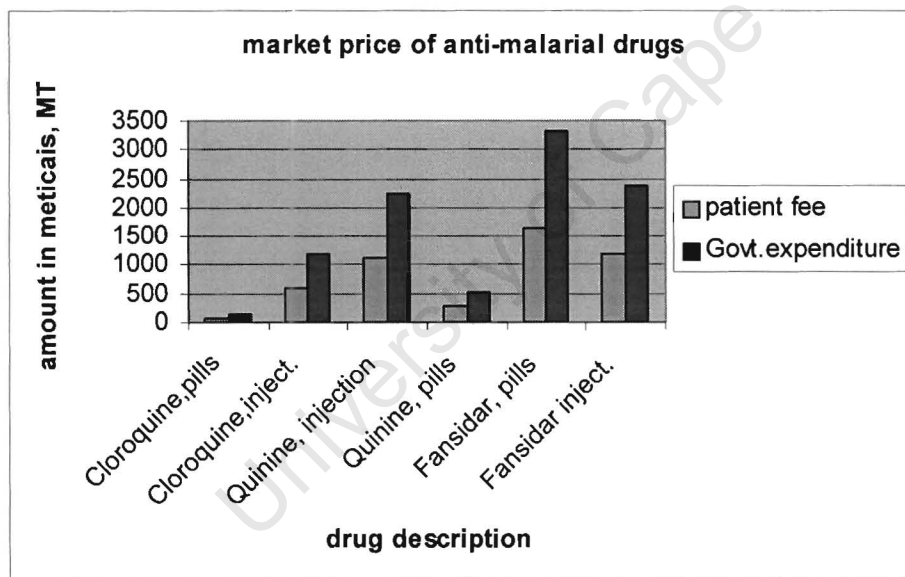
CATEGORY	COST (US\$) 1999	COST (US\$) 2000	COST (US\$) 2001
Medicines	14,896	8,198	12,008
Curgical material	1,961	1,627	3,774
Oral health	0	332	231
Injections	0	1,297	1,358
Blood bank	0	994	292
X-ray material	0	289	203
Chemicals	1,820	3,195	2,052
Lab. Materials	0	83	–
Others	463	16	516
TOTAL	19,140	16,031	20,434

As we can see from the above table, the pharmaceutical sector spends according to the funds they receive; the only alterations that take place are where the money goes to, in terms of the different categories. The latter probably depends on what is needed the most at the particular time when funds are disbursed.

6.4 Market prices of anti-malarial drugs

In the public sector prices for antimalarial drugs are highly subsidized hence for this study the most important figure will be what government spends on the purchase of these drugs, other than the costs incurred by consumers; which are almost insignificant. As far as the consumers are concerned their main preoccupation lies within the availability of the drug rather than its price because the government provides for these at very low prices as compared to what they pay for it in real terms.

Graph 6.4: Price list of drugs in public hospitals, 2001



Source: Ministry of Health-medical center, 1999

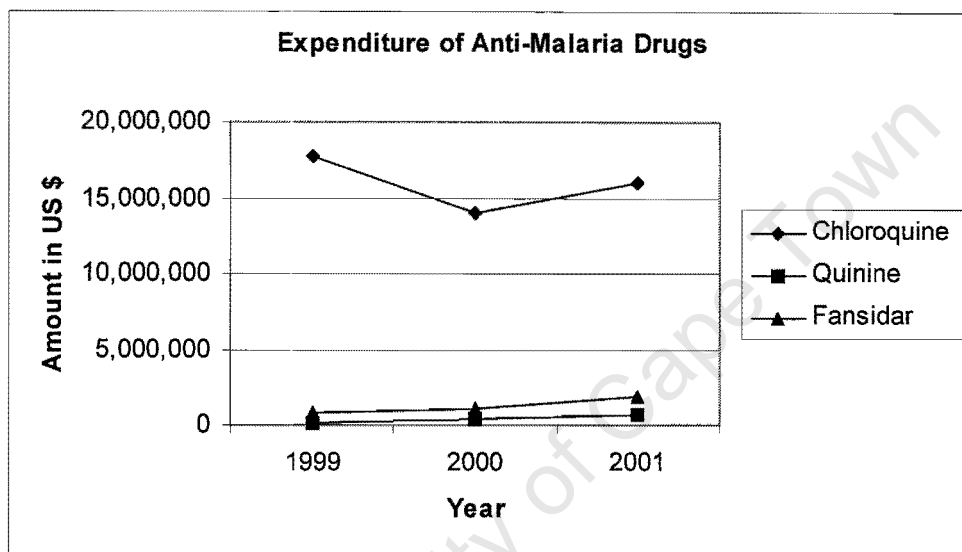
Prices only change marginally. Actually, the only price difference in the past years is the exchange rate and inflation and if we incorporate the exchange rate we would notice that the price gets lower and lower every year.

