The Political Economy of the Intellectual Property Rights Regime: Aids and the Generic Medicine Debate in South Africa

Juan Bester

Thesis presented in partial fulfilment of the requirements for the degree of Master of Arts (International Studies) at the University of Stellenbosch.

Mr. A.J. Leysens

March 2002

Declaration

I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

Abstract

This thesis is a descriptive and interpretive study into the political economy of intellectual property rights, the conceptual and practical implications for the phenomenon of global governance, and how developing countries experience problems with the implementation of national policies that infringe on international intellectual property rights. The specific area of interest is the generic medicine debate that ensued in South Africa after the alleged violation of patent rights of anti-HIV/Aids drugs by the Department of Health.

The research question that is addressed is to what extent has the existing international intellectual property rights regime been influenced and/or undermined by South Africa's intended application of WTO regulations in terms of compulsory licensing and parallel imports of "essential" medicines. In doing so, the paper examines the roles of the important states, international organisations, institutions, and private sector firms within the sphere of the political economy of intellectual property and how they impede upon or improve the functioning of the intellectual property rights regime.

The methodology entails analytical inquiries into documentary evidence on the nature of the international intellectual property rights regime. Areas that are examined are the agendas of the important actors, namely states and their respective departments; individuals and firms; and international organisations. The concept of intellectual property is examined to determine its dynamic role within the generic medicine debate.

The thesis concludes that the agendas of pharmaceutical firms and states are exploiting current political stalemates in the negotiations for a fair intellectual property rights regime. National health agencies, and specifically the South African Department of Health, are under enormous pressure to provide affordable health services. Specifically, the US Government and US pharmaceutical firms are dominating discussions on the architecture of the international intellectual property law regime. By using an analysis incorporating systemic, domestic interest, institutional, and ideational perspectives, it is argued that South Africa's drive for a more distributive intellectual property rights regime has placed the issue of health, Aids and generic medicine firmly within the sphere of the political economy of trade agreements.

Opsomming

Hierdie tesis is 'n deskriptiewe en 'n interpretiewe studie oor die politieke ekonomie van intellektuele eiendomsregte, die konseptuele en praktiese implikasies vir die verskynsel van globale regering, en hoe ontwikkelende lande probleme ervaar met die implimentering van nasionale beleid wat internasionale intellektuele eiendomsregte aantas. Die spesifieke area van belang is die generiese medisyne debat wat onstaan het na die beweerde skending van patentregte van anti-HIV/Vigs medisyne deur die Departement van Gesondheid.

Die navorsingsvraag wat beantwoord word behels die omvang van die impak van Suid-Afrika se voorgenome toepassing van WTO bepalinge, met betrekking tot die verpligte lisensiering en parallelle invoer van "essensiele" medisyne, op die bestaande internasionale intellektuele eiedomsreg regime. Hierdie tesis ondersoek vervolgens die rol van state, internasionale organisasies, instellings, en privaat sector firmas binne die sfeer van die politieke ekonomie van intellektuele eiendom en hoe hulle afsonderlik die funksionaliteit van die intellektuele eiendomsregte regime beïnvloed.

Die metodologie behels 'n analitiese ondersoek van die literatuur oor die aard van internasionale intellektuele eiendomsreg regimes. Areas wat ondersoek word, is die agendas van belangrike akteurs, naamlik die staat en sy onderskeie departemente; individue en firmas; asook internasionale organisasies en instellings. Die konsep van intellektuele eiendom word ondersoek om die dinamiese uitwerking daarvan op die generiese medisyne debat te verstaan.

Hierdie tesis voer aan dat die agendas van firmas, spesifiek farmaseutiese firmas en state die huidige politieke dooiepunt in die onderhandeling rondom 'n regverdige intellektuele iendomsregte-regime, uitbuit. Nasionale instellings, soos die Suid-Afrikaanse Departement van Gesondheid, is onder groot druk om bekostigbare gesondheidsdienste te lewer. Die VSA en farmaseutiese firmas domineer onderhandelinge vir 'n nuwe struktuur vir die internasionale eiendomsregte-regime. Deur gebruik te maak van 'n analitiese raamwerk wat sistemiese, interne belange, institusionele, en ideologies perspektiewe inkorporeer, word daar geargumenteer dat Suid-Afrika se pogings om 'n meer distributiewe intellektuele eiendomsregte regime te verseker, die probleem van

gesondheid, Vigs, en generiese medisyne binnne die sfeer van die politieke ekonomie van handelsooreenkomste, plaas.

CONTENTS

Aknowledgements

I would like to thank the following people for their share in this thesis:

- my parents for their continued support and love,
- Mr. Leysens, my supervisor, for his proffesional and friendly help,
- and Quentin for his moral support.

LIST OF TERMS USED IN TEXT

GATT	-	General Agreement on Trades and Tariffs
GEAR	-	Growth, Employment, and Redistribution (Act)
IP	-	Intellectual Property
IPR	-	Intellectual Property Right
IIPA	-	International Intellectual Property Alliance
IFPMA	-	International Federation of Pharmaceutical Manufacturing Associations
IT	-	Information Technology
LIEO	-	Liberal International Economic Order
MNC	-	Multinational Corporation
NGO	-	Non-governmental organisation
R&D	-	Research and Development
TRIPS	-	Trade related aspects of Intellectual Property
UNAIDS	-	The (Joint) United Nations Programme on HIV/Aids
UN	-	United Nations
US	-	United States (of America)
WHO	-	World Health Organisation
WIPO	-	World Intellectual Property Organisation
WTO	-	World Trade Organisation

CHAPTER ONE:
AIM, SCOPE AND METHOD

1.1 Background and problem statement

The growing scale and importance of the trade in intellectual property, highlights the economic and political impacts of the information age. With knowledge being the new hot commodity and with the power to shape values, welfare and the future, a whole new perspective on issues such as global governance, cooperation, international political economy, and health economics is necessary.

The issue of the violation of intellectual property rights (IPR's) affects those international actors who have vested interests in the continuation of a strong protective intellectual property regime. These violations are seen as "pirating" of intellectual property and poses a threat for the "New Economy" as envisioned by the US neo-liberal trade agenda. In an environment where competition is tough, this illegal competition is making it very difficult for the industry or country to maintain its comparative advantage and market share in for example the pharmaceutical industry (Coleman, 1997: 48-51). The pirate is especially threatening in countries lacking proper IPR frameworks. Under such conditions, there are few incentives for the transfer of intellectual property to legitimate private sector industries, such as the pharmaceutical industry, and for governments enforcing the WTO IPR agreement.

The US Government was significantly pressured in the 1980s to gradually replace antitrust laws with a regime for the protection of IPR's. This situation provided the background for efforts by US policymakers to include the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attached to the Uruguay round of GATT in 1986 (Sell, 2000: 175). This move laid out the path of future IPR disputes and indicated how the US had a definitive agenda in setting up an IPR regime to protect the very profitable US pharmaceutical industry. Hence, the US position within GATT was simple: if all countries will harmonize their IPR laws with the US, then the US will not impose trade sanctions on those countries. This resulted in a number of disputes during the 1990s in response to this explicit statement on the rules of the game. China, Thailand

and Taiwan were the first ones together with South African to challenge the US IPR hegemony.

It seems that despites efforts to impose a free trade agenda, the control of the exchange in intellectual goods will only come at the expense of aggressive laws. One can argue that a major reason for the US position on the protection of its pharmaceutical patents (a particular form of an IPR) is that only the US has the capacity and willpower to enforce IRP laws internationally and thus securing the compliance of other countries. The other side of the coin is that the US was enforcing its own unilateral economic agenda, via the Bush-administration, on the international IPR regime. South Africa challenged this agenda directly by questioning regulations pertaining to GATT and the WTO that allow for the violation of patent rights, through its 1997 Medicines Act.

South Africa's legal exploitation of clauses in the WTO IPR agreement in terms of compulsory licensing and parallel import of generic medicines when "essential", was done in order to secure cheaper medicines for the treatment and curbing of the anti-HIV/Aids epidemic. This move was done in accordance with international law and according to the WTO's patent protection agreements within the TRIPS Agreement. The pharmaceutical firms involved could not challenge the South African laws through the dispute mechanism procedures of the WTO, as only member states can do that. These firms could have taken the case with the South African Government to the World Health Organisation (WHO), but the contentious issue of Aids would have made a ruling in favour of the South African Government highly likely. The pharmaceutical firms subsequently had to fall back on national negotiations with the state involved. These negotiations did not prove to be fruitful, and the firms took the South African Government to the country's own High Court. This could set a precedent for similar legal moves of developing countries suffering from similar health service problems.

Using a holistic analytical framework, I firstly discuss the theoretical background to contemporary political and economic trends in order to establish the conceptual boundaries of the contemporary intellectual property right (IPR) regime. The role and importance of the state, institutional, and private actors are analysed and evaluated. The dynamic nature of intellectual property and the trade-offs between innovation and efficiency within the political economy of intellectual property is also explained.

In the second part I present detailed evidence on the debate surrounding South Africa's violation of WTO TRIPS regulations. The framework of Biersteker (1992) is used to order the analysis into a world level, an institutional level, a domestic level, and ideational level. In doing so, I highlight the different agendas of the actors, ranging from the supra-national and institutional, the state level, to the individual private firm actors.

The world system level of analysis entails an examination of the international IPR regime. The institutional level of analysis entails an examination of important institutions such as the WTO, WHO, and the World Intellectual Property Organisation (WIPO). The domestic level of analysis focuses on the political economy of the Aids debate in South Africa and it also includes a discussion of the pharmaceutical industry. The holistic framework incorporates the ideational level of analysis throughout these discussions.

The last part of the paper summarises the conclusions of the research, as well as recommendations for policy actions for South Africa.

1.2 Theoretical guidelines

The South African Government's IPR policies in terms of the violation of medicinal patent rights were causing considerable consternation within the US pharmaceutical industry. Additionally, the pharmaceutical industry's close political connections with Capitol Hill is the leading cause of the US Government's economic threats and diplomatic pressure that characterised South Africa's leading role in challenging WTO regulations. To understand the nature of the politics regarding the international IPR regime, it is necessary to understand the nature of the broader economic reforms being pursued throughout the developing world. Biersteker (1992: 108) describes these economic reforms as a reduction in and transformation of state economic intervention. States increasingly rely on market mechanisms to substitute their service providing functions. States thus increasingly support private sector actors, whether voluntary or involuntary.

There are various explanations that can be used to describe how the current economic and especially the trade regime came to being. The prevailing neo-liberal approach is a contemporary mainstream theoretical framework that can be used to analyse the processes within the Liberal International Economic Order (LIEO), i.e. the collection of rules, regimes, and institutions that regulate international economic co-operation (Kegley & Wittkopf, 1995: 35). Neo-liberalism gives meaning to a system where it is assumed that states are rational actors that try to maximise welfare through free trade. Such a system is anarchical, yet of an orderly nature. The structure of the world order is not an important point of analysis, rather the analysis of processes and trends within the system towards co-operation and harmonisation of policies is important.

Neo-liberalism assumes international co-operation and interdependence in terms of international law, economic interests, and political conflicts, thereby assuring a harmonious world order (Kegley & Wittkopf, 1995: 32). Neo-liberalism incorporates into its analysis the contribution of a variety of international and sub-national actors. Importance is given to the growing number of economically and thus politically powerful transnational actors, such as multi-national corporations (MNC's).

A specific strand of Neo-liberalism, namely Complex Interdependence goes even further in analysing the agendas of other important actors, such as transnational banks and large Research and Development (R&D) firms (Kegley & Wittkopf, 1995: 33). Complex Interdependence criticises the notion that states are the only important actors and that national security and military issues dominate nation-states' decision-making agendas. This analytical perspective explores issues that arise out of international economic interdependence of which the IPR debate is an example.

However, the assumptions of the above-mentioned perspectives partly disqualify them as an appropriate theoretical framework for the purpose of this thesis. The assumptions of co-operation and harmonisation of economic policies do not hold true in many cases in reality. States sometimes pursue goals that undermine international co-operation through constant efforts to achieve competitive economic advantage (Kegley & Wittkopf, 1995: 203). The result is that states, especially the rich ones, try to maintain and protect their knowledge and human capital stock through advancing their agenda in international organisations such as the WTO. These theoretical approaches thus do not prove to be

useful in analysing the political economy of the international IPR regime. The politics of IPR ask for a much more nuanced and fundamentally holistic perspective. Biersteker (1992) argues for such a perspective and presents four separate explanations on political economic reforms that he later integrates into a holistic explanation. They are systemic, domestic interest, institutional, and ideational explanations.

