

# World Trade Organisation Agreements: implications for equity and health in Southern Africa

Regional Network for Equity in Health in Southern Africa  
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## **World Trade Organisation Agreements and their Implications for Public Health and Drug Access in SADC Countries**

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### **INTRODUCTION**

*The question that arises is what intervention can the developing countries make to ensure that a process which, by its nature, will favour the rich, addresses also what are clearly the more urgent needs of our people, millions of whom lack the most basic things that a human being needs.*

South African President Thabo Mbeki, speaking on globalisation (opening address of the Non Aligned Movement Summit, Durban, August 31, 1998)

The aim of this paper is to inform people in the health sector about the impact of globalisation on health care and access to drugs in developing countries. It is especially concerned about the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPS), which will have repercussions on public health and the pharmaceutical industry.

In 1994, the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT) resulted in an agreement establishing the WTO, which came into being in 1995. Several treaties on trade in goods and services are annexed to the WTO convention and are binding to WTO members, among these are the General Agreement on Trade and Services (GATS) and TRIPS. The TRIPS Agreement will probably have the greatest impact on the health sector, especially in Africa. The main change required by TRIPS with respect to pharmaceuticals is the obligation of governments who are signatories to WTO to grant patent protection to pharmaceutical product and process inventions for a minimum of 20 years. The TRIPS Agreement gives the patent holder the legal means to defend against copies of patented drugs.

The reinforcement of Intellectual Property Rights (IPR) over pharmaceutical products comes at a time when 97% of drug patents are in Europe or the United States. TRIPS requires that all WTO member states protect patents held in Europe or the US, for instance. Previously, certain developed and developing countries had refused to grant patents for drugs. In order to meet their national requirements for drugs at a lower cost and to develop their technology, some countries copied products patented in industrialised countries through reverse engineering. Other countries with no pharmaceutical industry of their own bought these copies of patented drugs at competitive prices.

The concerns of the developing countries are twofold: one, that they will be unable to afford the patented drugs; and two, that the less expensive generic drugs will not be available. If the public sector is weakened in its ability to access and distribute generic and affordable drugs, this will further widen inequalities in health and health care. People who can afford the more expensive drugs will access these from private services, leaving public

authorities to provide inadequate health care for the poor. This could potentially be exacerbated by GATS measures that encourage private sector growth in health services, and reduce government regulatory controls over the liabilities of private purchasers and providers of health care towards wider public health needs. Section 3 discusses further the importance of national legislation to deal with these possible effects.

This paper seeks to investigate the consequences of WTO agreements relating to health, and primarily the TRIPS agreement on health care and drug access for Southern African Development Community (SADC) countries. It presents viewpoints critical and supportive of the WTO, for debates are strong and positions are often contradictory. The World Health Assembly asked the World Health Organisation (WHO) to examine the problems TRIPS could pose in developing nations. In presenting its analysis of TRIPS, this paper refers extensively to the World Health Assembly findings (1999) and the WHO publication *Globalization and access to drugs: implications of the WTO/TRIPS Agreement* by Germán Velásquez and Pascale Boulet (1999).

The paper also looks at how the rules may be adapted to preserve the interests of the countries where those "millions" President Mbeki spoke about live with limited access to health care.

The paper identifies and discusses a number of areas of concern:

- ◆ WTO/TRIPS has the potential for having profound effects on the health systems of developing countries. It has been put in place at a time when the HIV/AIDS epidemic is devastating the populations of the countries of southern Africa. Between 10-20% of southern Africa's adult population is reported to be HIV positive. In the current phase of transition from an HIV to an AIDS epidemic, the next five years will see a rise in opportunistic infections associated with HIV/ AIDS. Under the TRIPS Agreement, accessing drugs will be more difficult and more expensive.

- ◆ Theoretically, TRIPS legitimates the use of compulsory licensing and parallel imports by national governments. Over the past years, however, the United States government has put many developing countries and newly industrialised states on its Watch List, that is placed these countries under threat of trade sanctions under Section 301. (Article 301 of the 1974 Trade Act, amended by the Omnibus Trade and Competitiveness of 1998 creating Special 301 and a Watch list for countries suspected of not protecting intellectual property rights and liable for trade sanctions.) The United States government put South Africa on its watch list for patent violations, and the European Union, subsequently, accused the United States of violating WTO's intent and purposes. (See the South Africa Case Study in Section 2).

- ◆ In its legal aspects, WTO has reversed the notion of burden of proof. For instance, if a pharmaceutical company initiates civil proceedings for patent infringement of a process patent, WTO members states are required to put into law that the judge shall require the person suspected of infringement (not the plaintiff) to prove that an identical product has been obtained using a manufacturing process different from the patented process. In cases of violation of intellectual property rights brought by multinational pharmaceutical companies, the defendant, such as a developing country member, could have difficulty mustering the legal resources to prove itself innocent.

# 1. A BRIEF REVIEW OF GATT/ WTO AND THE WTO AGREEMENTS RELATING TO HEALTH

## 1.1 INTRODUCTION

After World War II, the Allied Powers sought to institute mechanisms for a return to an orderly economic system. They identified three major issues as key to building an integrated world economic system: exchange rates, reconstruction of Europe and the organisation of international trade in goods. The Bretton Woods Conference in 1944 responded to each of these issues by establishing three new international organisations. In 1944, 44 allied nations signed the Bretton Woods agreements establishing the International Monetary Fund (IMF) and the World Bank. The IMF was set up to manage the international monetary system and the World Bank, or as it was named at the time, the International Bank for Reconstruction and Development (IBRD), was initially intended to help the war-devastated European economies to finance production projects.

Three years later, in 1947, 23 nations met in Geneva to negotiate a reduction of barriers to international trade. From this conference the General Agreement on Tariffs and Trade (GATT) emerged, which became the main institutional framework for matters of international trade. Among the obligations of GATT signatories was the concession of most-favoured-nation (MFN) treatment to all other parties. In addition, the members agreed not to discriminate between national and imported products ("national preference"). Certain sectors, namely services, agriculture and textiles, were generally excluded from GATT.

Developing countries argued increasingly that GATT was detrimental to their interests. As a result, the first United Nations Conference on Trade and Development (UNCTAD) was called in 1964, when the principle of differential treatment was invoked. (UNCTAD is now a subsidiary body of the United Nations General Assembly.) Today, developing countries are using UNCTAD as a forum to correct the excesses of the World Trade Organisation that replaced GATT.

### 1.1.1 Moving from GATT to WTO

As the essential objective of GATT was to promote continuing liberalisation of international trade, a procedure was necessary for countries to negotiate tariff concessions. Each round of negotiations led to further trade liberalisation and reductions in customs duties: the Kennedy Round, 1964 to 1967; the Tokyo Round, 1973 to 1979; and the Uruguay Round, 1986 to 1990, extended to 1994.