In general, all drugs are subsidized in government/public sector hospitals and pharmacies. There is 50% subsidization because looking at the figures above anti-malarial drugs are practically offered to the public because they only pay a significant

amount for these drugs. But what must be noted is that if an individual gets a prescription from the private sector he/she is not entitled to purchasing those drugs from the public sector. This is done so as to ensure that those that cannot afford expensive drugs do not end up without them in the public sector.

The price paid by government on the purchase of antimalarial drugs is shown in the graph below:

Graph 6.5: Government expenditure on anti-malarial drugs:



As is shown in the graph, there is more money spent on the purchase of chloroquine, as this is the first-line drug treatment used in the country, particularly the public sector. Although quinine and fansidar are down the graph (probably because they are not used as much as chloroquine, hence not purchased in large amounts), they still show an increasing trend from 1999 to 2001. In 1999 government spent less on the purchase of the first line therapy, probably due to exchange rate difference or probably caused by a decrease in the incidence of malaria but in 2000 the expense went back up. All these drugs are imported from abroad, as there is no local production of anti-malarial drugs. The next section gives us more details on this issue.

6.5 Generic pharmaceutical companies

It is important to note that there are no anti-malarial drugs produced locally; all drugs used for the cure of malaria are imported and they are all generic drugs, at least for

public provision. In fact, there are only two drug manufacturers and these are private owned but also supply public institutes. These drug manufacturers only produce anaesthetics and painkillers and even so, they are very insignificant, as they do not export them. There are thirty-three companies of importation in the whole country, and most of them are either Portuguese or Indian owned. The public sector highly relies on generic drugs and the private sector imports both original and generics. The level of parallel importation depends on competition and the Mozambican government buys from companies that offer the lowest price and quality.

For many years at least until 1998, MEDIMOC was the only importer with authorization for the purchase of drugs in the country. This was due to the fact that the MoH lacked the capacity to provide for their NHS. The pharmaceutical department keeps all the information about the annual needs of stocks and updates these periodically. MEDIMOC assumed the responsibility for the central and regional storage functions while the MoH was responsible for provincial and district storage functions. Because storage facilities are generally in poor conditions and scattered, especially in Maputo, this contributes to problems of stock management and control.

In 1998 the pharmaceutical industry saw a significant increase in the number of private pharmacies. The number of pharmacies increased from 75 to 133 and the number of import companies increased from 1 to 29 but all in all in 2000 only 19 of these companies started operating. There has been an overall growth of 77% among the existing pharmacies in the country from 1997 to 2000.

The increase in pharmacies could mean an increase in the demand for drugs and because there is no local production this means there is an increase in the demand for imported drugs. If this is the case then Mozambique should critically analyze how the introduction of patents is likely to affect pharmacies in terms of high drug prices and if drugs are highly priced only a small number of the population is likely to use those drugs, especially because the demand for drugs depends on the finance available. Price is a critical issue for the accessibility of drugs in Mozambique hence the country's health officials should ensure that if there is any increase in prices due to the TRIPS Agreement, it should be a marginal increment; but the question is, would that be possible.

6.6 Drug Registration

The current drug registration system has been in place since 1999 only, hence its implementation only started last year. Before this registration policy Mozambique had no control of entry of drugs, which means there was increased importation of drugs even those that are inefficient. The legislation 4/98 passed on the 14th January established a new judicial basis regarding the medication and the practice of the pharmaceutical profession. According to this new legal basis the registration of medicines was made compulsory for their introduction and trade within the country. Decree 22/99 approved the regulation for registration on the 4th of May. This law makes provision for two types of drug registration:

- (i) Extraordinary
- (ii) Definitive

The extraordinary type of registration is a simple process of notification of the medicines existing in the market, which has to be done by licensed traders. This type of registration has a validity of three years but offers no right of extension or exclusiveness. The definitive type on the other hand is a normal process of registration of drugs, which should be complied with to acquire the authorisation for the introduction of drugs into the market. This type of registration has a validity of five years, has exclusivity and is renewable once approved.