In terms of a systemic level of analysis, the global economic trends have been strongly determined by the globalisation of production, concerns for protectionism, and extremely competitive economic competition (Biersteker, 1992: 112). Developing countries generally have no option when faced with these trends in the last two decades; either they participate or stand the chance of being marginalized. Even when they do join this "new" international system, the lack of competitiveness and responsiveness causes most economies not to share in all the benefits. The socialisation of developing countries within this new competitive environment is described by Robert Cox as the "internationalisation of the state" (1987: 253). He means with this "the global process whereby national policies and practices have been adjusted to the exigencies of the world economy of international production".

Systemic explanations have their drawbacks in explaining the contemporary economic trends, especially with regards to why change occurs and what the shifts in ideational aspects are. Systemic explanations alone do not specify the original forces that caused the economic changes. Additionally, systemic explanations seem to say that the international economic policy convergence is part of a natural process, instead of questioning whether it is only a temporary phenomenon (Biersteker, 1992: 114).

The domestic interest explanation goes somewhat further. This approach gives insights on political behaviour, especially with regards to the breaking up and formation of new coalitions. The emergence of new economic elites and their coalition with public sector actors is the single most important factor for the influence and direction shifts in economic policies.

Institutional explanations provide useful insights into the functions and influence of international institutions such as the WTO. The WTO was and is instrumental in outlining the international trade and production architecture. It is an example of how the

global economic regime "enhanced" the role of an international institution and made it representative of the established order (Biersteker, 1992: 116).

Ideational explanations provide useful insights in the leading role of the economic hegemon in the world's political economy, namely the US. The revival of Neo-Classical economics and neo-liberal policy agendas of the US influenced to a large extent the architecture of the current political economy (Biersteker, 1992: 119). It is especially the way these ideas gained legitimacy through the various networks of multilateral institutions and conventions that enabled it to become the dominant ideology. Ideational explanations cannot however explain the content and basis of change in a vacuum, as ideologies exist within a social and historical context. An integrated analysis is therefore necessary.

Biersteker's integrated explanation focuses on the importance of the dynamics of the current economic order. All the above-mentioned explanations have valuable analytical contributions to make in assessing the performance of the economic order. Systemic analysis provides the foundation for inquiries into the changes of economic policy, especially in developing countries. This approach gives meaning to the advent of trends such as the globalisation of production, the "increase in competitive pressures", and the "exhaustion of prior economic policy models" (Biersteker, 1992: 125).

The ideational approach gives meaning to the importance of the introduction of neo-classical ideas in trade as the global recession of the early 1980s forced new thinking on growth policies. The institutional approach explains how these ideas were embedded within international institutions, which were empowered to guard and implement policy agreements. The domestic interests approach gives insights to the rise of particularly strong private-to-private sector and private to public sector coalitions.

Using the explanatory framework of Biersteker in terms of the different components, one can analyse the origins and nature of the generic medicine and AIDS debate in South Africa in an eclectic and nuanced fashion. Firstly, policy convergence across the spectrum of economic issues became a necessity for those countries that opted to participate in the neo-liberal economic order. As South Africa transformed into a multi-party democratic system, it had no choice but to join the order through its membership of

international financial, trade and political institutions. The ideational and practical conditionalities embedded within these institutions ensured policy convergence.

Secondly, the neo-liberal order has seen, at first, incredible growth in many regions in the world since the early 1990s. In many ways the phenomenal growth has overshadowed other developmental issues such as health, education, and other welfare services provision. The Asian Crisis signalled a slowdown in world economic growth. The last two years saw the US economy struggling to keep up its high growth figures. Suddenly, the new-liberal order and its institutions are under scrutiny as the performance levels drop. From a systemic perspective, the internationalisation of the state has exposed many poor, developing states to the harshness of an extremely competitive international trade and production regime. International collaboration and global governance is difficult under such conditions, as there is growing disconsensus on the role and direction of the current neo-liberal economic order.

South Africa finds itself within a league of other developing countries that are dissatisfied with the declining importance of developmental issues in the neo-liberal order: the classic North-South debate. Although the South African government has pursued a neo-liberal growth strategy since 1996 in the form of the GEAR, it has increasingly begun to face the practical implications of its membership and affiliations with institutions of the global economic order. South Africa signed the TRIPS agreement and pledged to uphold the conditions of the treaty. Recently it found itself in a position where it must exercise one of the clauses of the treaty in order to secure cheaper medicines for curbing AIDS/HIV. The Government argued that it was merely exercising a clause of the WTO's TRIPS Agreement that allowed for compulsory licensing and parallel import of "essential" medicines. The relentless competition and attacks it faced from private sector interests, namely the pharmaceutical industry, as well as governmental pressure, namely from the US, is a case study that incorporates most issues of concern and disagreement in the new economic order, i.e. health, trade, institutional, and inter-governmental politics.

The theoretical background discussed here raises serious questions about the fundamental nature of international co-operation and multilateralism. How can multilateral agreement bring supposedly economic optimal outcomes for a large part of the world's economies? Sell (2000: 176) argues that the answer lies in the decisive "transnational private-sector

mobilisation of an OECD consensus", and the "collapse of developing countries' opposition" to them. This answer relates to Susan Strange's framework of addressing perceived power nuances in the global political economy. The question of "Who, or what, is responsible for change?" and "Who or what exercises authority – the power to alter outcomes and redefine options for others – in the world economy?" both relate to her inquiry into the diffusion of state power and how global governance is increasingly the terrain of multi-national public and private sector actors (Strange, 1996: 184).

In terms of Strange's framework, it becomes increasingly obvious that the benefits of the existing international IPR regime serves mainly the vested interests of powerful private sector firms and public sector institutions, keen on advocating neo-liberalism as the only approach towards trade and technology. As South Africa is challenging this international IPR regime, the analysis should extend towards examining the theoretical nature of the political economy of intellectual property, as well as the de facto legal regime of those private and public sector interests at stake.

The most important state actor within the international IPR regime is the US. When examining the role of the US in the generic medicine debate, one has to see the larger picture of the structure of the global political economic order to understand what the US interests in this regime are. Although it is popular to refer to the US as the world's hegemon in various fields, the term hegemon may be too narrow a description as it may only include the characteristics attached to a "dominant" actor. I subscribe to Cox's definition of "hegemony": "...a structure of values and understandings about the nature of order that permeates a whole system of states and non-state entities" (Cox, 1992: 140).

Cox in fact argues that what we are currently witnessing is the rise of a post-hegemonic order (1992: 141). This assertion implicitly assumes a certain difficulty for the construction of a new hegemony in the place of a declining one. This means that as the societal and economic values of the US supposedly decline in its importance and dominance, other "universals" will have a hard time to displace it.

Cox, fortunately, foresees stability as world actors find bases for common ground, such as ecological stability. There will however be the danger of social polarisation as new structures of production and vulnerabilities to competition create new sources of conflict. I would argue that we have to take Cox very serious on this warning and this is one of the

main premises of this paper. The current developmental and welfare goals of developing countries are being undermined by the interests of the integrated and rich of the world; not even Cox's "supra intersubjectivity" as a bridge between the separate subjectivities of the "different coexisting traditions of civilisation" (1992: 142) would be probable in such a world. With "supra intersubjectivity" Cox refers to a growing realisation across different civilisations that a common fate is shared. This growing connectedness is visibly manifested in the ecological movements in many industrialised countries. The growing realisation that the plight of the poor and sick, of which the Aids epidemic is a prime example, is a universal phenomenon may prove to be powerful breeding grounds for calls for a more distributive and equitable IPR regime.

Social polarisation between the different political subjectivities of the world can be easily traced in contemporary society. The dividing lines are, rather obviously, between groups that "became identified with and manipulated in the interest of economic and social cleavages" and those that benefited form it. Those that benefit from contemporary political economic arrangements are the US and the collective interests that it presents. Opposition to globalisation thus comes from those who are disadvantaged and want to determine their own political and economic goals.

A third theoretical framework which is useful to analyse the political economy of the international IPR regime and South Africa's efforts to go ahead with its own IPR policies, is that of the global public goods approach. The global public goods approach towards intellectual property may provide significant insight into the motivations of South Africa and similar developing countries to use it in alleviating specific health dilemmas, such as the HIV/Aids epidemic, through the production of generic medicines. Such an approach may also prove to be useful in analysing the effects on the IPR regime. I will discuss the background of such a connection, beginning with an analysis of public goods.

Public goods are recognized as having benefits that cannot easily be confined to a single "buyer". However, once they are provided, many can enjoy them for free. A clean environment and education are two examples. The substantial externalities that follow from the use of the above-mentioned goods make them "public" goods. These externalities are benefits in the case of public "goods", but they can be disadvantageous to society in the case of public "bads", such as pollution.

Traditionally, there have been three conceptions of public goods (Cerny, 2000: 453). Regulatory public goods, which include the maintenance and protection of market establishments, include such goods such as the protection of private and public property rights. The second type entails activities of production that are controlled for and provided by the state, such as public works programmes and public financing. They are called productive or distributive goods. Finally, there are redistributive public goods. They refer to goods that arise when states respond to the "political and public policy demands of emerging social classes" (Cerny, 2000: 454). Redistributive public goods normally refer to welfare and health services and environmental protection.

While public goods are understood to have large externalities and many benefits, a stricter definition relies on a judgement of how the good is consumed. If no one can be barred from consuming the good, then it is non-excludable. If many without becoming depleted can consume it, then it is non-rival in consumption. Pure public goods, which are rare, have both these attributes. Impure public goods possess them to a lesser degree, or possess a combination of them (Kual et al, 1999).

Cerny (2000:456) argues that globalisation means that especially states have difficulty in providing redistributive public goods. By implication this means that health services are (again) underprovided as access to pharmaceutical technological stock is inadequate. In terms of the Aids debate, the issue is whether the technologies produced by the pharmaceutical firms are strictly private goods or whether it can adhere to some of the characteristics of a global public good. Fieldhouse (2001: 174) argues that technology, rather than capital, is the main contribution that MNC's can and have made in developing countries. The problem, however, in practice is that firms strive inherently to obtain a "monopoly rent" in their respective industries, thus making competition imperfect (2001: 176). Together with pharmaceutical firms' motive of maximising profit, this characteristic results in the pricing of pharmaceutical products that are out of reach of developing country governments.

The term "global public goods" arises out of the realisation that with globalisation, the externalities are increasingly borne by people in developing countries. Issues that have

traditionally been merely national are now global because they are beyond the grasp of any single nation. They now reach across borders, generations and population groups. The distinction between public goods and global public goods is therefore not only geographical. There is a multi-dimensionality included that incorporates the sociological, economic and temporal dimensions (Kual, Grunberg & Stern, 1999: 12). Global public goods refer mostly to those systems and structures that arise when global co-operation takes place in terms of the environment, the economy, the social system, and other dimensions.

It is the conceptual existence of generational global public goods that makes the public goods approach applicable to the debate of intellectual property and patent rights. Generational global public goods provide benefits within and among various generations or to a specific generation that live at a given time (Sandler, 1999: 20). These benefits can be non-rival and non-excludable and are subsequently called pure goods. An example is the prevention of air pollution. An impure global public good lacks either the characteristic of non-rivalry or non-excludability. An example is the protection of the world's forests. More relevantly, such an impure global public good could be a just and distributive IPR regime with the existence of effective authority. The benefits of spill over effects which generational global public goods provide are an important base for increased international co-operation and incentives to produce these goods.

In the broad sense, impure global public goods tend towards possessing the characteristics of "universality". This means that they benefit more than one country or people or socio-economic group. At the same time, impure public goods do not discriminate against any population segment or set of generations. This, at the moment, cannot be said of the IPR regime as it is an economic oriented sphere and not a social oriented one.