At the beginning of the 1980s, it became apparent that GATT was no longer as well adapted to the realities of trade as it had been in the 1950s. GATT members were convinced that a renewed effort should be made to strengthen and enlarge the multilateral system. In 1986 a new round of trade negotiations began in Uruguay. Lasting until 1994, these wide ranging negotiations resulted in creation of the World Trade Organisation (WTO), which replaced GATT. The stated intent of WTO is to implement "fair practice in international trade", bring members to implement free trade practices, resolve trade disputes, and set up international rules and arbitration.

Today, the WTO has 132 member states and 29 additional countries have filed applications to join. The WTO has expanded the sphere of international trade and the jurisdiction of international organisations, particularly in regard to the protection of intellectual property.

### **1.1.2 How WTO differs from GATT**

The World Trade Organisation is fundamentally different from its predecessor, GATT, representing a fundamental shift in global governance.

- WTO applies to services (including health services) and intellectual property rights (notably affecting pharmaceuticals), which GATT did not.
- WTO is a permanent organisation having member countries; its rulings and agreements apply uniformly to all members. GATT, on the other hand, only had Contracting Parties with each party negotiating its level of free trade commitment.
- WTO includes an "Understanding on Rules and Procedures Governing the Settlement of Disputes" (DSU), and a Dispute Settlement Body (DSB) with authority over member states, and power to apply sanctions to which all members are bound and subjected. GATT, on the contrary, could not apply sanctions without consensus (including the consent of the sanctioned Contracting Party).

Intellectual property law, and especially patent law, is primarily national law. Before the Uruguay Round, many states did not issue patents for pharmaceuticals and this meant that the inventor had no particular rights over his or her invention in that country. This situation resulted in the proliferation of copies of patented drugs in some countries. The GATT did not deal with intellectual property protection, although it contained some relevant provisions.

During the Uruguay Round, the private advanced sector industries, especially the pharmaceutical industry, was concerned about the problem of counterfeit goods in international trade. It complained about taking commercial losses because of the weakness of intellectual property rights protection in most of the newly industrialising countries. In the absence of an international dispute settlement board for intellectual property, the Uruguay trade negotiators included intellectual property matters as part of its negotiations. As an annexation to the WTO Agreement, international patent protection became a prerequisite for the granting of benefits anticipated in the WTO Agreement.

Among the multilateral agreements annexed to the WTO convention, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) will probably have the greatest impact on drug supply and access. TRIPS establishes standards for Intellectual Property Rights (IPR) to which all member states must comply "...by modifying, where necessary, their national regulations to accord with the rules of the Agreement." The main change with respect to pharmaceuticals, compared to the pre-existing multilateral conventions, is the obligation to grant patent protection to pharmaceutical product and process inventions.

## **1.2 THE TRIPS AGREEMENT**

TRIPS concerns intellectual property, which includes cultural creation and industrial property. Industrial property includes trademarks, patents, geographical indications (for example, the EU-RSA wine dispute), industrial designs, and trade secrets. For developing

countries, the section on patents is having serious repercussions in the field of public health, especially for access to pharmaceutical products.

In general, pharmaceutical products are not regarded as ordinary goods or products, because consumers are not in a position to judge the quality of drugs. Drugs also play a significant social role in that they are an integral part of the realisation of a fundamental human right - the right to health. That is why they are classified as essential goods, to emphasise that they have to be accessible for all people.

### **1.2.1 Summary of the main features of TRIPS**

This section provides information on the TRIPS clauses, both as stated verbatim and as interpreted. While these are presented in some detail this is on the basis that review of the implications depends on a clear understanding of the terms and the opportunities and limits they include for national or regional actions.

The general paragraphs in the TRIPS Agreement (preamble and general provisions) stress the need to promote adequate and effective protection of intellectual property rights, but as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation. The preamble to the Agreement states that:

*"Members, desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."*

### **1.2.2 Relevant Articles**

#### **Article 1 - Nature and scope of obligations**

*"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."*

Member states are not obliged to grant greater protection than that set out in TRIPS. They are entirely free within the framework of their own legal systems and practices as to how they implement their obligations under TRIPS.

#### **Article 27.1: Patentable subject matter**

*"Patents shall be available for any inventions whether products or processes, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application... patents shall be available and patent rights enjoyable without discrimination as to the place of invention...and whether products are imported or locally produced."*

All countries must protect product and process patents, including pharmaceutical products, and modify their national legislation on patents to conform to TRIPS. Previously, many countries had excluded drugs from patentable inventions. Some had only "process"

patents on drugs, which has a more limited scope than "product" patent. If, at the end of the transition period, national regulations on patents are not provided for, or if they are not respected, the country in question may be the subject of a complaint before the WTO Dispute Settlement Body.

### **Article 27.2 and 27.3: Exceptions**

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

27.3: *“Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essential biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.”*

Article 27.3(b) provides that only plants, animals and essentially biological processes for the production of plants or animals may be excluded from patentability. Micro-organisms, as well as micro-biological and non-biological processes, however, are not covered and must be patentable. Micro-organisms only seem to be patentable on the condition that a real intellectual human contribution, which has to be new, is demonstrated.

### **Article 28: Rights conferred**

*“A patent shall confer on its owner the following exclusive rights:*

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

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

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

Article 28 confers on the patent owners the exclusive right to import the patented product or process. It is important to note, however, that a footnote to Article 28 limits the authority of the patent holder. Once the product has been put on the market, with the owner's permission, the patent holder can no longer control its subsequent circulation. The principle of the rights of exhaustion confers a monopoly on the invention (that is, the know-how) and not on the products legitimately resulting from this invention. The patent holder retains the exclusive right to manufacture the patented product and to put it on the market but, from that moment on, has no further right over the actual product. The patent holder thus loses his monopoly of importation and sale. (See Section 3 for more discussion on the rights of exhaustion and parallel imports.)

**Article 28.1(b): Protecting a product obtained by a patented process**

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

Only the product directly obtained by the new process enjoys the protection attaching to the new process. A manufacturer using the old manufacturing process could probably not be accused of infringement of the process patent. However, the extension of process protection to a product may lead to an increase in lawsuits, which may be a deterrent to small local companies.

**Article 33: Duration of patents**

Patents are uniformly extended to a minimum of 20 years from the date the patent application is filed. The logical consequence of this provision is that drugs will be sold at high prices, as is the case for all monopoly products, for a longer period of time, and manufacturers of generic products will have to wait longer before they can produce the drug in question and sell it at a more accessible price. The universally applied minimum length of protection, however, will mean that a patent will expire at the same time everywhere among the signatories to WTO.