Only registered companies can apply for the registration of drugs in Mozambique. These companies should also have headquarters in Mozambique with specification on the name of drug, its pharmaceutical form, its quantitative and qualitative composition of active components, as well as the manufacturer.

6.7 Likely effect for anti-malarial drugs

Having looked at the situation in Mozambique with regards to its drug policies and financing of the pharmaceutical sector there is only one way of analysing the likely effect of this agreement on anti-malarial drugs. Depending on the way in which the TRIPS agreement is used, this could have a positive impact in some cases and a negative impact in others. This will be done through the analysis of different scenarios. The first case scenario will be that of the use of generic drugs, which is basically the present situation. The second case scenario will be that of the use of patented drugs after the implementation of TRIPS.

Although this paper is only looking at the public sector, it should be noted that changing the first-line drug in the public sector alone might not have a substantial impact. According to WHO (2000) the role of the private sector is crucial in ensuring that drug distribution systems reflect public health policy and that the recommended treatment is available through all types of health care outlets used by the population. The common anti-malarial drugs that should be considered in drug selection, as suggested by the WHO are many and varied and these should vary according to country cases; there is no uniformity in the selection of a drug policy:

Here are some of the suggested drugs to be selected from; these have been randomly selected from the existing list.

Single therapy

- (i) SP-sulfadoxine-pyrimethamine
- (ii) ASU-artesunate
- (iii) MQ-mefloquine
- (iv) HAL-halofantrine
- (v) R-coartem

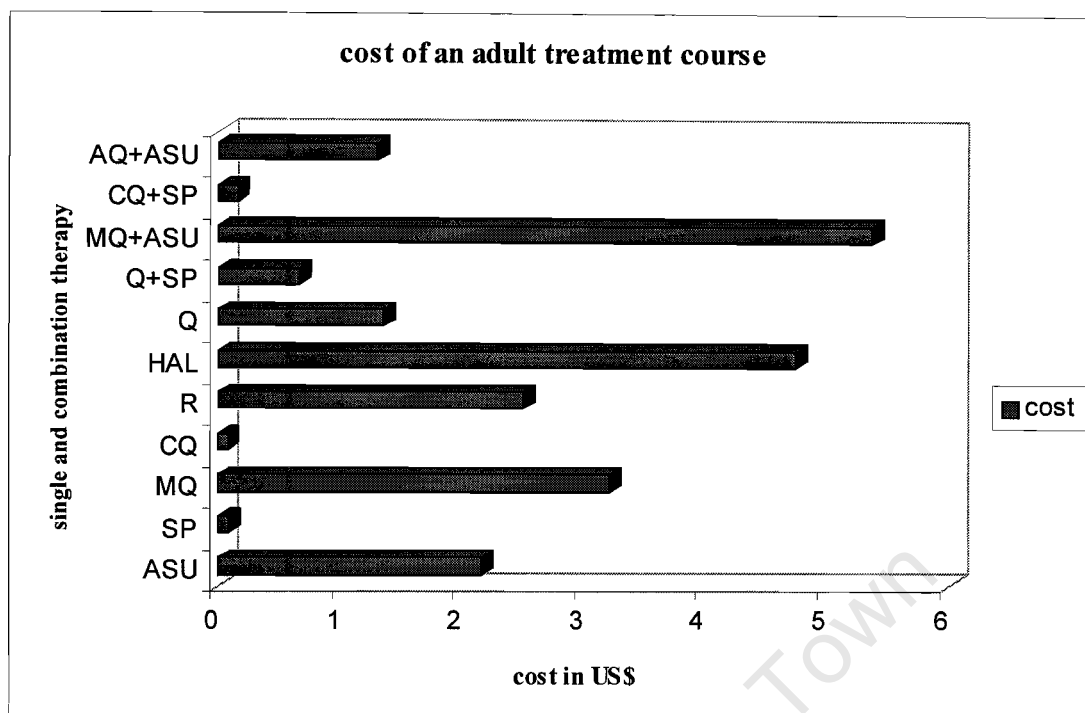
Combination therapy

- (i) Q+SP-quinine+ sulfadoxine-pyrimethamine
- (ii) CQ+SP-chloroquine+sulfadoxine-pyrimethamine
- (iii) MQ+ASU-mefloquine+artesunate
- (iv) AQ+ASU-amodiaquine+artesunate

The current situation is whereby Mozambique is using CQ as its first-line therapy and Q as a second line-therapy for severe cases of malaria. These drugs are generic medicines hence have very low prices. Some pharmacies provide for SP and AQ as well and these are also generics. These are not affected by patent issues hence there cannot be an impact, be it positive or negative, from the TRIPS agreement.