Kual, Grunberg & Stern (1999:4) identify another characteristic of impure global public goods, namely that they are "final" and "intermediate" global goods. These public goods might in the classical sense be called "inherent goods", such as peace, and "instrumental goods", such as an international regime that ensures that peace is maintained.

A redistributive global public-goods-approach can bring developing nations the prospect of a more equitable allocation of global resources to address priorities that matter to them. Such an approach would however necessitate a notion of distributive justice, which refers

to the drive to reconcile national "demands for social justice with global peace and security" (Kapstein, 1999: 88). The notion of distributive justice is exactly, I believe, the premise for South Africa's violation of IPR and patent rights by exercising WTO regulations. Such a project is underway and has been for decades in many developing countries, but as this thesis points out, it clashes with established private and public interests of rich industrialised countries.

A practical aspect of distributive justice, besides the manufacturing of generic medicines, could entail substantial infrastructural investments from pharmaceutical firms in the health systems of developing countries (Stiglitz, 1999:316). These investments can take the form of technical assistance in the production of generic medicine and medical assistance with the administering of anti-Aids medicines.

Before the redistributive project can be realised, there must first be international consensus on objective criteria for defining a global public good. The implication for distributive justice and redistributive global public goods should also be established. Another important factor that is lacking in the redistributive approach from developing countries is a common international authority that has to step in to create incentives for the creation of such global public goods.

Another important dimension of the drive for a more equitable distribution of global public goods involves civil society. Orr (1987: 21) notes that civil society provides the necessary understanding and campaigning to force private sector actors to fall in behind a redistributive drive:

> "Currently, consumer critics, international public interest organizations, and grassroots activist offer the greatest hope for protection of people's health against the pharmaceutical industry's aggressive pursuit of healthy profits."

It was very noticeable in the case of South Africa how the public outcry, NGO's and media attention overall mounted enormous pressure on US policymakers and the pharmaceutical industry to reduce their hard-line approach towards IPR's and health issues.

Arrighi et al (1989: 74) also note that the capitalist mode of production, i.e. the fundamental nature of the pharmaceutical industry, is effectively questioned by civil society:

> "...popular movements join forces across borders (and continents) to have their respective state officials abrogate those relations of the interstate system through which the pressure is conveyed."

Civil society is as strong as any force in the international political economy. It is largely responsible for the political achievements in the South African case. The pressure applied by relentless public attention necessarily shifts the priorities of the actors involved.

In the case of South Africa, civil society proved effective in convincing the US Government to ease its relentless political pressure regarding piracy and the IPR regime. Subsequently, former President Clinton announced that the TRIPS agreement of the Uruguay round would not be pursued within the framework of the WTO against countries who manufactured generic substitutes or parallel-imported essential medicines.

1.3 A Political Economy of Intellectual Property

1.3.1 Introduction

The integration of international actors' activities, especially trade integration brought along by the forces of economic liberalisation, gave rise to problems with regards to how these actors handle the issue of intellectual property and its accompanying rights. These actors, whether they are states, firms or NGO's, each have important claims as to how the trade liberalisation should shape the conditions and future of intellectual property. These processes of demand and supply and the agendas of the different global actors in terms of intellectual property, describe the political economy of intellectual property.

Intellectual property refers to "know-how." "Know-how" refers to knowing how to do things, for example how to organize a construction project. Employees hold know-how. Generally know-how is protected by contract legally binding an employee to secrecy. When a corporation or government finds its secrets have been betrayed, it is possible in most countries to take the matter to the courts. Sometimes, for example when a senior

executive of General Motors moved to Volkswagen, it may not be possible to insure the secrecy.

IPR's concerning know-how and trade secrets are imperative for the continuation of IP trade in particular and the workings of the global economy in general. Firms and individuals therefore have to have the ability to legally enforce these rights and protect it from piracy through enforced IPR's.

Patent, trademarks, and trade secrets are the major classifications of copyrights that are protected by IPR's throughout the world. On the one hand, copyrights protect the rights of authors of literary and artistic works, such as books and other writings for a minimum period of 50 years after the death of the author.

On the other hand, copyrights also protect industrial property. Industrial property can usefully be divided into two main areas. Firstly, industrial property is characterised with the area of the protection of distinctive signs, in particular trademarks. Trademarks distinguish the goods or services of one undertaking from those of other undertakings. Geographical indications, which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin, are also included in the definition of distinctive signs.

The other area of industrial property is that which is protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The protection is usually given for a finite term (typically 20 years in the case of patents).

IPR concepts are essentially North American and European legal concepts. As a general rule, to get protection for IP, the inventor, author, or entity must go through the legal process of the country where she seeks protection for her property.

The exception to the general rule occurs when a country has signed an international agreement with respect to IPR's where rights are granted to citizens of the signing countries. Gikkas (1996:15) notes that there are many multilateral and bilateral

agreements signed in the world regarding intellectual property. These will be discussed in the chapter concerning the international IPR regime.

The potential financial as well as economic benefits of trade in intellectual property is a function of the extent of the protection of IPR's. For hundreds of years, the basic theory of intellectual property has existed based upon the assumption that creation is facilitated by the provision of a temporary monopoly, which ensures that the inventor alone will benefit from the profits (Gikkas, 1996). The Lockean concept of land property was used to justify the extension of proprietary rights in intellectual property. The metaphor of a land estate has facilitated the notion of the ownership of ideas.

Formal IPR's such as copyrights, patents, registered industrial designs and trademarks, are justified to protect creativity or give incentive to further creativity. Without these rights, others could use IP freely. In return, society expects creators to make their work available and that a market will be created in which such work can be bought and sold, i.e. the process of commodification that is discussed in the theory section. Society wants to encourage creativity but in order to prevent deficiencies; it does not want harmful monopolisation of market power. The state therefore builds in legal limitations to the rights granted to the creator. Such limitations include both time and space. Universally, IPR's are granted for a fixed period of time and it protects only the product or creation in a material form, such as a written contract.

As the concept of the ownership of ideas was accepted, a specific theory of intellectual property was gradually formed. In the abstract sense, intellectual property is knowledge that is protected by some intellectual property law in such a way that it is possible to keep it a secret. It can simply refer to knowledge that is hidden. This means that intellectual property is a property that is intangible and indivisible (Gikkas, 1996: 3). It also implies that an unlimited number of users can consume it without depleting it. The fact that information is intangible means that, in the absence of property rights, the producer of information will find it difficult to sell the information in the marketplace to recover any investment made. This causes a dilemma for the way we comprehend intellectual property as a commodity.

The dilemma basically entails a tension between two perspectives. The first perspective emphasises the need for the incentive to produce, thus intellectual property is seen as a private good. The other perspective emphasises the need to prevent monopolies; there must be a free flow of information. Each one has its merits and it embodies the main camps within the political economy of intellectual property. The balance between these two perspectives is very fragile. As former World Bank economist Joseph Stiglitz (1999: 312) argues, the process of technological growth is under a constant threat of stagnation because of governments' appropriation of intellectual property, such as patents, for use in their own public sector programmes. Countries stand to lose out through irresponsible appropriation, as the producers of life-saving medicines, namely the pharmaceutical firms, lose the incentive to invest capital in R&D.

However, Stiglitz (1999: 312) also highlights the economic deficiencies that arise when pharmaceutical firms use their monopoly-like positions to inflate prices and profits of pharmaceutical medicines. Coupled with the relative long duration of patents (on average 17 years), this means that medicines are under-produced. Countries that experience health problems of crisis proportions such as the HIV/Aids epidemic also sometimes abandon R&D on "essential" medicines because of the fear of appropriation of intellectual property.

1.3.2 Intellectual property and globalisation

The political economy of intellectual property must be understood within the larger context of globalisation. Nel (1997: 1-3) summarises the features of "globalisation" as a "transnationalisation"; an "interconnectedness or interpretations of events, relations and dimensions; and a "homogenisation of practices, norms, and values". It is important to note that what happens in one context is exactly replicated in other contexts. As Nel puts it, globalisation "does not transcend cleavages, but these cleavages are being reconstituted by globalisation in ways which make them all the more difficult to identify." This difficulty to identify subjective and contextual cleavages is exacerbated by conscious efforts of obfuscation by those that benefit from transnationalism and interconnectedness, and "those who find their marginalized position deteriorating exactly because of these processes" (Nel, 1997: 3).

Wealth creation in the global village is shifting from a resource to a knowledge base. The economy is increasingly dependent on innovation to create, to sell, to explain and to solve problems (Chartrand, 1995). The knowledge-based economy emphasises intellectual property as the important commodity that is increasingly traded in the world's virtual market places, such as the Internet. Intellectual property had to be commodified in order to exploit it for capital gain. Etzkowitz & Webster (1995: 497) explain that while knowledge per se is "evanescent and temporary" and has the qualities of a public good, it had to be institutionalised and legalised within a special time frame. Only then does intellectual property have the means to be patented and copyrighted.

Nel (1997: 20) clearly doubts whether globalisation and the latest life cycle of commercialised knowledge will be conducive to the diffusion of "know-how to alleviate problems such as... diseases" to those end-users who need it most. Our knowledge-driven economy is creating cleavages in the global society and it raises questions about the capacity of international institutions to provide democratic control over life-saving knowledge that is increasingly controlled and dictated by the "agenda-setting activities of transnational epistemic communities" (Nel 1997: 21). The pharmaceutical industry, like many other knowledge intensive industries, is extending its reach and increasingly qualifies as such a transnational epistemic community.

Due to its capabilities to convey information, technological advancement, know-how and ultimately economic and political power, intellectual property can be regarded as the legal form of the knowledge-based economy (Post, 1998). As this thesis will point out, there are however different conceptions as to how intellectual property serves different global actors' interests. This conflict of interests is a fundamental characteristic of the international IPR regime. Although there is an international political framework for the analysis of intellectual property within the institutions of the IPR regime, there is also amongst these institutions disconsensus on the role and direction of how intellectual property should be put to use. South Africa's challenge of the current IPR regime is a prime example of the diversity of views present in the international arena.

Despite the political disconsensus, the information age is moving relentlessly forward, facilitating highly innovative and competitive firms who can somehow manage to acquire comparative advantage. Governments, being the other main actor, routinely attempt to

modify trade laws for intellectual property according to unilateral agendas. These dynamic interactions between state and private sector actors characterise the globalisation process of intellectual property. In order to understand the dynamics of intellectual property globalisation and its effects on the South African situation, I next move on to describe the nature of the international IPR regime.

CHAPTER TWO:
THE INTELLCTUAL PROPERTY RIGHTS REGIME

2.1 Introduction

The international IPR regime refers to those institutionalised procedures and rules for the collective management of global IPR policy problems (Kegley & Wittkopf, 1995: 14). Krasner's (1982) conceptualisation of "regime" provides useful insights into the dynamics of the international IPR regime:

> "Regimes can be defined as sets of implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations converge in a given area of international relations. Principles are beliefs or fact, causation, and rectitude. Norms are standards of behaviour defined in terms of rights and obligations. Rules are specific prescriptions or proscriptions for action. Decision-making procedures are prevailing practise for making and implementing collective choice." (1982: 186)

The main purpose of an IPR regime is to protect the technology and value embedded in intellectual property. Secrecy of intellectual property is of the utmost importance to maintain comparative advantage in terms of technology and know-how in the international marketplace. Patents of certain sought after medicines, for example, are sometimes far more valuable that all of a firm's capital stock or its money balance. These patents should therefore be protected, from the perspective of the owner, in order for it to continue to be of commercial use.

An IPR regime also entails that the owners of patent rights, i.e. pharmaceutical firms have the ability to legally enforce these rights and protect them from piracy. There are, however, different conceptions as to how such an IPR regime should function. In order to analyse the impact of South Africa's actions on the international IPR regime, it is necessary to comprehend the scope of and nature of the current regime.

The international IPR regime is firstly characterised by its capacity to govern issues relating to intellectual property. Czempiel (1992: 250) defines governance as the "capacity to get things done without the legal competence to command that they be done." Governments rely on rule of law to govern, coupled with the threat of force. Governance relies only on the execution of power relations without the threat of force.