**Article 34: Process patents: burden of proof**

*"For the purposes of civil proceedings in respect of the infringement of the rights of the owner ... if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process: (a) if the product obtained by the patented process is new; (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used."*

TRIPS sets the principle of the "reversal of the burden of proof," meaning that in patent cases being disputed, the defender must prove there was no violation of IPR. This is also true in case of unsound product, monopoly marketing practices, products dangerous for human, animal health or the environment, etc., where the burden of proof falls on the defendant.

**Article 65: Transitional arrangements**

In general, a developed country has one year following the date of entry of the WTO Agreement to implement TRIPS; a developing country is entitled to delay for a further four or five years from the date of application. By 2000, they should have introduced into their national regulations on intellectual property the various rules of the Agreement they accepted by acceding to the WTO. Developing countries that did not have product patent protection for pharmaceuticals have 10 years (up to 2005) to make the necessary changes. Least-developed countries are given 11 years, with a possible extension, to harmonise their regulations with the new international obligations.

For those countries that did not provide product patent protection for pharmaceuticals already as of January 1995, the Agreement will apply only to new drugs for which a patent application has been made after the entry into force of the WTO Agreement. These applications for pharmaceutical product patents are stored until modified national patent laws are adopted. If the application is accepted, a patent will be granted for the remainder of the 20-year patent term counted from the date of filing the application.

**Article 70: Protection of existing subject matter**

*“This Agreement does not give rise to obligations in respect of acts that occurred before the date of application of the Agreement for the Member in question. “*

**1.2.3 Additional Clauses**

• *“...patents shall be available and patent rights enjoyable without discrimination as to the place of invention... And whether products are imported or locally produced.”*

TRIPS imposes the National Preference and Most Favoured Nation clauses, which means that it forbids "discrimination" between national and foreign inventions that may be nearly similar, or between different foreign inventions.

- TRIPS forbids discrimination based on the local working of a patent. Patented products may be imported without the patent holder being required to work the patent locally and thus without technology transfer.
- TRIPS sets up strict limitations on data disclosure. Intended to restrict capacities for generics, it consists of strict obligations of secrecy in the process of patent recognition.
- Member countries may be brought in front of the DSB (Dispute Settlement Body) and be sanctioned if the DSB considers that they have not provided sufficient protection and means to prevent imitation of a patented drug.
- The decisions by the DSB are binding and the DSB has enforcement mechanisms; it is closed and members of the panel represent trade administrators and trade law expertise.

**1.3 GENERAL AGREEMENT ON TRADE AND SERVICES (GATS)**

The full implications of TRIPS are better understood by taking other main agreements into account, notably the General Agreement on Trade and Services (GATS). Like TRIPS, GATS is one of the new domains of competence assigned to the WTO. Aimed at liberalising trade in services, it is compulsory for all signatories to WTO. GATS may have consequences in the field of public health because it provides for member states to open their domestic market to foreign suppliers of hospital and medical services.

Services and Agriculture were not included in the previous round of negotiations, were not part of GATT, and thus their inclusion represents one of the totally new features of WTO, and is one of the fundamental departures from GATT. Services include a wide variety of domains (from computer software to insurance) and it includes health, notably the provision of health care and government procurement. Unlike the TRIPS agreement, the negotiations on GATS are ongoing and for some countries, just beginning.

GATS provisions on health potentially require transparency and competition within public sector procurement. This implies more latitude for private actors in publicly contracted service provision and may potentially enhance private sector growth in health services.

The EC claims that purchasing by governments in the world market amounts to nearly 15% of a given country's GDP. If that process is not transparent, it can distort trade and reduce potential growth in real income. For these reasons, the EC wanted government procurement of goods and services to be included in the WTO Agreement. While recognising the time constraints in setting forth a framework and procedure to monitor government procurement, the EC encouraged WTO members to build on existing programmes on transparency in procurement and the GATS work on procurement of services.

The EC prepared a statement on government procurement for the WTO meeting in Seattle in 1999. An excerpt follows:

*"The GATT and then the WTO have been largely successful in progressively liberalising trade and eliminating discriminatory treatment in international commerce. However, leaving government procurement outside the scope of the multilateral trading system remains a costly omission with real trade effects."*

At the same time there is substantial debate on the implications of widening WTO provisions to include trade liberalisation in health services. One of the most important areas of this debate is on the extent of continuing authority by the state to regulate such liberalisation in the interest of public health, given this provision in WTO agreements.

In the late 1990s, the Organization for Economic Cooperation and Development (OECD) hosted discussions to establish a Multi-Lateral Agreement on Investment (MAI) that would have expanded the global market in health and social care. MAI governments and NGOs objected because of what they perceived as the "unfairness of allowing private providers from other countries to challenge national public social provision or national government subsidy to non-profit providers" (Deacon 1999).

MAI investment obligations would have covered the full range of health and social services, from child-care centres, not-for-profit hospitals and community clinics, to private labs and independent physicians. MAI would have considerably restricted the ability of national and provincial governments and regional authorities to manage and regulate health and social services by attaching conditions to the receipt of public money and by providing for equal public grants between national and international health providers.

Deacon (1999) warns that this issue is now resurfacing under GATS. "A background working paper by the Secretariat of the WTO Council for Trade in Services confirms this (Koivusalo 1999). The document (WTO 1998) notes that the forthcoming round "offers members (of the WTO) the opportunity to reconsider the breadth and depth of their commitments on health and social services, which are currently trailing behind other large sectors". It notes with approval signs of an increased global trade in health care from developing to developed countries "with better off-people seeking rapid access to high-quality services abroad." The document is exercised by under Article 1:3(c) of GATS that says that excludes from free trade obligations services being provided in the exercise of governmental authority neither on a commercial basis nor in competition. It notes that "the

coexistence of private and public hospitals may raise questions, however, concerning their competitive relationship and the applicability of the GATS.” It agrees that it is unrealistic to argue for the continued application of Article 1.3 to these situations.”

#### **1.4 GENERICS: THE BOLAR PROVISION**

At the expiration of the 20-year life of its patent protection, a copy of the product may be manufactured and put on the market as a generic drug. Legal mechanisms to permit preparation of the generic while the patent is still valid are necessary if the life of the patent is not to be extended for several years. The USA, Canada, Australia, Israel and Hungary have provisions for advanced registration of generics. The EU has not, as a whole, agreed to the Bolar Provision although the European Parliament had recommended it four years ago.

The Bolar Provision enables all scientific and regulatory requirements for registering a generic medicine to be made during the period of the patent. Because making generics can take up to two the three years, the patent protection would be extended by that amount of time if no provision had been made for advanced generic registrations. TRIPs provides for this provision in Article 30. Although not explicitly stated it is well understood that the term *taking into account interests of third parties* covers this.