The second situation is whereby after the implementation of TRIPS Mozambique is obliged to purchase drugs that are under patents, such as HAL and R, there will be a problem because these drugs are priced more than twice as high as CQ. These situations can be best described in the **graph below**.

Graph 6.7: Costs of generic vs patented anti-malarial drugs



It is more than evident from this graph that the cost of drugs more than doubles in the case of patented drugs as compared to generics, especially as compared to the first-line therapy currently used in Mozambique (CQ). The government will have to increase their expenditure on anti-malarial drugs after the implementation of the TRIPS agreement.

Because of the continued increase of resistance to anti-malarial drugs in many regions of the world, with the resultant effect on morbidity and mortality, it is essential to ensure rational use of the few remaining effective drugs, to maximise their useful therapeutic life while still ensuring that safe, effective and affordable treatment is accessible to those at risk. This requirement has resulted in a re-examination of the potential of combinations of existing products and the development of new combination drugs. One of the factors against combination therapies is the fact that they incur higher costs.

As we can see in the graph above, although the cost of a combination therapy is not as high as patented drugs (except for the patented combination therapy-MQ+ASU) it is still more than twice as expensive as the single therapy. Mozambique therefore has to

deal with the cost of a combination therapy first before having enough funds to finance patented drugs. This situation does not only reduce access but also causes a significant increase in government expenditure for drugs. Although there is a possibility that prices may lower as demand increases, these will never be priced as low as CQ and SP.

It should not be excluded though that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health; therefore TRIPS should not prevent Mozambique from using generic versions of patented medicines for the treatment of malaria. Even for cases of R and HAL, which are patented, there have been some negotiations between WHO and some manufacturing companies of these drugs to introduce a preferential pricing arrangement for an adult treatment course to be priced lower than would have been otherwise. Even if this is the case, countries like Mozambique that have resource constraints will still lack the funds to finance these drugs because this reduction of cost will still be high in terms of what is spent now.

This case still brings another situation, which is that of the reluctance of manufacturing such drugs, since they do not generate income for these companies. The incentive to invest in anti-malarial drugs therefore decreases and this means the situation in Mozambique and other Southern African countries suffering from this disease will continue. Many of the medicines created for the developed countries markets are equally important for developing countries. However, developing countries clearly have different drug demands than developed countries (Lanjouw, 2001). Developed countries do not for instance, demand so much drugs for tropical diseases and developing countries do not for example, so much demand drugs for heart diseases; at least not as much as their counterparts.

The diseases of the poor attract very little R&D efforts by the large pharmaceutical industry, since they do not promise to generate income. R&D is driven by market considerations. According to Correa, R&D targeting diseases found in developing countries is marginal. For instance, according to the UNDP (1999), of the annual health related research and development worldwide, only 0.2% goes for pneumonia, diarrhoeal diseases and tuberculosis; yet these account for 18% of the global disease

burden. It is important therefore to realise that the pharmaceutical industry may not be expected in real life, to distribute a lot of money in areas where their profits are low even if strong patents were granted.

There is no visible increase in R&D for diseases such as malaria, despite the fact that most developing countries already grant product patents for pharmaceuticals and those that have not are still bound to do so. Although these industries are an essential part of the solution to health problems in developing countries this is still not the main instrument to bring the new medicines needed for the devastating diseases that affect the poor. Therefore, strong patent protection may be of little relevance for the solution of the dramatic problems of poor people in the developing world.

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DISCUSSION AND CONCLUSION

7.0 Discussion

This discussion is an evaluation of the extent to which the research objectives have been realized. The chapter outlines the general conclusions derived from the study.

At the current moment, producers with the ability and willingness to supply the world market with low-price medicines under patent in developed countries are principally located in developing countries, such as Brazil, China and India. These countries' producers have the ability to manufacture under local law in compliance with TRIPS because pharmaceuticals were not yet patentable until recently. Countries like Mozambique that do not provide patent protection for pharmaceutical products are currently allowed under TRIPS to import low-price medicines from Brazil, China and India because there is no TRIPS authorized export or import restriction.