The assertion therefore is that the international IPR system is one of global governance. This is so because the scope of the globalisation of intellectual property issues that have traditionally been only national are now global as they are beyond the scope of any single nation's activities. The international IPR system is also a regime because it refers to Krasner's "principles, norms, rules, and decision-making procedures" as illustrated by the functioning of the GATT, WTO, the TRIPS Agreement, and WHO.

Secondly, the international IPR regime is also characterised by conflict. These conflicts, such as the generic medicine debate, arise out the interaction between the different actors and institutions. Czempiel (1992: 27) argues that these conflicts are part of the highly complex systems of global governance as economic interdependence is growing in importance. Although it is fairly easy to grasp that the world is not merely a world of state actors, it is (not yet) a world society. It is rather a "societal" world where the interests of a variety of societal actors are eminent. Czempiel states that a global governance perspective prescribes the need to direct the system of governance "in such a way that the most effective causes of ...unjust distribution of values, are being affected and diminished" (1992: 270). In terms of the international IPR regime, Czempiel's view provides some principles with which the IPR regime can be analysed.

2.2 A history of Intellectual Property Rights

Some countries' views in terms of IPR's can be seen as protectionist and of only national interest. Generally for a country importing intellectual property, IPR's are seen as cumbersome as they hinder growth of technological stock. The exporters are however in an advantaged situation. There exist varying degrees of technological stock protected by IPR's in different countries. One therefore finds that the stage of industrialisation of a country determines where the country will be on this ladder of varying degrees of advantages.

Conceptions of intellectual property originated in the US and in Europe (Gikkas, 1996:2). The US IPR regime has its origins in the notion that once a patent applicant has gone through all the legal procedures, the state will provide full protection of this property, as is the case with other private properties. An exception may occur when a state bilaterally

or multilaterally is connected with an international agreement on IPR's. The TRIPS Agreement, for example, has a clause that permits the compulsory licensing and parallel import of "essential" medicines such as anti-retrovirals for the use in the fighting of HIV/Aids. This clause allows (in theory) for the violation of private property rights, namely patents, which would otherwise have been protected under the IPR laws of the country that issued the patents.

Until the recent round of the General Agreement on Tariffs and Trade (GATT), IPR's were not subject to formal international trade negotiation. Rather, IP were subject only to international conventions such as the Rome and Paris Conventions concerning copyrights and specifically patents. These conventions require "national treatment", which means equal treatment to both foreigners and nationals. Conventions do not, however, require the unification of rights granted by different countries. Accordingly, if a given nation chooses to limit protection for its creators, then no greater protection is available to foreigners.

Furthermore, a number of countries, including many former Soviet Bloc countries and many Asian countries, have not yet or only recently signed international conventions. They are therefore not bounded to protect rights of foreign firms. Weak domestic laws and refusal to sign international conventions has permitted piracy and copyright infringement, particularly in Asia and the former Eastern Bloc.

The oldest of the multilateral international conventions is the International Convention for the Protection of Industrial Property, also known as the Paris Convention of 1883 (Auriol & Pham, 1992: 15). This convention covers patents, industrial designs, trademarks, and unfair competition. It requires "national treatment" (read "equal treatment") of the intellectual property of foreign nationals. Inventors should also apply within a given time frame for protection of their intellectual property in any signatory country of the convention. The protection relates back to the registering date of the first application in the home country. For patents, the registration provisions are important because without them, an inventor could be barred from filing simply because she is a foreign national or because she first registered her patent in another country.

The GATT regulations as a part of the grander scheme of the WTO trade reform process are the most important regulations determining the intellectual property regime. The Uruguay round of 1986 was the birthplace of a new multilateral trade policy agenda that expanded the scope of dimensions covered and also introduced the dispute resolution mechanism (Sell, 2000: 174). Multilateral agreements on trade, for the first time, incorporated policies on intellectual property and its accompanying rights. These agreements culminated in TRIPS Agreement.

The TRIPS Agreement sets standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions, must be complied with. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne and Paris-plus agreement

The TRIPS Agreement requires, in terms of patents, that Member countries make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1). An important exception is enshrined in the Agreement and entails that Member countries may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)). This exception facilitates the compulsory licensing and government use of pharmaceutical patents without the authorization of the right holder. This is discussed in a later section.

TRIPS' inclusion within GATT is the outcome of relentless drive from powerful U.S. private sector actors (Sell, 2000: 175). The role and importance of the US is discussed later in this chapter. The US Government's transactional corporate affiliations and connections can largely be attributed to TRIPS calls for the standardization of Pier's among the signers. TRIPS diverts in two aspects from normal GATT regulations. Firstly, TRIPS "orders" the signing countries to protect intellectual property rights pro-

actively. TRIPS also applies "to the private rights of individual rights holders and not to goods" (Reiter, 1994: 199-200).

An important economic implication of TRIPS is that less-developed countries do not have the option of appropriating other industrialised countries' intellectual property to help build their own economies. Another implication is that the price of information and technology is raised considerably as private sector actors strive to protect their monopoly-like industries. Roderick (1994: 449) argues that the short-term impact of TRIPS will by a large relocation of capital and resources from developing to industrialise countries.

2.2 Anglo-American IPR law tradition and the role of the US

Anglo-American law generally takes a pragmatic approach. IPR's are used to commercialise inventions. IPR's are more instruments of commerce than of culture. An important point in this tradition is that competitiveness should be primarily protected rather than the inventor's rights. Although the US Patent Office has some of the most stringent patent application procedures to ensure competitiveness, once granted it would do anything in its power to protect the inventor (Aurio & Pham, 1992: 16). The political strength of the interest groups, as we will see further in the paper, strongly influences the willingness of the US government to extend and protect these patent laws.

Where the Anglo-American emphasises economic rights, developing countries emphasise social or community rights. The distinction in views in terms of IPR's are between societies and countries "which see IPR's simply as part of a liberal market economy and those which consider them to be an important factor in national development." (Auriol & Pham, 1992: 18).

This distinction has led to the controversy between industrialised and developing countries in the recent GATT negotiations in terms of IPR's. One therefore finds that in the preamble to the draft GATT treaty concerning TRIPS, community IPR's are excluded. The TRIPS agreement explicitly states that IPR's are recognized only as private rights. This excludes all kinds of knowledge, ideas and innovations produced in the traditional environment such as villages among farmers, in forests among tribal peoples, and even in

universities among intellectuals (Chartrand, 1995). By implication, South Africa's legal challenge of the international law with regards to IPR's is a challenge of the legal regimes of those state actors that benefit most from the current law regime.

The importance of the role of pharmaceutical firms in US policy issues can be traced to the importance that the production of pharmaceutical industries holds for the US economy. US exporting pharmaceutical firms rely heavily upon the production and protection of intellectual property. These firms were growing increasingly more frustrated with both legitimate competition and the increasing threat of piracy since the 1980s. Coupled with the growing trade deficit of the 1980s, the US policymakers felt that US hegemony in the world's economy was under pressure (Kegley & Wittkopf, 1995). US policymakers therefore pushed for strongly worded clauses on the protection of intellectual property

The challenge to the international IPR regime by countries such as South Africa is thus a challenge to US competitiveness in technological know-how. IPR's, and for that matter patents, were already a trade issue during the mid-1980s. Post (1998: 5) argues that piracy and intellectual property have, in fact, been linked since the beginning of trade. Besides being related to the US's own growing trade deficit, there were the additional strains on the large US economy as it was busy transforming from an industrial to a service one, especially an information driven one. Technology production increased and presented problems for US policy writers to manage, hence the considerable insistence on protectionism in this regard.

Protectionism with regards to intellectual property is too a large extent driven by the phenomenon of intellectual property piracy. Although not officially called piracy, parallel imports are threats to the US sponsored IPR regime. International piracy of intellectual property provided a convenient answer as to why the US was having difficulties in the world market. Piracy also provided US firms with a visible enemy, which could be fought, unlike the domestic and economic problems at the root of the problem.

South Africa is not alone in its calls for distributive justice. Political pressure is mounting through a fragmented and uncoordinated effort by developing countries. Before 1994, the

TRIPS Agreement officially only recognized IPR's when they generate profit. The Agreement made no legal provision for compulsory licensing and parallel import when "essential" medicines need to be produced cheaply. The pressure from the WHO officials and governments of developing countries, such as India and South Africa, that had urgent national health needs, culminated into the inclusion of these clauses.

Until the Uruguay Round of the GATT, IPR's were not subject to formal international trade negotiation. Rather, intellectual property was subject only to international conventions such as the Berne and Rome Conventions concerning copyright. These conventions require "national treatment", which means equal treatment to both foreigners and nationals. The conventions do not, however, require the unification of rights granted by different countries. Accordingly, if a given nation chooses to limit protection for its innovators, then no greater protection can be available to foreigners. Furthermore, a number of countries, including many former Soviet Bloc countries and many Asian countries, have not yet or only recently signed international conventions. They are therefore not bound to protect rights of foreign firms. Weak domestic laws and refusal to sign international conventions has permitted piracy and copyright infringement, particularly in Asia and the former Eastern Bloc.

South Africa is one of the developing countries that inherited its patent legislation from its colonial ruler, namely the UK. The UK introduced patent legislation to protect its interests and especially those enterprises that enjoyed a monopoly on exports to the UK. Now, South Africa is in the process of reforming its IPR legislation to try to address public interests. As mentioned, it applied a clause of the TRIPS Agreement that allowed for the compulsory licensing and parallel import of "essential" medicines such as anti-retrovirals to curb HIV/Aids. The important actors within the international IPR regime and notably the US and pharmaceutical industry, reacted strongly. Hence, South Africa, as many other developing countries, is "wary of – if not hostile to – any international regime the standards of which would be uniformly applicable to all countries" (Auriol & Pham, 1992: 16).

Therefore, the Anglo-American IPR law tradition is manifested in the system of institutions such as the WIPO and the WTO, and foreign industrial and trade policy mechanisms that collectively make out the international IPR regime.

Against this backdrop of a US dominated drive for the protection of IPR's and patents, the international IPR regime became a hotly contested issue during the Uruguay round of GATT. This is because the protection of IPR's "is becoming increasingly closely linked to the conditions of competition and international trade" (Auriol & Pham, 1992: 17).

History has shown that developing countries such as South Africa find IPR's too expensive to maintain and to enforce. There is therefore little or no incentive to protect them or to pay licensing fees accompanied by patent rights. This policy is known as "free riding." The free riding economy is boosted by not having to pay the overhead costs of creating a new product or of not having to pay for royalties associated with a respected trademark.

The pharmaceutical industry by nature lends itself to be a "victim" of free riding. Medicinal products are costly and risky to develop, yet relatively easy to copy. Chartrand (1995) lists several IPR problems in developing countries, which are conducive to free riding. For example, India recognizes no patents for drugs. Thailand and Brazil also lacks proper protection for pharmaceuticals. Taiwan has extremely weak patent protection for pharmaceuticals.

2.4 Compulsory licensing and parallel import

The two exceptions within TRIPS that the South African Government wanted to pursue after the passage of its Medicines Act of 1997 were those of compulsory licensing and parallel imports. Compulsory licences refer to the action when products are produced or imported without the permission of the patent holder and when a government feels it necessary to do so to address domestic issues. It is allowed under Article 31 of the TRIPS Agreements on the grounds determined by each Member country's "health-sensitive" patent laws. In terms of the HIV/Aids and other national health emergencies, Article 31 makes provision for compulsory licensing when patent holders "refuse to deal" with the Member country, or when "a national health emergency" should be addressed, or "anti-competitive practices" such as excessive prices exist, or other instances where the "public interest" is at stake (Correa, 2000: 114).

Compulsory licensing can, according to TRIPS, also be executed through the parallel import of "essential" medicines. The principle of parallel imports means that anyone can freely import the legitimate copies of intellectual products, such as patents on medicines, without seeking permission from the right holders beforehand (Correa, 2000: 120). The right holders, especially US firms, argue that they should have the exclusive right of importation to guarantee the quality and service on the goods as well as reasonable pricing for each individual market. Hence, they have been demanding for the ban on parallel import.

The issue of exhaustion of rights and parallel imports both involve the legitimate copies made by the right holders or through their consent. The point is how far the right holders should be allowed to hold the exclusive right of distribution of the goods. This question is of relevance only when the principle of exhaustion involving patent and trademarks, applies.