## **2. IMPACT OF WTO AND TRIPS ON HEALTH AND HEALTH CARE**

### **2.1 BACKGROUND**

Other documents in the EQUINET policy series outline the significant challenges to health and health care facing SADC countries (Loewenson 1999). They also indicate the gains made in health through specific investments in public and primary health care systems, particularly in enhancing vertical equity in access to health care in previously under-served communities. In the 1990s, the most marked new problem is the HIV/AIDS epidemic, with an average of 10-20% of the working age population HIV infected. This has reversed mortality gains, reduced life expectancy and added a significant burden of illness directly related to HIV and related to the social and economic poverty associated with it.

TRIPS poses economic and health related problems for countries in the SADC region. TRIPS provisions that increase the cost of patented drugs come at a time when most SADC countries have slashed public health budgets both because of the requirements of structural adjustment programmes and due to increased debt obligations. Dr K Balasubramaniam (1999) of Health Action International fears that:

*“The WTO/TRIPS Agreements, if implemented in the way the TNCs are proposing, will eventually help pharmaceutical market researchers to identify a ‘global middle class drug consumer’ with preference for expensive brands and leave billions of poor consumers, out in the cold, without access to even a few basic essential drugs to treat common illnesses which make their lives a misery.... Globalisation of pharmaceuticals will be a feast for the rich and tragedy for the poor.”*

Private health care supplies are most often linked to large pharmaceutical companies that have a vested interest in “brand name” as opposed to generics with a markedly lower profitability. This preference in private providers to use brand rather than generic names is itself an issue that has been tackled with varying degrees of success in the SADC region. One of the implications of a wider shift beyond the public sector towards generic drug use is a reduced level of foreign currency spending on drugs, as well as reduced overall national health spending in this area. The outcome of the GATS talks on trade in services will have consequences for the ability of governments to regulate or use other means to widen the use of generic drugs within private health providers.

If generic drugs are limited to use by government-supported health systems to treat those who cannot pay, this would limit the profitability of the generics industry and make it dependent on government that, in turn, is often donor dependent. In this situation, governments will feel doubly the cost of not producing their own drugs and relying on private investors: large bills for imports of pharmaceutical products and debt reimbursement.

In practice, the health-related Agreements attached to WTO can effectively limit governments’ ability to impose regulatory measures (and shift sanitary standards decision to private or trade expertise as opposed to health-related experts such as WHO).

## **2.2 PROS AND CONS: TRIPS’IMPACT ON DEVELOPING COUNTRIES**

There are a number of ways in which the TRIPS agreement is perceived to have an impact on developing countries. These are argued from different angles, with one set of arguments projecting that TRIPS is fair and will protect public health and advance greater trade and development within health systems. Another angle is that TRIPS is unfair and will limit the ability of developing countries to protect public health and national health systems. These different positions and their component arguments are summarised in Table 1.

### **2.2.1. Testing TRIPS in practice: managing the AIDS epidemic**

The conflict between the WTO TRIPS Agreement and the demands for managing the AIDS epidemic has already become evident in the SADC region. Problems have emerged in how countries with 10-20% of their adults HIV positive will find the means for treatment and care using new antiretroviral treatments (ART), and how they will set up the quality of public health services for managing of ARTs. Apart from the conflict between cutbacks required in the fiscal/budgetary policies of the international lending institutions, rising costs of drugs under TRIPS make newly developed ARTs unaffordable to the countries and populations of the region.

Treating existing diseases that favour HIV transmission and virulence has not been a priority of global AIDS programmes initiated 15 years ago. Marketing of condoms and behaviour modification cost a lot less, shift the burden to the individual, and do not jeopardise fiscal austerity imposed on all the countries of the South before and during the AIDS epidemic. Obviously, prevention by education is useful, but it would only become efficient if accompanied by a global effort to increase access to health, primary education and poverty alleviation.

**Table 1: TRIPS: Fair or Unfair?**

<b>'FAIR' TRIPS</b>	<b>'UNFAIR' TRIPS</b>
<p>TRIPS is necessary to protect Intellectual Property industry needs strong IPR to invest in R&amp;D and the costs of drug development.</p> <p>TRIPS will encourage industry to do research on all diseases that it did not do today because most countries did not respect intellectual property rights, and no patent legislation.</p> <p>The argument taken up in the US Patents and Trademark Office explanation of the US position is that TRIPS will improve the situation regarding lack of drugs in developing countries. Not to support IPR is to kill the goose that lay the golden egg (Boland 1999).</p>	<p>The R&amp;D investment of industry is highly exaggerated. The case of antiretrovirals (ART) exemplify corporations from public investments in R&amp;D. For example, ddI, was an anti-cancer drug developed at the National Cancer Institute. Another ART, ddI, also came from public research; d4T came out of the University, and new potent anti-HIV drugs came out of Walter Reed Army Institute. Industry estimates R&amp;D at USD 500 million. Ralph Nader's estimated R&amp;D investment at 5 million.</p> <p>Developed countries resorted to reverse engineering and waited to have developed pharmaceutical industries before putting in patent laws for drugs (e.g., US, Japan, etc.)</p> <p>The market could never find poor people with tropical diseases interesting</p>
<p>TRIPS will enhance the capacity of developing countries to patent their own inventions.</p>	<p>Many developing countries do not have their own patent offices and/or do not file U.S., EU patents blindly.</p> <p>Today 97% of drug patents are in advanced sector industries. IPR protection places most emerging countries and LDCs in a situation of dependency.</p> <p>A significant percentage of new drugs come from copying traditional medicine in China and Africa. Yet the poorest countries are denied reverse engineering on the end product.</p>
<p>TRIPS permits compulsory licensing,</p>	<p>Only a few emerging countries (e.g., India, China, Brazil and Argentina) have national drug manufacturing capabilities, and a few could develop self-sufficiency. The majority of LDCs do not have this capability. They cannot engage in reverse engineering, and they will need parallel imports.</p>
<p>But may impose limitations-</p> <p>"The US government does not generally support compulsory licensing of patents. Further, it regards compulsory licensing as unnecessary.</p> <p>The US government takes the above position in bilateral discussions. The fact that this view is not shared</p> <p>In the TRIPs agreement, in the multilateral context, is fully acknowledged. In our bilateral discussions, we continue to regard the TRIPs agreement</p>	<p>Countries will have to invoke exceptions such as public health, national emergency to justify compulsory licensing – clauses listed under TRIPS – that may be taken to the Dispute Settlement Body of WTO by governments alleging trade discrimination.</p> <p>Furthermore, TRIPS is defined in a restrictive manner by governments protecting the interests of industry, such</p>