But the United States and other Members are pressuring developing Members to accelerate the adoption of patent protection on pharmaceutical products. These countries obviously promote the adoption of strong patent protection, and discourage an extension of transition timetables. The arguments that they put forward are the same as those we saw in the theoretical review of the justification for intellectual property in chapter 2. They persistently argue that patents encourage research and development on new pharmaceuticals; strong patents encourage FDI, and promote revelation of technical information. The argument to support the latter does not change *'if an innovator cannot use the innovation to provide a market advantage, there is a disincentive to enter the market, especially where others in that market can charge lower prices because they do not need to recover the costs of R&D, nor invest in new research and development'*.

But for a country like Mozambique, where is the gain of revealing technical information? How can a country without the capacity and infrastructural ability to manufacture drugs gain from such strong regimes of patent protection. They have nothing to protect in the pharmaceutical area hence there is no clear vision as to how

such benefits mentioned above will occur to them. This country has relied on the importation of drugs for a very long time and such a change, although not clearly obvious now, is not likely to bring any fruitful gains for this country. Mozambique does not have the human, financial, let alone intellectual resources to produce pharmaceutical products of immediate need for their most persevering diseases. Full drug development is expensive and currently unrealistic for Mozambique; the latter is not research-based. As we have seen in the last chapter, this country relies heavily on others for financial resources and material resources hence if there is any changes that should be done it has to be done in light steps and not drastically.

Although Article 29 of the TRIPS Agreement states that an innovator must disclose all the technical details of the invention with the intention of encouraging the flow of information to the public, including competing manufacturers, this is unlikely to benefit a country like Mozambique in the nearest long run. Mozambique is still steps behind with regards to technological advances that would enable them to put this information into good use. What the country needs is to know that they can get drugs at a reasonable price instead of means of producing those drugs because that would mean also getting human and capital resources to do it.

According to Maskus (2000) "it is demonstrable that as countries reach higher levels of economic development they tend to adopt stronger patent protection but this does not demonstrate a causal link between patents and invention". This may indicate that as countries reach higher levels of economic development their tendency is to shift the allocation of capital toward the development of new technologies and that as capital is shifted into R&D, investors seek to protect their capital investments with patents.

The TRIPS Agreement does not particularly promote the affordability of medicines, other than by allowing Members to grant compulsory licenses when prices charges by patent holders are too high, by permitting the authorization of parallel importation and by recognizing the right of Members to enforce competition law, such as price control measures (but this does not assure that drugs will be made available). But regardless of this, technology-dominating countries like the United States have threatened trade sanctions against WTO Members when they propose to grant compulsory licenses or authorize parallel importation. But given the small share of the market in developing

countries, it is likely that developed countries are doing this because they are more concerned about the spill over effects of these measures to industrialized countries. It is for this reason that developed countries attempt to make the use of these policy instruments as difficult as possible.

In the case of anti-malarial drugs for instance, where the WHO is negotiating a deal with manufacturers to provide the medicine at a reasonable price, what is likely to be unavoidable is a situation whereby manufacturers stop researching and investing in this type of drug because it does not render them profits if they have to provide them at a non-competitive price. Therefore, whichever way you look at it there is likely to be a disadvantage for developing countries like Mozambique.

According to the UNDP “in defining research agendas, money talks louder than need—cosmetic drugs come higher on the list than a vaccine against malaria. Tighter control of innovation in the hands of multinational corporations ignores the needs of millions. From new drugs to better seeds for food crops, the best of the new technologies are designed and priced for those who can pay. For poor people, the technological progress remains far out of reach”, (UNDP, 1999:68).

Also, the pharmaceutical industry has not, in the last 2 decades, suffered from any provable shortage of funds for R&D. For all these years pharmaceutical companies have invested a high percentage of its sales in R&D, and was one of the most profitable sectors in industrialized countries, mainly the United States. All along this was possible despite the fact that a large number of developing countries (including those with the largest pharmaceutical markets, such as Argentina, Brazil, Egypt, India and Mexico) did not grant product patent protection at all during that period, or only introduced it during the 1990s.

So, the question running through our minds is why it is so important now for developing countries to introduce patent protection. It may well be the case that the cost of R&D has gone up maybe because of new possibilities or it becomes more difficult to develop new products. But the rate of innovation (measured by the development of new chemical entities) is said to have decreased since the 1990s (Correa, 2001). Now that all countries are obliged to recognize pharmaceutical

patents, these firms will be able to generate patent-based income almost universally, since basically the whole world is contributing or will soon contribute to their R&D budgets and profits.