On their website, the WIPO (www.wipo.org, 2001) states that the there are three kinds of practices concerning the exhaustion of IPR's and the subsequent possibility of parallel import. First, the "national exhaustion of rights" means that the right holders in any particular country have the exclusive rights of distribution, which will be exhausted after the first sale of such goods in that country.

Second, the "the regional exhaustion of rights" means that the right holders in any regional economic community such as the European Union, have the exclusive right of distribution which will be exhausted after the first sale in any member state. The European Union has a well-established practice of intra-Community exhaustion and extra-Community non-exhaustion.

The third kind is the "international exhaustion of rights" principle, which means that the IPR holders will be deemed to have exhausted the exclusive right of distribution after the first sale of their goods anywhere in the world. The last alternative does back up the idea of global sourcing and global marketing as well as global pricing.

The debate gets more complicated when attention is paid to the public interest in terms of choice of products. If it is in the public's interest not to buy legitimate goods, such as

anti-retrovirals, only from the right holders or their agents, then one can argue that the international law principle of parallel import should remain. This argument can be used when considering the plight of poor developing countries that need cheap medicines. In the case of South Africa, the Health Department has violated some USA IPR laws when it allowed generic medicines to be made at discount prices. The lawsuits are still going on.

The technological gap that exists hampers economic growth and eventually convergence towards the richer industrialised countries. It is thus inevitable that we will see the continuation of so-called "pirating" by developing countries. As long as the R&D costs for new technology stays high, these countries will not have the incentive to produce it themselves. The incentive to instate strong IPR laws and enforce them properly will be of secondary importance to the political will to address developing countries' main immediate problems of which cheap medicines for the curbing of the HIV/Aids is a prominent example.

CHAPTER THREE:
INTERNATIONAL ORGANISATIONS AND THE PHARMACEUTICAL INDUSTRY

3.1 The role of international organisations: WTO, WHO, WIPO and TRIPS

There is no doubt that the GATT regime was responsible for the unprecedented expansion in international trade through the provision of concrete arrangements that reduced barriers of trade and discriminatory policies (Young, 1992: 173). The liberal trade regime, however, threatened the interests of many countries that were not reaping the full benefits, such as the major economies of which the US is the leader. The rise of the structuralist challenge in the 1970s and the institutionalisation of these countries' vision in the New International Economic Order signalled growing dissatisfaction with the liberal trade regime of the world. Together with protectionist challenges from the US as a result of its huge trade deficits in the 1980s, it forced countries that were suffering from developmental problems to question the prevailing order.

The growing dissent from mostly Southern countries was never really a threat for the functioning of GATT, according to Young (1992: 174). The constant pressure from those countries that had significant interests in a neo-liberal trade regime assured the functioning of GATT. The US's growing protectionism towards IPR's should be seen as efforts to protect the economic interests that the US had in the pharmaceutical industry and its ability to function in a neo-liberal order. The economic interest in pharmaceutical firms was related to the substantial foreign exchange these firms were earning in the 1980s when the US was facing large trade deficits. The 1990s saw the US ease up on its protectionist policies of the 1980s and coupled with numerous other factors, the US economy continued to grow until the end of 1999.

However, two factors forced US policymakers to show signs of renewed protectionism in terms of IPR's. The first one is the fears of growth recession in the USA as prospects for investment and consumption started to dwindle since the end of 1999. The second challenge comes from private sector actors, especially pharmaceutical firms, who expanded viciously during the 1990s by making use of the liberalisation of international trade but now found their investments being threatened from growing welfare and

redistributive challenges of developing countries. The pharmaceutical industry's aggressive lobbying and pressure on US government officials illustrates this assertion. These factors present significant challenges to the functioning of the GATT and WTO.

When evaluating the roles and effectiveness of international institutions and specifically those of GATT and its follower, the WTO, Young (1992: 175-193) provides useful criteria. They entail questions of transparency, robustness, power distribution, transformation, government capacities, interdependence, and the extent of intellectual influences.

Transparency entails the ability to monitor or to verify the policy implementations of the WTO with regards to the main prescriptions and principles of its constitution, i.e. if it is possible to see whether it does what it is supposed to do. Robustness refers to the longevity of "social-choice" mechanisms enshrined within the policies, i.e. the ability of WTO policy agreements to withstand the test of time and minor crises in world trade.

The criterion of power distribution refers to the degree of symmetry of material power distribution between the members of the institution, i.e. whether there are sharp differences in economic powers between the have and have not country members of the WTO. Asymmetry hinders the working of an institution, as the powerless will feel ill done by.

The criterion of transformation effectiveness involves the ability of the institution to facilitate change and to restructure in response to world conditions according to its won legislative procedures, i.e. whether the WTO can adapt consistently to changes in the international trade system the way it should be. Finally, the criterion of government capacity refers simply to the ability and capacity of member governments to implement policy provisions. When evaluating the role of the WTO and GATT in the intellectual property debacle regarding the violation of patent rights, one cannot help but to agree with Young when he states after his analysis: "If I am right, institutional arrangements do matter in international society..." (1992: 193).

The Director-General of the WTO, Mike Moore welcomed the TRIPS Council's special discussion, "Intellectual Property and Access to Medicines", that was initiated in June 2001, by concerned members, especially the African Group members of Africa. He

acknowledged the importance of generic medicinal and parallel import issues for developing countries that struggle with their health care programmes. He sees TRIPS, not surprisingly, as a framework for sustainable economic development, not necessarily an obstacle (WTO News, 2001). His optimism summarises many officials' stance towards the WTO and TRIPS:

> " (TRIPS) strikes a carefully-negotiated balance between providing intellectual property protection — which is essential if new medicines and treatments are to be developed — and allowing countries the flexibility to ensure that treatments reach the world's poorest and most vulnerable people."

Moore outlines the ongoing tripartite commitments of the WTO, the WHO, and WIPO towards the implementation of the TRIPS regulations. The commitments with the WHO involve public health policy formulation, while those with the WIPO entails technical assistance to developing countries to their health programmes and the implementation of the TRIPS Agreement by 2006.

Gor Bruntland, the Director-General of the WHO, states that he and his organisation are committed to ensure reduced medicine prices for those countries that really need it. The WHO is committed to partnering with commercial enterprises (Brundtland, 2000:1). The working group of the International Federation of Pharmaceutical Manufacturers Association (IFPMA) is a telling example of how international governmental organisation is increasingly working with private sector actors. This working group is supposedly helping developing countries with research and development. It is however not yet clear how "dissident" countries, such as South Africa, India, and Brazil's unilateral violation of WTO regulations, affect this relationship. Will the working group only provide assistance to those countries that obey the regulations? Will it be possible to exclude other developing countries from benefiting from R&D? These questions remain to be answered.

Where Brundtland remains adamant on the WHO's commitments to IFPMA, he also states that the agenda of the WHO is that of its member states. This is heading for a clash of interests as he argues that patent protection is still a "very necessary and effective incentive for research and development for needed new drugs". He acknowledges that essential pharmaceutical medicines are not just commodities to be priced according to

profit concerns and pleads for "equitable" pricing of essential medicines (Bruntland, 2000:2). It is obvious Bruntland is in favour of a negotiated settlement between private and public sector interests, but it seems hard to reconcile this with his implicit argument against protectionism from developing countries.

The WIPO is perceived to be sympathetic to developing countries' health and welfare interests in a distributive international IPR regime. In 1995 the WIPO conducted a study on financial and other implications of the implementation of the TRIPS agreement for developing countries (*The Financial Gazette*, 15 March 2001). A report was released in 1996 and the observations and recommendations proved to be significant for the cause of distributive justice in the international IPR regime. The report noted the historical role of intellectual property in the world economy. The report argued that a too tight patenting system would inflate the prices of protected products in highly patent-sensitive industries such as the pharmaceutical industry. The report noted that the generic medicine debate in terms of efforts to curb HIV/Aids is an issue of humanitarian intervention. Such an issue should put be put ahead of issues concerning trade and investment that the TRIPS agreement endeavoured to address.

3.2 The Pharmaceutical Industry

The role and influence of shifts in comparative advantage stands out as the most important factor determining international trade in intellectual property (Smit & McCarthy, 1998:66). Comparative advantage entails an advantage in terms of pricing, marketing and sales of a manufactured product in a domestic market.

Comparative advantage is in turn determined by the extent of the technological gap that exists between the foreign and domestic industries. A technological head start means that a firm or industry is first to patent or license the manufactured intellectual property. The technology gap is a function of cost considerations and the time to acquire the necessary technology. Cost considerations for the development of intellectual property can largely be related to R&D costs. The enormous financial outlay for R&D, as well as the uneven accessibility of technology, explains why the rich industrialised countries and corporate

actors in these countries hold the technological comparative advantage in the production of intellectual property.

Pharmaceutical firms find themselves in a technology-intensive sector, which is an environment of constant change, short product life cycles, and small market windows (Bartlett & Goshal, 2000: 406). Pharmaceutical firms are also very dependent on each other for R&D. Alliances in the industry are common as they are "risk-hedging" tools for the pooling and leveraging of resources and capabilities (Boshal & Gartlett, 2000: 407).

In the knowledge-based economy, competitiveness means the ability to work smarter and harder. Competitiveness means that firms will spend billions of dollars in response to consumer demand for customised goods and services, higher quality, and more applications. The pressure for competitiveness is responsible for fierce competition in new and innovative designs. However, these designs can only be researched and designed (R&D) after huge capital investments and time consuming labour.

Mossinghoff & Bombelles examined the pharmaceutical industry and argues that the industry is highly sophisticated, research-intensive industry, and highly protected by patents (1996: 38). The industry keeps its knowledge close at hand even after patents have expired. The pharmaceutical firms are known to combine the ingredients of obsolete medicines to form new medicines which they then patent again. This effectively keeps the monopoly power in their hands.

The average cost of developing a new drug was $54 million in 1976. This has increased to $87 million by 1982, and to $359 million in 1993 (Keegan, 1997: 19). It would be fair to estimate that amount to be at least two to three times higher in 2001. In the $200 billion pharmaceutical industry seven countries account for 75 percent of sales (Keegan, 1997: 19). The US pharmaceutical industry is by far the largest and most powerful.

The concept of global competitiveness has introduced new concerns in terms of economic transactions. The accelerating pace of technological displacement is bringing a whole new dimension to international trade. It is especially in the area of trade in intellectual property and patent rights that one is witnessing the problems of the dynamics of comparative advantage and competitiveness. The accompanying problems of the

protection of IPR's and patents of the pharmaceutical industry create interesting dilemmas. South Africa is now such a problem for the US pharmaceutical community.

The position of the pharmaceutical industry can be summarised by the statement by Mr. Harvey Bale, the Director-General of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in Geneva (Bale, 1999:1):

> "If anyone wants to kill incentives for further research into a targeted disease area (e.g., AIDS) then one of the quickest ways to do this is to institute a compulsory licensing regime for drugs that treat that disease. Compulsory licensing benefits nobody except the fortunate commercial entity that is the beneficiary of the largesse offered by such licenses. In the medium and long-term, it is patients who will lack new treatments for serious diseases that suffer, as researchers will undoubtedly stay away from targeted disease groups subject to CL policies. Compulsory licensing seriously detracts from the purpose of the patent system, which as the 16th President of the US, Abraham Lincoln said, 'provides the fuel for the fire of genius.'"

Generally US pharmaceutical firms have a twenty-year patent protection. This protection amounts to considerable monopoly-pricing power. The exception to the rule is when the authorities have a large interest in the R&D of a specific medicine and would then demand lower prices. The official position of the industry is however clear: no protection of patent rights – no incentive for innovation and R&D for life-saving medicines.

The pharmaceutical coalition showed their strength in the case of South Africa's challenge of the IPR regime, by their consistent and comprehensive legal assault on the Department of Health. Their case was based on the alleged violation of the 1978 Patents Act. The case of protection of intellectual property was still undecided by the High Court, even though the 1996 South African Constitution made the right to private property prevalent in its Bill of Rights.

The pharmaceutical coalition secondly showed their strength in effectively lobbying US politicians to react strongly with renewed calls for protection of IPR's. This was despite a specific WTO TRIPS regulation that allowed for parallel imports (Article 6), and compulsory licensing (Article 31) (WTO News, 2001). The pharmaceutical coalition

also managed to avoid questions on the use of compulsory licensing methods by the US, Germany, and England.