agreement that establishes minimum standards for protection and, in certain situations, we may, and often look for commitments that go beyond those found in TRIPS agreement." (Boland 1999)	US government.
TRIPS permits parallel imports, necessary to limit exclusive rights of IPR holders	Countries will only be able to engage in parallel imports if they have legislation for "exhaustion rights" in their national legislation on patents (which Africa does)
TRIPS provides overall a large degree of freedom for countries to resort to compulsory licensing and parallel imports.	The South African Medicine Act is in conformity with TRIPS. The US government's interpretation of TRIPS is restrictive. As the RSA-US case exemplifies, a bilateral political and trade agreement is applied on countries to have a restrictive interpretation of TRIPS, leading to compulsory licensing and parallel imports.
TRIPS allows for the protection of real inventions and protects consumers and countries against counterfeit medicines	Developing countries have limited expertise to draw appropriate legislation, to register patents, or to fight battles in case of disputes within
TRIPS requires protection for health registration	Data exclusivity could prevent governments from carrying out compulsory license or producing generics
TRIPS will not work against the generic industry. The Bolar Provision can be invoked by States (again if it is in their national legislation) that allows work to be done on generic drugs prior to the end of a patent, to be on the market from the moment the patent expires.	TRIPS provides for product and process patents. Industry systematically uses secondary patents (bearing on aspects of processes in manufacturing for example), and, if not addressed, this second patent can mean an extension of patent exclusive rights "ad infinitum": plainly, it could endanger generic production (Velasquez and Boulet)
<u>IN THEORY</u> WTO-TRIPS IS A FAIR MULTILATERAL AGREEMENT THAT BALANCES PUBLIC NEEDS AND PROTECTS PRIVATE INTELLECTUAL PROPERTY	<u>IN PRACTICE</u> WTO-TRIPS IS IMPLEMENTED IN A RESTRICTIVE FASHION TO PROTECT IPR INTERESTS OVER PUBLIC NEEDS. IT IS APPLIED IN MULTILATERAL TRADE DEALS.

Access to effective treatment for a number of conditions will impact on HIV / AIDS progression: The results of the study in Mwanza, Tanzania, involving 6 000 people to treat STDs showed that among those treated for STDs, the progression of the HIV epidemic was reduced by half. Scientist at the National Institute of Health's NIAID demonstrated that mycobacterium had a synergistic reciprocal effect on HIV, so that people infected with one were more likely to become infected with the other and that each disease may increase the virulence of the other. Curing TB not only diminishes and eventually stops TB epidemics but may considerably slow down HIV as well. In addition, HIV patients at risk for TB may use condoms but condemn their families to TB death in the absence of treatment.

Prevention of MTCT (Mother-to-Child Transmission) with a short course treatment with Nevirapine has been demonstrated to be efficient in preventing transmission of HIV from mother to child.

SADC member countries would have to declare AIDS a medical emergency to trigger TRIPS options to permit compulsory licensing and parallel imports, if this is also already enabled in national legislation. In 1997 South Africa amended its legislation to allow it to parallel import pharmaceuticals and non-exclusive compulsory licenses, according to TRIPS regulations. The South African case study that follows demonstrates the difficulties South Africa faced in conforming to US and drug company wishes, meeting its own public health, local civic and patient needs, all the while adhering to economic reforms that call for fiscal restraint and maintain a level of health spending that will facilitate an effective response to AIDS.

### 2.2.2 A case study: South Africa and the WTO

#### South Africa's Dispute with the WTO

In 1996, the South African government reviewed its drug policy in order to expand its reach of health services. As a result of the review, the government amended its Medicines and Related Substances Control Act in 1997. While streamlining registration and regulation procedures, the new legislation enabled South Africa to parallel import pharmaceuticals and to allow the issuing of non-exclusive compulsory licenses (Gossens 1999).

According to Gossens, Charge d'Affairs at the South African Permanent Mission, before the World Health Assembly (WHA) January 26, 1999, the clauses in question provided an enabling legal framework for two TRIPs compliant strategies aimed at making medicines more affordable, namely:

a. The international exhaustion of patent rights is not prohibited by the TRIPS agreement and does not violate patent rights. Additionally, parallel importation is practised within the EU and is enshrined in European law. The international exhaustion of other intellectual property rights is well established in jurisprudence in many countries.

b. Compulsory licensing for local production is permitted by the TRIPS agreement. This legislation addresses a range of issues to ensure all South Africans have access to safe and affordable medicines.

The Pharmaceutical Research and Manufacturers Association (PhRMA) challenged the legislation, arguing that the amendments seriously undermined the terms of intellectual property and patent protection for pharmaceuticals in South Africa, specifically, Article 15C of the new law that states:

*“That the Ministry of Health may notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent”*

PhRMA argued that the authority provided under this clause appears to permit the Minister of Health to find that a foreign sale of pharmaceutical product exhausts the patent owner's rights in the product. Such an authority, if invoked and applied, would conflict with the obligations of South Africa under the TRIPS Agreement. It would do so by violating the principle of independence of patents and by eliminating the exclusive rights of the patent owner to prevent others from importing the patented invention, as defined in Article 28 of the TRIPS Agreement. The authority also conflicts with South Africa's internal legal regime, which has incorporated and applied the TRIPS Agreement. According to PhRMA, the new law thus presents a serious threat to the viability of US pharmaceutical investment in South Africa.

The pharmaceutical industry also accused the South African Health Ministry of not protecting confidential information submitted as part of the registration and marketing approval process for pharmaceutical products. At least one important product of a US pharmaceutical company has had generic competitors registered in South Africa because the competitors had access to the originator's registration file. South Africa is obliged by TRIPs Article 39.3 to protect registration against unfair commercial use. Its failure to do so conflicts with its obligations under the TRIPs Agreement.

Numerous PhRMA member companies have indicated that new investments in South Africa, in some cases valued at more than US\$50 million, have been suspended as a result of the new legislation. Further, the US government placed South Africa on its 1998 and 1999 Watch List for, among other reasons, its amendment of its Medicines Act. According to the US Trade Representative, this new law "appears to empower the Minister of Health to abrogate patent rights for pharmaceuticals. It also would permit parallel imports" (USTR 1998-1999). The US government imposed trade sanctions (under Section 301) against South Africa on the basis that South Africa did not protect the patents of pharmaceutical products.

Under pressure from AIDS activists, the US government lifted the sanctions. And South Africa did not go forward with its plan to resort to compulsory licensing and parallel imports for drug supplies.