Even though the TRIPS Agreement allows countries to grant compulsory licenses for medicines under patent, no developing WTO Member has yet done it. It would be a good idea for developing countries to find out and address the reasons for this. One reason is similar to the one above, whereby governments may fear that potential foreign direct investors will react negatively to an environment in which compulsory licensing is allowed. Another reason could be due to the threat posed by the United States and European Union to Members that show intentions of applying for a compulsory license. Besides all that, there are administrative procedures involved in issuing compulsory licenses and these can be rather bureaucratic and not very easy to manage, that is of course for those countries that have already established such licenses and this is not the case for Mozambique. Although they have all the intentions of making use of these, just the process of getting it started will be problematic.

What we should not forget is the fact that a developed or developing WTO Member applying only Article 31 of the TRIPS Agreement, as the basis for granting a compulsory license for export or medicines would face a potential conflict with the express text of Article 31(f). This leads to a contradiction. The WTO Members that are able to take advantage of the compulsory licensing provisions of the TRIPS Agreement to supply essential medicines are the countries with the capacity to manufacture medicines under patent, and this may exclude the countries most in need of medicines from taking advantage of compulsory licensing. Mozambique does not fall into that category.

The purpose of allowing WTO Members to grant compulsory licenses is to allow them to put public interests before private interests when the need arises. If developing countries' Members are not allowed from addressing public interests because of lack of local manufacturing capacity, the purpose of the Agreement in general and Article 31, in particular is in vain; which is a contradiction to the whole objective of this Agreement because this means the well off Members would be able

to take advantage of its public interest but its least well off would not. Also, it is hard to understand why developed countries negatively view the grant of compulsory license and parallel imports because these are unlikely to threaten the long-term viability of drug R&D. This is because developed countries' markets already provide a large amount of resources for R&D, and the pharmaceutical firms have had large sales in many developing countries, including the largest markets, even in the absence of patent protection. The contribution to R&D that could be made by some developing countries is insignificant in global terms. Africa for instance only accounts for around 1.3% of world pharmaceutical sales (Correa, *ibid*).

And as a matter of fact it is hard to understand why developing countries that are not producing drugs should adopt strong patent protection when in actual fact the pharmaceutical industry in the developed countries has devoted very limited/insignificant attention to diseases that are highly prevalent in the developing countries, malaria for instance. Additionally, there is nothing in the TRIPS Agreement that obliges this industry to use the increased patent profits gained from developing countries for research on diseases like malaria, prevalent in those less fortunate countries.

According to Abbott (*ibid*) there is no public interest constraint imposed on the pharmaceutical companies with respect to the increased profits that will be made from patents extended by the developing WTO Members. There is nothing preventing the increased income from being spent on R&D for lifestyle drugs that appeal mainly for OECD consumers. In the author's words "the pharmaceutical industry is the beneficiary of an extremely valuable public policy instrument- the TRIPS Agreement- and has not been made accountable for its use of the benefits. It is important to note that the role of patent protection in a country will be different depending on a number of factors, including the level of economic development, capacity for innovation and local market size; therefore to apply a one size fits all approach to patents does not make economic, political, moral nor ethical sense.

Despite the fact that strengthened patent protection for pharmaceutical products may at some point in the future provide benefits to developing, there is no sound empirical basis for developed countries to demand immediate introduction of such protection by

developing countries. As is shown in the previous chapter, Mozambique relies heavily on importing anti-malarial drugs and there is no company manufacturing these drugs at the present moment. Therefore there is no possibility even in the nearest long run for this country to develop a new drug for which patent protection might be useful, as a general suggestion Mozambique has no reason to provide patent protection for pharmaceutical products other than to pay higher prices to OECD-based pharmaceutical companies. OECD-based companies do not generally invest in diseases principally affecting countries like Mozambique, such that higher prices paid for drugs will benefit these countries in a very remote way. The likely result of introducing patents on pharmaceuticals in Mozambique will be to reduce the number of individuals who can afford to buy them because government as the main provider will not have sufficient funds to import all the needed drugs.

According to Correa (2001) the public sector contributes significantly to pharmaceutical research, including the discovery and/or development of many important drugs. The public sector role is not substantially dependant on the availability of IPRs. For many university inventions, for instance, that were funded with public monies the results of research would be published in any case. Firms in many cases would have the incentive to work with and develop what comes out of university research. They usually can patent the developments, or gain the advantage of a head start on the market, or both. No ex-ante grant of an exclusive license is needed to motivate this work. Traditionally the award of the patent has come after something useful has been achieved, rather than well before that stage. Conclusively, a significant part of pharmaceutical R&D is not directly dependant on the availability of IPRs, since invention undertaken by public laboratories would take place in any case. But this is not to say manufacturing companies do not face substantial costs to commercialize academic research.