South Africa's situation can be compared to the similar case of Bangladesh in the early 1980s. Not only was the government threatened with US foreign aid cuts, but also by the pharmaceutical companies themselves who threatened to stop their sales of essential medicines. Of all institutions, it was the World Bank that ordered the Bangladesh government to reform their IPR laws in accordance with international IPR laws (Werner & Sanders, 1997: 129-36).

Part of the strength of the pharmaceutical industry lies in its ability to maintain very good public relations. Werner & Sanders (1997: 94) argues that the reason for this is the enormous amounts that the industry spends on advertising, even more on average than on the R&D for new medicines. Lobbying US politicians with "soft money" and campaign contributions are part of the lavish advertising expenditure. Werner & Sanders (1997: 95) calls the cosy relationship between US pharmaceutical firms and politicians the "pharmaceuticalization of health care". It remains one of the main structural features that South Africa's challenge to the US IPR regime has exposed.

In trying to establish motivations for aggressive US political pressure as a reaction on South Africa's IPR policies, it is useful to examine the connections between the private and public sector in the US. The Centre for Responsive Politics is an NGO based in the US, which, amongst other things, reports on material contributions from the private sector to official institutions and individuals. According to a report of the CRP in 1999, major pharmaceutical firms such as Pfizer, Bristol-Myers Squibb, Eli Lilly, Glaxo Wellcome, and Novartis, donated millions of dollars to US politicians (Baily, 1999:1-5). According to the report the 1997 to 1998 congressional elections mid-term elections saw a 53 percent increase in donations to the political parties and officials.

There is a large degree of interconnectedness of US political interests and the pharmaceutical industry (*Business Day*, 20 July 1998). The Republican senator R. P. Frelinghuysen of the state of New Jersey proposed the wording for a clause on foreign aid that demanded that US aid to South Africa would be cut if the Government continued

with the implementation of its Medicine Act. Incidentally, the pharmaceutical industry is New Jersey's largest employer.

This business- to- public affiliation is an important point to digest in the light of South Africa's leadership in making the international IPR regime more distributive by nature. South Africa tested the waters; and US policy makers responded by making turning threats to their vested interests in the IPR regime into counter-threats.

As a kind of compromise between developing countries' health interests and the pharmaceutical industry's economic interest, UNAIDS introduced the concept of "tiered pricing" or "equity pricing". This programme entails that different prices are charged for essential medicines in industrialised and developing states. Pharmaceutical firms could still stand a chance to make a reasonable profit. The demand for anti-retrovirals is expected to increase dramatically so that pharmaceutical firms would earn sustainable revenues from selling medicines even at near cost prices.

A compelling argument for pharmaceutical firms to agree to "equity pricing", is the threat of drug-resistant strains of HIV. Pharmaceutical firms could stand to lose their foothold in markets if the medicines they manufacture are administered too late or incorrectly. The resistant strains could even spread to higher-income markets and make expensive anti-HIV medicines obsolete.

This argument was presented at last year's Aids Conference in Durban and illustrates a dynamic process of bargaining, threats and counter-threats. One the one hand the South African Government challenged the international IPR regime with its moves to apply parallel import and generic manufacturing. On the other hand, they try to convince pharmaceutical firms to lower the price of medicines. It is true that many of the better known anti-retrovirals such as AZT, are already trading at much cheaper prices. Glaxo Wellcome, a well-known international pharmaceutical firm, already felt the political and legal pressure and agreed, in conjunction with UNAIDS, to investments in anti-Aids programmes and technical support of aids advocacy groups (Mukherjee, 2000: 3).

Another stance of the pharmaceutical industry was summarised by two reports in 2001. The first one by was by Amir Attaran and Lee Gillespie-White, titled "Do Patents for

Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa." The second one was a PhRMA survey titled "Facts and Figures on Patenting and Access in Africa" and presented by Tom Bombelles at the American Society of Law, Medicine & Ethics (ASLME) conference on Law and Human Rights (*CPTECH*, 16 October 2001).

Both reports questioned the validity of arguments in favour of an IPR regime that condoned the violation of pharmaceutical patent rights. These reports argued that patents are not important barriers to the treatment of HIV/Aids in Africa. Access to anti-retroviral medicines, if freely and cheaply available, will not make up for the deficiencies in the capacities of African governments, such as South Africa, to deliver in terms of public spending on health care.

The pharmaceutical industry's strong lobbying and economic pressure on the South African Government for the protection of their patent rights is better understood when one examines their economic interests in the South African market. South Africa's huge GDP in comparison with the rest of sub-Saharan Africa (almost 40%) and its on average R25 000 per capita annual income means substantial buying power (*CPTECH*, 16 October 2001). The health care system boasts above-average infrastructure by African standards, which means that the administering of anti-retrovirals can be done without too much difficulty. Finally, coupled with the estimated four to five million HIV+ persons in the country, it is easy to understand why the South African market is "lucrative" for pharmaceutical manufacturers of anti-retrovirals and other anti-HIV/Aids medicines.

The decision of the South African Department of Health to import cheap medicines for the fighting of HIV/Aids, unleashed unprecedented pressure from the US pharmaceutical industrial community. The coalition of the transnational pharmaceutical firms threatened the Government that they would withdraw their investments from the country. The pharmaceutical industry had a powerful ally in the form of the then Vice-President of the US, Al Gore. Gore had two important motivations for his hard-line approach towards the South African Government. Firstly, he defended US interests in that its firms should not lose market power. Secondly, Gore's coalition enjoyed considerable "soft money" contributions, i.e. mostly campaign contributions.

CHAPTER FOUR:
AIDS: THE SOUTH AFRICAN SITUATION

4.1 Introduction

The structural inequality that defines South Africa is largely unchanged. It appears to have been reinforced by economic (especially macroeconomic) policies that exclude the majority from the circles in which power and opportunity circulate. While the richest 20% bracket of income-earners was modestly de-racialised in the 1990s, the poorest 40% remain overwhelmingly African and female (Marais, 2000: 2). The country's rate of poverty (a measurement of the extent of absolute poverty) is 45%, which translates into just over 3 million households living below the poverty line. The situation will probably remain relatively unchanged for the next four years.

The low quality education and poor health situation further enforces the above-mentioned factors and are by large the main reasons for the widespread occurrence of Aids. The demographical dimension of Aids in South Africa is shocking; in 1999, South Africa was home to the world's fastest-growing HIV infection rates. One in five adults are infected with HIV (*Time*, 24 July 2000). Studies have reported that at least 16% of the adult population, 20% of pregnant women and 45% of the armed forces are HIV-positive (Department of Health, 2000). The black population group in general has the highest risk to contract HIV due to their socio-economic position. Additionally, between six and ten million South Africans are likely to die of AIDS in the next 10 to 15 years, out of a current population of forty million. By 2010, there could be two million Aids orphans in South Africa (*The Economist*, 27 May 2000).

The macroeconomic impact of AIDS is also serious. South Africa's already painful shortage of skills will grow worse. As the government divert their savings to pay for health care, the amount of domestic funds available for investment will ebb. These are but a few facts that surfaced at the Aids Conference that was held in Durban, South Africa, during July 2000 (Mukherjee, 2000:1). This conference provided the facilitation of different discourses surrounding the Aids epidemic. The conference was somewhat disappointing in the light of the Government's stance towards Aids and its position on the

implementation of its proposed Medicines Act was unclear.

The defensive political style adopted by President Mbeki on issues such as the Aids epidemic amounted to much criticism of the South African Government's agenda (*Financial* Mail, 18 December 1998). Fortunately, power is consolidated within a democratically elected parliament where the ruling ANC party enjoys high support levels. This inspires confidence that the government is strong and decisive as a whole.

Patrick Bond (1999), an active and influential Aids-campaign activist, criticises President Mbeki's perceived inability to strengthen confidence levels in the Government's policies on HIV/Aids. President Mbeki is now renowned for his efforts to shift attention from South Africa's ineffective HIV-AIDS policies. His stance was that the Government could not blame all the problems on just AIDS/HIV. He continuously stressed the importance of poverty as the major underlying cause of disability, starvation, reduced life expectancy, mental illness, and other symptoms of an impoverished society. He implicitly denied a link between HIV and AIDS and was backed by the board of researchers that the Health Department appointed.

One can argue that the Mbeki-administration predicted in advance that even cheap generic medicines would not be cheap enough and that the Government's health and welfare budgets would be pressured to administer and provide these medicines. Dr Costa Gazi, health secretary of the Pan-Africanist Congress and formerly the head of public health at Cecilia Makiwane Hospital, was one of the intellectuals whom argued for the introduction of a national prevention scheme of mother- child transmission of HIV (Bond, 2000: 4). The reason was that his research indicated that that the treatment of HIV+ children for Aids-related ailments would cost the state enormous amounts for it to be effective. His research indicated that anti-retroviral injections for the estimated 70 000 HIV+ expectant mothers would cost the state R90 million annually. This scheme could save lives and money. However, one doubts whether the South African healthcare system actually has the capacity to care for sick HIV+ patients and especially the infants.

Nicoli Natrass, an economist from the University of Cape Town, highlights the problems that could arise if the Government does not go ahead with its scheme to prevent mother to child transmission of HIV (*Daily Mail & Guardian*, 16 July 2001). According to her, the

intended use of anti-retrovirals could save the Government more than R850 million a year – the cost of caring for HIV/Aids orphans.

At an international Aids conference during 2001 in Buenos Aires, Argentina, a South African medical research team from the University of Witwatersrand showed conclusively that anti-retrovirals could be successfully administered to people "in resource-poor settings" (*Daily Mail & Guardian*, 16 July 2001). The evidence was collected from 16 clinical trials involving almost 800 HIV-positive people. Anti-retrovirals should however be cheap enough in the first place. The efforts to attain this goal are the single biggest motivation for government action.

What are the advantages of cheaper medicines? According to Zwile Mkhize, the KwaZulu Natal provincial minister of health, administering anti-retroviral medicines to South Africa's 4,2 million HIV+ residents would amount to almost R90 billion per year (Bond, 1999: 5). This would be the case if it were done under the present pharmaceutical-pricing constraints, i.e. without the benefit of parallel imports. This amount compares bleakly against the national budget of less that R300 billion and an official budget for HIV prevention of less than R200 million. If one compares this, for interest's sake, to the R900 million earned by a Chief Executive Officer of a certain pharmaceutical firm (Bond, 1999:1), one realise how dire the situation is.

A recent effort by the South African and Botswana governments was the initiation of the world's largest Internet-based HIV treatment and care programme (*Daily Mail & Guardian*, 16 July 2001). This programme aims to drastically reduce the costs of HIV/Aids treatment by facilitating the sharing of information on patient diagnostics, treatment and general care of HIV/Aids victims. This project could help to bring the treatment costs down to as little as R8 per person per month. The data collected through this programme would be used to advise pharmaceutical manufacturers, epidemiologists, doctors, and patients. Interestingly, the programme was designed in the US and it provided for generic medicines being used in the treatments.

4.2 The 1997 Medicines Act

Addressing the HIV/Aids situation is of the utmost importance for the South African Government. The Government is motivated by the economic losses the country would suffer if Aids takes its projected toll. Prevention is seen to be much cheaper than treatment, but the current statistics indicate that the immediate problem is that of treatment of Aids victims. The externalities of an active anti-HIV/Aids treatment campaign amount to safe and healthy environments that will be conducive to economic growth. The Government thus has a large responsibility in initiating legislation that facilitates the most efficient anti-HIV/Aids treatment programme. Coupled with the Government's obligation to provide adequate health care as a fundamental human right, the legislation is aimed at curbing the Aids epidemic of the current generation, but also to facilitate sustainable treatment and prevention of Aids. These arguments presented the main motivations for the passing of the Medicines and Related Substances Control Amendment Act ("Medicines Act") in 1997 by then Minister of Health, Dr. Zuma. (RSA, 1997: 6-7)

The ANC promised during the 1994 election campaign that the elected government would provide essential medicines for the treatment of various conditions at discount prices. After the election, this promise culminated into the Essential Drugs List (EDL), established in 1996 by the Government. The Department of Health pledged that the "EDL medicines will be available at all district hospitals, public providers and accredited private providers" (Department of Health, 1996: 35).