US trade sanctions have raised doubts about the validity of TRIPs/ WTO as a "fair" treaty intended to bring similar constraints and obligations on all members for an orderly process in international trade relations. The EU took the US government before the DSB to resolve the status of the US trade sanctions. Unilateral trade sanctions, without referring to the WTO mechanism to resolve disputes, it said seems to be in violation of the terms of the treaty itself. The EU's main argument was that membership into WTO obliges members to abide by certain rules of fair practice, including arbitration of disputes through the DSU and DSB. According to the EU position the US government's use of Section 301-310, applying unilateral trade sanctions undermined the WTO, not only in practice but also in its juridical framework.

The Dispute Settlement Panel decided against the EU when it ruled that "Section 301 law does not violate international trade rules", but with certain conditions. The Panel based its finding in favour of the US on commitments made by the US in its Statement of Administrative Action (SAA) issued as part of the US bill implementing the Uruguay Round trade agreements. Under the SAA, the US Trade Representative is required to base any Section 301 sanctions on WTO panel and Appellate Body reports. The Panel warned the US that: "*[S]hould [these commitments] be repudiated or in any other way removed by the US Administration or any other branch of the US government, the findings of conformity contained in these conclusions would no longer be warranted.*"

The EU welcomed the ruling and did not appeal. It would appear, however, that for SADC Countries, the ability to implement any WTO provision that allows for government limits to WTO provisions in the interests of public health will demand legal and wider diplomatic and political measures that may be difficult for any one country to mount.

### **3. RESPONSES TO TRIPs / GATS IN THE SADC REGION**

As argued in previous sections, there is a potential conflict between the demands for patent protection and the benefit it confers in the development of new drugs, and the demand in SADC countries to protect public health concerns. For SADC countries there are important steps to be taken to manage this potential conflict.

### **3.1 THE PUBLIC INTEREST**

The TRIPS Agreement enables WTO members to give the highest possible priority to protecting the public interest (in this case public health) and to remedying abuses of the monopoly by the patent holder. This means that one central element of the response to TRIPS is the way in which the SADC countries exercise their right to protect public health.

As outlined in articles 7 and 8 of the TRIPS Agreement, the objectives and principles provide a strong public interest framework for the interpretation and implementation of intellectual property rights. Article 7 sets out the need to balance intellectual property rights protection with the promotion of technological innovation and the transfer and dissemination of technology “in a manner conducive to social and economic welfare.” Article 8 outlines the rights of members to adopt measures to protect public health, to prevent abuse of intellectual property rights

and to prevent obstruction of international technology transfer, provided that these measures are consistent with the provisions of TRIPS. The measures outlined below draw on this framework of protection of public health. SADC countries can exploit this to the fullest.

### **3.2 LEGAL RESPONSES**

Signatories to TRIPS have a certain amount of flexibility in regulating the agreement. The ways in which countries formulate their national legislation on intellectual property will determine whether or not they can use the exemptions to the monopoly conferred by patents in the interest of public health. The inclusion of these exemptions is thus of paramount importance.

#### **3.2.1 Writing legislation**

Legislators must be aware of all the possibilities when they amend their legislation. Each country's strategy in regard to globalisation of drug production and distribution will have to be incorporated into its national pharmaceutical policy, a component of national health policy. It is essential that all involved in this sector should understand what is at stake and play an active part in the reforms of intellectual property regulations now under way.

These general provisions were included in TRIPS to balance the rights of patent holders and their obligations with those of society. From a social and health policy perspective, the provisions open up the possibility of establishing national regulations, taking into account the imperative of guaranteeing the best possible access to drugs.

#### **3.2.2 Pooling legal capacities in SADC**

On a regional level, SADC countries might join together to work on the recognition of patents. Through a co-operative venture, patents could be examined individually and not accepted blindly on the word of the US or EU as to their content.

In addition SADC could pool its resources to deal with trade law, patents, constitutional law and the complex legal cases that are bound to arise. A centralised legal

resource for the SADC countries would permit the best drafting of national legislation in regards to compliance to TRIPS, while leaving the door open for governments to take appropriate measures to safeguard public health.

Within the WTO, under the Dispute Settlement Understanding, SADC could work to achieve more transparency in proceedings and more developing country representation in the decisive litigation board.

The Africa Trade Network has welcomed moves towards transparency in government procurement, but called on developing countries to make sure that elements on transparency should all be in the nature of guidelines and binding obligations, particularly for Africa.

### **3.2.3 Defining terms**

TRIPS does not define the terms invention and discovery, yet their definition could have important implications in the biotechnological field. This question is extremely important. Indeed it is the only one for which TRIPS planned a review. Developing countries rich in natural resources, should, in their new regulations, define the ambiguous terms “biotechnology” and “invention”, in order to benefit from these new provisions.

### **3.2.4 Ensuring legal access to essential drugs**

TRIPS provides two means of obtaining exceptions and limiting the exclusive rights conferred by the patent on its owner. These two provisions may be used to ensure greater accessibility to essential drugs.

Article 30 of the Agreement allows “exceptions to the exclusive rights” of the patent holder. This is the situation in which a person can use the patent object with no need to ask the holder for authorisation and without being in an illegal situation. Those exceptions are national legal exceptions and therefore need to be set out in the national patent law.

Article 30: *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

These exceptions are subject to three following conditions:

- they must be limited
- they must be duly justified, and
- they must not reasonably affect the patentee’s legitimate interests.

### **3.2.5 Compulsory licensing**

Governments may provide limited exceptions to the patent holder’s exclusive rights in their laws. When justified by the public interest, national public authorities may be allowed to issue compulsory licences against the patent owner’s will.

Article 31 of the Agreement states that:

- *authorisation of such use will be considered on its individual merits;*
- *authorisation will be granted only if the proposed user has made efforts to obtain the licence on reasonable commercial terms;*
- *the scope and duration of the authorisation must be limited;*
- *authorisation is non-exclusive;*
- *the authorisation is non-assignable;*
- *the predominant objective of the authorisation must be supply of the domestic market;*
- *the authorisation will be suspended if the circumstances that led to it cease to exist;*
- *the patent holder will be given adequate remuneration, taking into account the economic value of the authorisation.*

These are the main minimum conditions stipulated by the Agreement and member states must fulfil them when they grant compulsory licences. These conditions must therefore be included before the end of the transition period in the new national legislation on patents. They must be respected whenever a public authority issues a compulsory licence.

Five kinds of use without authorisation of the right holder are expressly envisaged by the Agreement:

- licences for public non-commercial use by the government
- licences granted to third parties authorised by the government for public non-commercial use
  - licences granted in conditions of emergency or extreme urgency
  - licences granted to remedy a practice determined after administrative or judicial process to be anti-competitive
  - licences arising from a dependent patent.

These are not the only cases authorised by TRIPS. Member states are not limited in regard to the grounds on which they may decide to grant a licence without the authorisation of the patent holder. They are, in practice, only limited in regard to the procedure and conditions to be followed.

Compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices.

Compulsory licensing is represented by a government giving a license to manufacture/ distribute a product, in this case a drug, to satisfy national health requirements (with payment of a fee to the patent holder). Any government may resort to compulsory licensing, but only a few nations have the capacity to produce drugs or access to raw materials. There are many instances of regulations that envisage compulsory licences for reasons of public health. In practice, if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy, such as a vaccine against AIDS or malaria, the national law may provide for the granting of a compulsory licence, under the conditions of Article 31.

The clause of national emergency can be the basis for governments to grant compulsory licenses. The US does not generally support compulsory licensing of patent but it does accept that a national emergency may give rise to the need for patent compulsory licensing (Boland 1999). This is all the more important in the face of the AIDS epidemic in many developing and emerging countries, notably SADC, which may lead governments to invoke a national emergency.

The arguments that have been raised against compulsory licensing refer to the fact that patents themselves are not the only obstacles to access to drugs; that most essential drugs are not under patent and that drug access problems often relate more to inadequate health care infrastructures. These proponents note options of negotiated reductions in drug prices for certain countries, or donor funds to support drug purchases, a route that has been more recently pursued by countries in the North in relation to ARTs. They also argue that most pharmaceuticals, whether essential drugs or not, have their origins in countries with strong patent systems. Those strong patent systems have certain features in common, one of which is minimal, if any, compulsory licensing. Compulsory licensing it is argued, will undermine those systems and will amount to "killing the goose that lays the golden egg" of those drugs.

Counter arguments advocating compulsory licensing, such as by Médecin sans Frontières, note that countries using compulsory licensing of patents or other policies to meet obligations to protect public health interests should not be subjected to unilateral trade pressures from WTO countries. The argument is made that countries that do not have sufficient domestic markets to make feasible domestic production of pharmaceutical drugs could benefit from the import of a product under a compulsory license. For example, a country such as India with a population of one billion can support a sophisticated domestic pharmaceutical industry, but smaller economies such as Botswana or Nicaragua cannot. They argue that it makes no sense to have a global trading system that would permit China, Brazil, India, Argentina, Germany, the United States, Japan and other large domestic markets to benefit from compulsory licensing, while smaller market countries cannot.

TRIPS Article 31 says that in most cases, compulsory licenses should be used predominately for the domestic market, and some companies have indicated they will ask that countries not be permitted to export products produced under a compulsory license. Such exports would be appropriate and permitted under the TRIPS Article 30 regarding exceptions, when the export market has a TRIPS-compliant compulsory license in place. MSF argue however that it is economically inefficient to limit national procurement of pharmaceutical products to domestic suppliers alone.

### 3.2.6 Exhaustion of rights and parallel imports

As noted earlier, the principle of exhaustion of rights is a prerequisite to the right to parallel imports and sales. An Intellectual Property Right is exhausted when the manufacturer or patent holder first puts the patent product on the market. At that point the patent holder loses its monopoly on sales and imports. The TRIPS Agreement leaves members free to decide whether to apply this principle in their territory. If it is not applied, it is illegal to import a patented product (or parallel importation) without the authorisation of its patent owner.

One of the fundamental rules of the TRIPS Agreement is non-discrimination between member states. A member state wishing to apply the principle of the exhaustion of rights has three options:

- an international exhaustion of the rights of the patent holder; this gives the member state the widest range for sourcing products. It may import from any country where the product is legally sold with a license of the holder).
- a regional exhaustion of the rights, limited to SADC, for example.
- national exhaustion of the rights, limiting circulation to those products put on sale by the intellectual property holder in that State.

This provision allows distributors to shop globally or regionally for the best prices of a given product. It improves accessibility through importation and moderates prices through competition. Countries could make drugs more available by establishing that once a patent holder has marketed the product in any country or region, the patent holder cannot claim exclusive rights in any other country. These goods imported from another country, even though they are manufactured in the importing country, are called parallel imports.

Parallel imports are not prohibited and are particularly important for smaller economies that suffer from inadequate competition. Where allowed, parallel imports have shown to be effective in lowering drug prices. A study of the price of HIV drugs in the United Kingdom shows that parallel imports offer an average saving of 41 percent from the list price and a 30 percent saving from the best contract price.

Although parallel importation is legal, questions of economic strategy arise. While parallel importation may help to bring down prices through competition, it may also discourage patent holders from granting licences for local working, and thus run counter to some countries' technological development. Some authors, therefore, advocate a conditional authorisation of exhaustion of intellectual property rights. They argue that parallel imports should be allowed only if, after a certain time has elapsed, the patent holder is not working the invention locally or is not meeting local demand at reasonable prices. In that case, the authorisation of parallel imports would be motivated by the country's desire to industrialise and to supply the local market with sufficient drugs at affordable prices.

According to other authors, the effect of international exhaustion of rights would be that right holders would set a single worldwide price for their products. This price would probably be the price the market can bear in the wealthier countries.

Others argue that manufacturers will hesitate to license for production outside the country of origin if many countries adopt the international exhaustion mechanism. Clearly the potential of using parallel imports for drug supplies is extremely important.

### **3.2.7 Powers to produce generics during a patent**

At the expiration of the 20-year life of its patent protection, a copy of the product may be manufactured and put on the market as a generic drug. Legal mechanisms to permit preparation of the generic while the patent is still valid are necessary if the life of the patent is not to be extended for several years at higher costs to consumers.

The Bolar Provision enables all scientific and regulatory requirements for registering a generic medicine to be made during the period of the patent. Because making generics can take up to two the three years, the patent protection would be extended by that amount of time if no provision had been made for advanced generic registrations. TRIPs provides for this provision in Article 30. Although not explicitly stated it is well understood that the term *taking into account interests of third parties* covers this.

Protection of trademark rights should not interfere with sound public health policies to promote the greater use of generic drugs or to regulate marketing. Countries can require generic drug substitution, substitution by generic name or the printing of the generic name on the packaging of the product.

Médecin sans Frontières recommends that WTO clarify that TRIPS would not prevent a country from requiring certain packaging and labelling requirements in areas where the regulation is to promote public health. This is particularly important for the implementation of generic drug policies.

MSF also urges member states to support discussions on the issue of patent exceptions for medical research. It suggests asking WHO to request comments from the academic and commercial research community on the barriers to medical research presented by current intellectual property regimes, and to advise the WTO on the issue of the legitimate interests of third parties in medical research. It also suggests that countries provide the WTO with strong statements in favour of Bolar-type patent exceptions that permit generic drug companies to perform tests on bioequivalence and other issues on patented drugs in preparation for applications for approval as generic drugs. In addition, it suggests that countries and international organisations like the WHO can support the legitimacy of such patent exceptions, emphasising the public health benefits of generic drug competition.