In terms of pricing, according to Gollin (2001) to address the problem of access to medicine in poor countries, it is necessary to address the pricing of the medicines and this is where differential pricing comes into play to rescue these countries. He argues that there are many approaches to bring prices down, for instance in the case of HIV/AIDS, malaria, tuberculosis, and vaccines. In the case of HIV/AIDS, a generic

company (Cipla) offered to provide triple therapy for these patients for less than \$600 per year, and an innovator company reduced its prices even lower than that.

What the author is trying to put into argument here is the fact that price is a highly negotiable and negotiated term in any transaction, whether between private enterprises or between private company and a government regulator. In Gollin's words, "as a negotiated term, pricing is subject to bargaining power, and the more bargaining power that poor countries have, the lower a price they will be able to negotiate". This means that tools like compulsory licenses and the expansion of generic manufacturing, as well as negotiations with original manufacturers can help bring down the price of drugs in poor countries.

7.1 Recommendations

In light of the existing situation, no developing country that wishes to have access to low price medicines under patent elsewhere should provide patent protection for pharmaceuticals. But this might have some externalities for both the pharmaceutical sector and other business sectors; for instance the likely side effects might be in the form of trade-restrictions. The TRIPS council should be directed to undertake an objective in depth study, in cooperation with the World Health Organization, of the effects of the TRIPS Agreement on the prices of pharmaceuticals, the identity of the beneficiaries of pharmaceutical patent protection, and the level and direction of research by those beneficiaries.

The TRIPS Agreement should address the issues of compulsory licensing more transparently whereby there is no situation where commercial investors are at more advantage than public health concerns. It should be clear that commercial investors recognize the risks posed by public health threats such as malaria, and should not see a compulsory license given to redress such a crisis as evidence of a risk to general commercial investment. There is a need to overcome any kind of obstacles that makes the granting of compulsory license to address public health crises fast and cheap. Developing countries should get together and seek a firm commitment with drug manufacturers that no Member should be penalized for granting a compulsory license.

It looks like not much can be done with regards to the strengthening of patents hence given this fact compulsory licenses might be the only way out for developing countries. Even developing countries that are currently capacitated to export off-patented drugs will lose that capacity with regards to newly developed patented drugs. When this happens, affordable access to on-patent drugs in developing countries will become highly dependent on compulsory licensing.

If the prices of drugs offered by patent holders are too high relief will be sought through the issuance of compulsory licenses. It does not look like Mozambique can do much on its own in terms of solving the problem that is foreseen after implementing the TRIPS Agreement. There is a need for SADC countries to negotiate collectively in order to increase bargaining power. It seems fundamental for developing countries to establish a joint position; a position founded on the demand for a balance of rights. These countries might join together to work on the recognition of patents. Through a co-operative venture, patents could be examined and not accepted blindly on the word of the US or EU as to their satisfaction. In addition, SADC could pool its resources to deal with trade law, patents, and the complicated legal cases that are still to come in the near future.

Even though it is impossible to explicitly quantify the serious implications for the pharmaceutical sector in general, and anti-malarial drugs in particular, it is essential that everyone involved in this sector should understand what is at stake. The Mozambican national drugs policies should define strategies and guidelines today for the new regulations on patents. Governments and international organizations must engage in dialogues regarding trade agreements and health care technologies. Maybe national governments should be included in WTO consultations that have a direct bearing on health, such as the TRIPS Agreement.

7.2 Conclusion

The future development of new drugs is in the hands of the pharmaceutical industry but some assumptions made with regard to pharmaceutical R&D and the patent system need to be looked at objectively. It seems quite evident that commercially driven R&D organizations are unlikely to provide solutions for the diseases that mainly affect countries like Mozambique. Mozambique is on the verge of providing

compulsory licenses and parallel imports in its national law as a mechanism to lessen the market power given to patent owners. The use of these safeguards may make it easier for Mozambique to have access to patented drugs and to generics after the expiration of the relevant patents. There is no conclusive evidence that this measure will cause any harm to the funding of future R&D let alone affect the global R&D as a whole.

According to Correa most of the R&D made by large pharmaceutical companies is not for the development of new drugs but is for substitutes to competitor's drugs with the intention of extending their monopolistic position that patents give them. And if the commercial interests of the patent owner are the only ones taken into consideration then the intended objectives of the Agreement is defeated. But this is only a problem where minor changes of new drugs are accepted for patents and in most cases they are not.