The increased health care budget since 1994 provided for a substantial increase in the contribution of clinics especially in rural areas. At a rate of four per week, this cost the Department of Health roughly R400 million per year (Department of Health, 1997: 8). The Government was thus also under the obligation to provide the necessary medicines to care for the increasing number of HIV/Aids patients that were streaming to these clinics.

South Africa's violation of US IPR and WTO laws officially began with the passing of the 1997 Medicines Act. This law condoned parallel imports and the production of generic medicines, especially anti-retrovirals for AIDS/HIV, within South Africa. The law ordered the Department of Health to override the TRIPS regulations of the WTO

agreement with South Africa. The provision was, however, only for the violation of patents in cases of extreme emergencies, such as the curbing of the HIV/Aids epidemic. The rationale behind the parallel importation of generic medicines is the enormous price advantage: in theory, generic medicines could be imported from markets such as India and Brazil at 5% of the original product's cost.

India was a source for such imports because of the availability of generic medicines. Multinaltional pharmaceutical firms were charging anything from R80 000 to R120 000 per year per patient for their patented anti-Aids combination medicines. In India, the generic producer Cipla, only charged between R1000 to R2500 per year per patient for the generic versions (Maine, 2000).

AZT, ddI and ddC are some of the more well-known anti-retrovirals. These were developed in the US. AZT is a "universally" targeting anti-retroviral medicine and is the cheapest and easiest to manufacture. AZT is currently made by the pharmaceutical firm Glaxo-Wellcome, and costs about R22 000 per year per patient in South Africa. The generic version could however be purchased in India for just R4 500 per year per patient (Bond, 1999: 3). Even if the so-called "equity pricing" was applied in South Africa, the incentive would have been there in any case to opt for the generic version due to the huge price savings.

Parallel imports are a direct threat to those pharmaceutical firms that have vested interests in South Africa, or those who wants to invest. Up till now, a few pharmaceutical firms have enjoyed almost full monopoly market power. Not surprisingly, the major transnational pharmaceutical firms immediately objected to the Medicines Act. These interest groups took the South African Government to court under the umbrella of the International Federation of Pharmaceutical Manufacturing Associations (IFPMA).

Worldwide support for the South African Government's IPR policies was increasing at the same time. Developing countries particularly were very vocal in their criticism of the US for interfering and putting pressure on South Africa. The US and especially former Vice-President had to deal with increasing international political pressure. It culminated in Gore's concession to President Mbeki at a meeting between them in September 1999 that the South African Medicines act had some merit. Then President Clinton officially

agreed at the Seattle WTO summit of 1999 that his administration would not bargain for the stricter enforcement of TRIPS to protect US pharmaceutical firms (Bond, 2000: 9).

At this point, the South African Government made an error in its health policy: instead of taking advantage of the US concession, the Mbeki-administration sidestepped the implementation of decisive anti-AIDS programmes. It subsequently did not pursue either the generic medicine production programme or parallel imports of these medicines.
In countries where alternative or generic medicines are available, the price of a branded product usually falls as a result of the competition it faces from low-priced alternatives. When the Brazilian government began producing AIDS drugs generically, for example, the prices of equivalent branded products dropped by 79 per cent. The same brand is sold at a higher price in countries where there is no competition from generic producers.

4.3 The Government and the TRIPS Agreement

During June 2000, the WTO TRIPS Council held a special discussion on patents and access to medicines. This was after a plea from the Africa Group to address important issues that arose out of the 1994 TRIPS Agreement. The Africa Group, consisting of most of the member countries of Africa including South Africa, proposed a decisive plan to reduce the high prices of patented medicines. The proposal was strongly supported by a host of sympathetic NGO's and culminated into a separate plea from them as presented by the prominent NGO, OXFAM (Maine, 2000: 2). The Africa Group's proposal was motivated by concerns over the major socio-economic impact that the HIV/Aids epidemic could have on most of the developing world. The Africa Group was specifically annoyed with the pharmaceutical industries for their monopoly-like behaviour in the blocking of competition from other lower-cost generic producers.

Before the advent of the 1994 TRIPS Agreement, member countries were allowed more exception clauses on the protection of patents by their national patent laws. Many countries (almost fifty) did not have laws for the protection of patent rights of pharmaceutical products (Maine, 2000: 3). The TRIPS agreement now puts developing countries in a position where they cannot legally challenge the pharmaceutical industry's monopoly on essential medicines.

However, there is a clause that empowers countries, in theory at least, to import or produce essential medicines when national health interests require it. This clause refers to the principle of compulsory licensing and parallel importation, which was discussed earlier on.

Although legal experts on the TRIPS Agreement have foreseen that the existing provisions on compulsory licensing and parallel importation can be exploited (Maine, 2000: 4), countries willing to utilise such clauses in the international IPR regime were put under considerable pressure. Brazil had been taken to court within the WTO legal framework for its production of generic medicines. South Africa, actually the Department of Health, had been taken to South Africa's own High Court by a coalition of multinational pharmaceutical firms for its decision to make use of parallel imports.

Clause 15(c) of the 1997 Medicines Act is the most controversial one. It provides that South Africa must seek the lowest world price for a medicine by implementing the principle of "parallel importing" (RSA, 1997). The Government is also allowed to implement "compulsory drugs licensing". The pressure first came form the Pharmaceutical Research and Manufacturers of America (PhRMA), a coalition of US based firms. This did not succeed in convincing the Government to scrap the law. Subsequently, the coalition of 40 South African and international pharmaceutical firms took the matter to the High Court.

After about a year of intense legal haggling, threats, diplomacy and negotiations, the Pretoria High Court ruled against the Pharmaceutical Manufacturer's Association in favour of the Department of Health on the 19th of April 2001 (*Die Burger*, 20 April 2001). Consequently, the much debated medicinal legislation can now be implemented. The Government pledged that it would consult the pharmaceutical industry in its decisions and that it would not use the controversial article 15(c) to sidestep patent rights. The ruling is only a moral victory, as the Government lacks the money and infrastructure to provide cheaper anti-retroviral generic medicines soon. However, the ruling does set a precedent for the Department of Health's continued efforts to address important health issues by challenging the US pharmaceutical industry's IPR interests.

Danny Schecter, a US television producer and independent filmmaker, also criticises the behaviour of the ANC-led government (2001: 1-7). His article proposes that the ongoing debacle on parallel imports of generic medicines is a political plot by the Government to enable a radical reduction in the prices of "essential" medicines such as anti-retrovirals. He also implies that this strategy of the Government is deliberately benefiting domestic pharmaceutical firms in which the Government has considerable economic interests. Nevertheless, there does not exist official evidence for this allegation. Pharmaceutical firms, and for that matter US government officials, well versed in the game of bargaining and bluffing, do practice such tactics during negotiations. If it turns out that South Africa is conducting such a strategy, the impact for the international IPR regime will be tragic, as it will discredit developing countries.

CHAPTER FIVE:
CONCLUSION AND RECOMMENDATIONS

Has South Africa's challenge of the WTO TRIPS agreement on the principles of parallel import and compulsory licensing brought about significant impacts on the international IPR regime? The answer symbolises a new trend that can be analysed using Biersteker's approach.

In terms of a systemic analysis, the case study offered a prime example of how the present economic order exacerbates developing countries' lack of access to and capacity of technological stock, welfare systems, and bargaining power in the international political economy.

Domestic interests, whether state-led or pushed by civil society, have led to considerable pressure on South Africa's government to implement drastic measures. As the government responded with health system reforms, its actions damaged the interests of the US and US pharmaceutical firms. These processes led simultaneously to the formation of new coalitions, for example the pressure groups that civil society formed in response to US political pressure, and also the consolidation of established coalitions, for example the coalition between US politicians and US pharmaceutical firms.

In terms of ideas and ideology, the case study examined contains a mixture of all the more important ideologies. The clash between the marginalized South and the integrated North is (again) present, reflecting the gap between the haves and have-nots.

In terms of an institutional analysis, the case study illustrated how the international institutions facilitate the neo-liberal trade agenda of the world's production and trade hegemon, namely the US. These institutions can however be used for the benefit of those countries that are not fully benefiting from such an order, as South Africa has shown.

A view that was prevalent in the discussion was that South Africa, and developing countries for that matter, regard essential medicines as a fundamental human right. This has substantial implications for the policy measures that developing countries with health system problems will adopt. The global goods approach provides a useful analytical

framework for the ideational underpinnings for such a view. This approach explains developing countries' pressure for a distributive IPR regime.

Another prevalent view is that the implementation deadlines within the TRIPS agreement for medicines in terms of adopting WTO standards for IPR's, were not found to be either enforceable or equitable, hence the option to exploit the compulsory licensing and parallel importation.

The private sector pressure on the South African government was significant. If it can be shown that differential pricing of medicines is a concession by the pharmaceutical firms, governments will continue to exploit the clauses in TRIPS with the hope of further concessions. This haggling over price and legalities may continue indefinitely and reduce the effectiveness of the WTO and the IPR regime in general.

South Africa's challenge of the international IPR regime can have important implications for how potential investors other than pharmaceutical industries see the legal regime in the country. These firms will only be willing to invest and to transfer technology in circumstances in which the legal, economic, political, and social environment are such that IPR's are guaranteed. Even if it is a well known fact that the government wants to exploit WTO regulations to address important health issues, the perception will be that South Africa is a rogue state unable to comply with international IPR laws regarding pharmaceutical patents.

It is significant to note the enormous bilateral political pressure from the US. Clearly South Africa was taking the international leadership in IPR's relating to important South issues, namely health and distribution of wealth. This put the world hegemon under pressure to react and defend the interests of its own firms. The challenge that South Africa posed to US pharmaceutical firms was a reaction to counter-threats such as the withholding of US aid and punitive sanctions against South African exporters.

The international IPR regime is therefore not only the playfield of intellectual property, patents, health issues, trade regulations, and private sector firms. The political economy of the IPR regime is significantly more complex and illustrates the most important dilemmas of the current international political economy. As Mr. Ian Roberts, special

advisor to former Health Minister, Dr. Zuma, put it after the WHO passed a revised drug strategy in 1999 in response to pressure from South Africa and other developing countries:

> " The main importance of this resolution is that health now has a role in all international trade and finance agreements" (*Financial Times*, 29 March 1999)

Finally, through the international leadership of South Africa in its challenge of the international IPR regime, developing countries have been shown how to effectively use international institutions in a democratic way to address their developmental problems. Through the global governance system of multilateral negotiations, South Africa has found ways to counteract the powerful forces of the private sector through legal bargaining within the WTO TRIPS regime.

South Africa has challenged a "tight" IPR protectionist regime. One consequence of a too tight IPR regime amounts to uneven distributions of essential intellectual property stock between developed and less developed countries. Another consequence is inefficient production of intellectual property, which inevitably affects health and living standards in less developed countries (Stiglitz, 1999: 315). The precedent set for other less developed countries is that they can challenge the US IPR law regime as long as it is done under the auspices of international organisations and international law agreements.

In terms of recommendations for future policies, it is first and foremost important that South Africa draws up a comprehensive, clear-cut, and decisive strategy in terms of its current and planned IPR policy considerations. Uncertainty and "grey" areas in the Constitution do not contribute to meaningful bilateral and multilateral discussions on the issue of patent rights and intellectual property in particular. The state departments that negotiate on such issues should have a clear mandate during discussions on IPR related issues, whether they are participating in the WHO, WTO, WIPO, or in bilateral discussions with US government officials and US pharmaceutical firms.

A clear cut stance will make negotiations easier, but it will also indicate a base point from where the Government and civil society of South Africa are willing to negotiate. This is essential for the maintenance of the important leadership role that South Africa has assumed within the South. Such a recommendation presupposes, however, that the

political leadership has to have the will and stamina to promote the cause of distributive justice.

In dealing with the US government, the South African Government will have to keep in mind the powerful private interests that influences politicians in the US. Although the private and public sectors are two separate spheres, the interdependencies necessitate a holistic approach.

The structural tendency for the protection of US interests is an important factor to keep in mind. In dealing with the US, South African policymakers will have remember that as US interests feel threatened, they will be extremely defensive in their trade and industrial foreign policies.