The TRIPS Agreement must be seen as a way in which public health can be achieved through the incentive to innovate. In other words, the objectives of the patent system cannot be fulfilled if it only serves to make innovation that will benefit those who control the innovations. In Abbott's words "the TRIPS Agreement is not only about protecting pharmaceutical industry profits; it is also about the health of the global economy, and about the health of individuals".

If the Agreement is to benefit countries like Mozambique then it should abide by its objectives and purpose, which are clearly stated in Article 7 "*the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge*". Conclusively, any opinion on this matter should be assessed critically because this is a very sensitive issue that may significantly influence future developments in the area of intellectual property.

The way developed countries have been advantaged from the issue of TRIPS in general and IPRs in particular is like having Manchester United playing against a soccer team that has a few good players — and others who have never played the game.

7.3 Suggestions for further research

As shown in the first chapter, there were certain constraints that limited the study in terms of sample size and composition. As we saw the study was restricted to the public sector only but we all know that the impact of TRIPS will fall under the country as a whole and hence will not only be felt by the government and its Health Ministry. For such reasons therefore it is important for a broader study to be carried out, on a much wider scale with full coverage of the country. Such a study will help generalize the conclusions, without being too reliant on assumptions.

Also, this study was only looking at the case of anti-malarial drugs, which could lead to a biased conclusion with regards to the impact of the TRIPS Agreement because most of these drugs are generics and those that are not are still under negotiation with different drug companies hence the case of malaria can still be solved without being much affected by patents. What would be more challenging would be to study the potential impact of TRIPS in the pharmaceutical industry as a whole, all drugs coming into the country involved.

As a matter of fact, the whole analysis of the implications of the TRIPS Agreement for the pharmaceutical industry in Mozambique is merely the starting point for a continuing process. Ongoing changes in the structure of the economy, regulations, patent laws and a number of other factors mean that further study will be needed. The provisions of TRIPS with relation to patentability, the effects of protection or term os patents, transitional period arrangements, compulsory licensing and parallel importation will need further review.

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APPENDIX I

QUESTIONNAIRE

SECTION 1: WTO/TRIPS IN MOZAMBIQUE

1. Has Mozambique started implementing the TRIPS agreement?

Yes _____ No _____

a) If yes, when was it first implemented?

b) if not, when will it be implemented?

c) if not, what is being planned?

d) Have there been any obstacles?

2. What provisions of the TRIPS agreement are incorporated into the national legislation?

3. What national priorities and policies does the proposed implementation take into account?

4. Are there policy instruments outside the intellectual property rights that are used to address issues of prices of anti-malarial drugs e.g price controls?

5. What are the TRIPS safeguards that are provided for under the agreement that the government has adopted or intends to adopt and how are these safeguards being utilised or how will they be utilised, e.g. compulsory licence?

6. What is the current policy situation with regard to parallel importation?

7. How could the exemption criteria be used in Mozambique?

8. What is the future of the WTO/TRIPS agreement in Mozambique?

9. What rules existed before TRIPS in relation to intellectual property?

10. Is this change likely to affect the pharmaceutical industry (opinion)?

SECTION 2: PATENT LAWS

1. When was the patent law introduced in Mozambique?

a) Has this law been amended since then?

b) If yes, why?

2. Are there any antimalarial drugs that are locally produced that are under patents

3. What are the measures that the pharmaceutical patent authorities have put in place to monitor prices of drugs, especially antimalarial drugs?

4. Does the patent law make provisions for parallel importation and compulsory licences?

SECTION 3: THE HEALTH SECTOR

1. What is the situation analysis in Mozambique with regards to the pharmaceutical sector?
2. How are anti-malarial drugs financed in the country, e.g taxes, premiums, user fees, etc.?
3. How does the drug financing differ between private and the public sector?
4. What are the criteria for subsidization of the anti-malarial drugs provided in this country?
5. What is the drug registration policy?
6. What is the extent of the total expenditure on the pharmaceutical sector?
7. What is the extent of total expenditure for generic anti-malarial drugs?
8. Are there any anti-malarial drugs produced locally?
9. How much does the health sector spend on patented anti-malarial drugs?
10. What is the extent of parallel importation?
11. What is the market price of anti-malarial drugs in the public sector?
12. Any comments about the implementation of this policy?