In order to bypass certain inefficiencies that may occur when the IPR regime is used to protect intellectual property, alternative methods can be used. There are also alternatives for certain intellectual property products when the legal and political environment in the foreign country makes licensing too risky. Gikkas (1996) lists five primary alternatives to a licensing agreement from pharmaceutical firms. For the pharmaceutical firm, this means making a direct foreign investment, selling a turnkey package, participating in a joint venture, selling equipment or investing in existing capital in the foreign country. These alternatives may prove to be of use in the near future when developing countries are still consolidating their IPR law regimes and the judicial systems. After they are consolidated, conventional licensing agreements can again be used to secure the rights on imported intellectual property.

Stiglitz (1999: 312) also suggests a strategy of how governments can deal with the under-production of pharmaceutical medicines without violating IPR's. This involves that governments should support their health programmes directly. This strategy presupposes that the South African Government should raise substantial revenues without large costs, whether through aid donor programmes or private sector support. The Government then would have to "effectively discriminate between good and bad research projects" (Stiglitz, 1999: 312). In South Africa, this strategy was followed half-heartedly but due to the enormous resources that are needed to curb the HIV/Aids epidemic, the government was forced to manipulating its IPR laws in order to secure cheap medicines.

Stiglitz (1999: 316) suggests that governments, once in the position to bargain with the pharmaceutical industrial establishment, could negotiate for a cut of the return on innovations of pharmaceutical firms. This cut, whether in the form of infrastructural or financial support, could help to "replenish the global knowledge commons" in terms of the technology fight against HIV/Aids. South Africa could take this next step to challenge the international industrial establishment (incidentally also dominated by the US economy) by arguing for these "welfare taxes". The criteria would however have to be clear: only those activities relating to the production of anti-HIV/Aids medicines should be applicable. A prerequisite would have to be that the Government finalises its IPR laws to foster investor confidence and certainty on policy directions.

This thesis implicitly raised questions on whether the current international IPR regime is representative of a world with conflicting interests in economic efficiency and equity. The conclusion is that the regime is dominated by US economic interests and not by a distributive and equitable agenda. In challenging and criticising the regime, South Africa should be careful not to take advantage and enhance its own self-interest in the global knowledge commons. Its leadership role means substantial responsibility in ensuring an equitable and yet efficient international IPR regime for all nations.

BIBLIOGRAPHY

Arrighi, G., Hopkins T. and Wallerstein, I. 1989. Anti-Systemic Movements. Verso: London.

Auriol, L. and Pham, F. 1992. "What Pattern in Patents?" in OECD Observer. No. 179. December 1992/ January 1993.

Bale, H. 1999. "IFPMA position on compulsory licensing". Email communication to Treatment-access forum (treatment@CritPath.Org). Geneva, April 15, 1999.

Bailey, H. 1999. "Bitter pills: The battle over prescription drug prices" in Centre for Responsive Politics Money in Politics Alert. Vol. 5 (17). May 17, 1999. [Online]. Available at http://lists.essential.org/pharm-policy/msg00091.html.

Bardhan, P. 2000. Social Justice in the Global Economy. University of California at Berkeley. [Online]. Available at http:// http://www.ilo.org/public/english/bureau/inst/papers/sopolecs/bardhan.

Barlett, C.A. & Ghoshal, S. 2000. Transnational Management. McGraw-Hill.

Bethlehem, D. 2001. "International Economic Relations" in Dugard, J. 2001. International Law: A South African perspective. Juta Law: Cape Town.

Biersteker, T.J. 1992. "The 'Triumph' of Neoclassical Economics in the Developing World: Policy Convergence and Bases of Governance in the International Economic Order" in Rosenau, J.N. and Czempiel, E-O. (eds.) 1992. Governance without Government: Order and Change in World Politics. Cambridge University Press: Cambridge.

Bond, P. 1999. "Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians" in International Journal of Health Services. Vol. 29, no.4. [Online]. Available at http:// http://aidc.org.za/archives/pbond_pharmaceutical_pricing.html.

Bond, P. 2000. "A Political Economy of South African AIDS" in ZMAG. 16 July 2000. [Online]. Available at http://www.zmag.org/bondsaaids.htm.

Brundtland, G. 2000. "Opening remarks IFPMA Roundtable". World Health Organisation. 15 November 2000. [Online]. Available at http:// www.who.int/director-general/speeches/2000

Cerny, P.G. 2000. "Globalization and the Changing Logic of Collective Action" in Frieden, J.A. and Lake, D.A. (eds.) 2000. International Political Economy: Perspectives on Global Power and Wealth. (Fourth Edition). London: Routledge.

Chartrand, H.H. 1995. "Intellectual Property in the Global Village" in Government Information in Canada/Information gouvernementale au Canada., Vol. 1, (4). [Online]. Available at http://www.culturaleconomics.atfreeweb.com/global.htm.

Coleman, P. 1997. "The U.S. competitive advantage in intellectual property trade" in Chemtech (The American Chemical Society). September. Vol. 27 (9).

Correa, C. 2000. Integrating Public Health concerns into Patent Legislation in Developing Countries. University of Buenos Aires: Buenos Aires. [Online]. Available at http:// http://www.southcentre.org/publications/publichealth/toc.htm.

Consumer Project on Technology (CPTECH). October 16, 2001. "Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on Antiretroviral drugs in Africa". [Online]. Available at http:// http://www.cptech.org/ip/health/africa.

Cox, R.W. 1987. Production, Power, and World Order: Social Forces in the Making of History. Columbia University Press: New York.

Cox, R.W. 1992. "Towards a Post-Hegemonic conceptualisation of World Order: Reflections on the relevancy of Ibn Khaldun" in Rosenau, J.N. and Czempiel, E-O. (eds.) 1992. Governance without Government: Order and Change in World Politics. Cambridge University Press: Cambridge.

Czempiel, E-O. 1992. "Governance and democratisation" in Rosenau, J.N. and Czempiel, E-O.(eds.) 1992. Governance without Government: Order and Change in World Politics. Cambridge University Press: Cambridge.

Department of Health. 1997. Annual Report. Pretoria, Republic of South Africa.

Department of Health.1996.. Towards a National Health System. Pretoria, Republic of South Africa,

Department of Health. 2000. National HIV and Syphilis Sero-Prevalence Survey of women attending Public Antenatal Clinics in South Africa. Republic of South Africa. [Online]. Available at http://www.doh.gov.za/facts/index.html.

Du Plessis, S. J. 1987. International Economics. Eds.: Smit, B.W. and McCarthy, C.L. 1998. Heineman: Johannesburg.

Etzkowitz, H. & Webster, A. 1995. "Science as intellectual Property" in Jasanoff, S. et al. (eds.) Handbook of science and Technology Studies. Sage: London.

Fieldhouse, D. 2001. "A new Imperial system? The role of the Multinational Corporation reconsidered" in Frieden, J.A. and Lake, D.A. (eds.) 2000. International Political Economy: Perspectives on Global Power and Wealth. (Fourth Edition).: Routledge: London.

Gikkas, N.S. 1996. "International Licensing of Intellectual Property: The Promise and the Peril" in Journal of Technology Law and Policy. Vol. 1, (1). [Online]. Available at http://journal.law.ufl.edu.

Kapstein, E.B. 1999. "Distributive justice as an international public good: a historical perspective" in Kaul, I, Grunberg, I. & Stern, M. (eds). 1999. Global Public Goods: International Co-operation in the 21st century. New York: Oxford University Press for the UNDP.

Kaul, I, Grunberg, I. & Stern, M. (eds). 1999. Global Public Goods: International Co-operation in the 21st century. New York: Oxford University Press for the UNDP.

Keegan, W.J. 1997. Principals of Global Marketing Management. International Edition. Englewood Cliffs: Prentice Hall.

Kegley, C.W. and Wittkopf, C.R. 1995. World Politics: Trend and Transformation. St. Martin's Press: New York.

Krasner, S.D. (ed) 1982. International Organization. Cornell University Press.

Marais, H. 1999. "His Masterful voice" in Leadership Magazine. October/November 1999. [Online]. Available at http://www.leadership.co.za/issues/1999octnov

Mayne, R. 2000. "Patents and medicines: The WTO must act now!". OXFAM. [Online]. Available at http://www.oxfam.org.uk

Mossinghoff, G.J. and Bombelles, T. 1996. "The Importance of Intellectual Property Protection to the American Research-Intensive Pharmaceutical Industry" in Columbia Journal of World Business. Vol.31, (1).

Mukherjee, S. 2000. "Take Your Medicine: Why cheap AIDS drugs for Africa might be dangerous". The New Republic Online. 24 July 2000. [Online]. Available at http://www.tnr.com/072400/mukherjee072400.html.

Nel, P. 1997. The Politics of the Globalisation of Science, and Technology. Monograph. University of Stellenbosch: Stellenbosch.

Orr, J. 1987. "Rexall for profits". Dollars and Sense. No.128, July-August 1987.

Post, D. G. 1998. Some Thoughts on the Political Economy of Intellectual Property: A Brief Look at the International Copyright Relations of the United States. Temple

University Law School/Cyberspace Law Institute. September 1998. [Online]. Available at http://www.temple.edu/lawschool/dpost.

Reiterer, M. 1994. "Trade-related Intellectual Property Rights" in The New World Trading System: Readings. OECD: Paris.

Republic of South Africa. 1997. Medicines and Related Substances Control Amendment Act. Cape Town.

Rodrik, D. 1994. "Comments on Maskus and Eby-Konan" in Deardorff, A and Stern, R. (eds.). Analytic and Negotiating Issues in the Global Trading System. University of Michigan Press: Ann Arbor.

Sandler, T. 1999. "Intergenerational public goods: strategies, efficiency and institutions" in Kaul, I, Grunberg, I. & Stern, M. (eds). 1999. Global Public Goods: International Co-operation in the 21st century. New York: Oxford University Press for the UNDP.

Sell, S.K. 2000. "Big Business and the New Trade Agreements: The Future of the WTO?" in Stubss, R. and Underhill, G.R.D. (eds.) Political Economy and the Changing Global Order. (Second Edition). Oxford University Press: Ontario.

Schechter, D. 2001."Mbeki's muddle: South Africa's Aids Debate" in Zmag. July 13, 2001. [Online]. Available at http://zmag.org/mbeki.htm

Stiglitz, J.E. 1999. "Knowledge as a Global Public Good" in Kaul, I, Grunberg, I. & Stern, M. (eds). 1999. Global Public Goods: International Co-operation in the 21st century. New York: Oxford University Press for the UNDP

Strange, S. 1996. The Retreat of the State: The Diffusion of Power in the World Economy. Cambridge University Press: Cambridge.

Young, O.R. 1992. "Effectiveness of International Institutions: Hard cases and critical variables" in Rosenau, J.N. and Czempiel, E-O. (eds.) 1992. Governance without

Government: Order and Change in World Politics. Cambridge University Press: Cambridge.

Werner, D. and Sanders, D. 1997. Questioning the Solution: The Politics of Primary Health Care and Child Survival. HealthWrights: Palo Alto.

WIPO. 2001. "International Exhaustion and Parallel Importation" in WIPO's Website for Small/Medium Enterprises. October 18, 2001. [Online]. Available at http://www.wipo.org/sme/en/ip_business/export/international_exhaustion.htm

WTO News. 2001. "Moore: Countries must feel secure that they can use TRIPS' flexibility". NEWS ITEMS. 20 June 2001. [Online]. Available at http:// www.wto.org/english/news_e/news01_e/dg_trips_medicines_010620_e.htm

Newspaper articles

Business Day. July 20, 1998. "Plan blunts long-term threat to US aid for SA."

Daily Mail & Guardian. July 16, 2001. "Using the Web to slash Aids care costs."

Die Burger. April 20, 2001. "Medisyne-reuse skik".

Financial Mail. December 18, 1998. "A future to count on."

Financial Times. March 29, 1999. "Campaign over drug licensing to grow."

Time Magazine. July 24, 2000. "The Politics of Aids."

The Economist. May 27, 2000. "South Africa's President and the Plague."

The Financial Gazette. March 15, 2001. "WTO treaty on trial in SA."