Table 2 summarises the major requirements and possible areas for legal action that the SADC countries could take in response to TRIPS.

### **3.2.8 Mandatory patenting of life forms**

The developed countries, through the TRIPs, now want the mandatory patenting of life forms and some natural processes. But the African Trade Network (ATN) recommends that Article 27.3(b) of TRIPS be reformulated to exclude the patenting of life forms. This would be to prevent the theft of biological resources and traditional knowledge of African countries.

According to ATN, the review process of Article 27.3 (b) should clarify that plants and animals as well as micro-organisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organism should also not be patentable.

**Table 2: Requirements and Areas for Legal Action**

<b>REQUIREMENTS</b>	<b>POTENTIAL FOR ACTION</b>
<p>TRIPS &amp; national legislation</p> <p><i>All countries joining WTO must <u>modify their legislation</u> so as not to conflict with the pre-agreed Agreement.</i></p> <p>National legislation must include recognition of Trade Related Agreement on Intellectual Property Rights.</p>	<p>SADC could pool resources as to its trade law, patent law and procedural law expertise. This would require the best drafting of each country's national legislation in regards to compliance with TRIPS while leaving the doors open for governments to take appropriate measures to safeguard public health.</p> <p>A joint programme would be essential to deal with the litigation that is bound to arise, within the WTO, under the Dispute Settlement Understanding as well as domestically (between government and government) or in bilateral negotiations (as in the South Africa versus US case).</p>
<p>The deadlines: January 1996 was the date when the TRIPS Agreement was to be put into place in national legislation in developed State and some emerging countries such as South Africa. Most developing countries have 6 years to comply: January 1, 2000.</p> <p>Developing countries who had not met the deadline for the reduction of patents had 10 years (till 2005) and until 1996.</p>	<p>After the break up of the ministerial meeting in Seattle in November 1999, a number of developing and newly industrialised countries requested delays in implementation (for TRIPS/TRIMS) at the January 2000 General Council meeting. In opposition to renegotiating, the US representative has agreed to review the matter "case by case."</p>
<p>The way in which countries formulate their national legislation on Intellectual Property will determine whether or not they can use the exceptions to the monopoly conferred by patents in the interest of public health. The inclusion of exemptions is thus of paramount importance.</p> <p>The clause of national emergency is provided by TRIPS Agreement (and also specifically by the US Government) as justifying a government seeking a licence.</p>	<p>Member states may decide to grant a licence without the authorisation of the patent holder on several grounds, including national emergency, or under other circumstances as provided by that State's government.</p> <p>However, the TRIPS Agreement seeks to restrict this possibility.</p> <p>Thus, pursuant to Article 31 of the Agreement:</p> <p>Authorisation of such use will be considered on its individual merits.</p> <p>This could be grounds for litigation.</p> <p>In drafting national legislation, it is more important to include clauses for exception to the monopoly such as public interest and "conditions of national emergency."</p> <p>AIDS could now or in the near future justify the declaration of a state of national emergency.</p> <p>The principle of the exhaustion of Intellectual Property is that Intellectual Property is exhausted when the manufacturer puts the patent product on the market - at that point the patent holder loses monopoly on sales and profits.</p>

<p>The inclusion of this principle in the national legislation allows for parallel imports by that Member.</p> <p>The TRIPS Agreement leaves member free to decide whether or not to apply this principle on a territorial basis.</p>	<p>This principle was understood in the African Medicine Act of 1997, and as provoked the anger of PhRMA (Pharmaceutical Research and Manufacturers of America) who lobbied the government for trade sanctions.</p> <p>International exhaustion permits a Member to import from any other country in the region provided it does not discriminate - i.e. a regional provider over another.</p> <p>National legislation must include exhaustion rights principles for that Member to be able to engage in parallel imports.</p> <p>National access to essential drugs is a question of strategic importance. The ability to develop regional manufacturing capabilities and a diversified array of sources for drug imports represents a sound economic and military policy.</p>
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### 3.3 Policy and Health System Responses

#### 3.3.1 Essential drugs

Effective national drug policies and the adoption of essential drug lists are factors in lowering drug prices. A study of international drug pricing done in the 1980s showed that the presence of successful national drug policies was a major factor in lowering drug prices. Furthermore, countries that adopt essential drug lists will have a mechanism for determining what drugs are needed according to the disease patterns in their own countries and can base approvals and/or government procurement based on need, efficacy and price.

MSF recommends that countries support discussions on proposals to exempt essential drugs from certain TRIPS obligations. The WHO published the first Essential Drugs List (EDL) in 1977, defined as: *"those [drugs] that satisfy the health needs of the majority of the population [that] should therefore be available at all times in adequate amounts and in the appropriate dosage form."* The inclusion criteria for the WHO's EDL are not only safety and efficacy, but also economic considerations, specifically the price of the products.

Many drugs that are considered essential from a therapeutic or public health point of view are not included, because of their high cost. Thus, it is useful to appreciate that the EDL itself is dependent upon the prices of drugs, and the prices are related to the intellectual property rules applied to those drugs.

#### 3.3.2 Trade and price options

**Multi-level pricing** or tiered pricing is common in many economic and marketing activities. Anyone who has travelled knows that passengers on the same class of the same plane pay different prices for their trips. Similar products on the shelves of supermarkets are marketed at widely different prices with only changes in labels and presentation.

Health experts are seeking a way out of confrontation on drug pricing and TRIPS. Attending a MSF meeting, an official of the World Bank responsible in part for the

US\$800 million worth of drugs purchased by the Bank yearly admitted that the drug-price structure “shows an increasing disconnect with the needs of the majority of the people in the world.” He said the Bank was “comfortable” with compulsory licensing and parallel imports and that the pharmaceutical industry may be nudged towards a tiered pricing arrangement in which the West would pay one price for a drug and developing countries another (WIPO 1998).

**Generic drugs:** Under TRIPS, the emergence of a generic drug sector may be harder to duplicate. In the past, in a number of developing countries, the generic drug sector represented a set of successful social policies. In the field of pharmaceuticals, India has been successful in the past with a home-based manufacturing of generics, and massive exports of cheaper drugs.

International Generic Pharmaceutical Alliance spokesman Greg Perry told a conference on TRIPS in Geneva in early 1999 that:

*The originator industry, for its part, could agree to a) provide new products at a «subsidised price» for an agreed number of years and b) accept a series of government actions aimed at stimulating the generic sector in the off-patent area. The governments, for their part, could agree to prevent parallel importing between their countries and grant fast authorisations for new products on their markets. In this way the originator industry could generate its high income in the normal way from advanced and middle-income countries but ensure access in lower income markets without the fear of parallel trade.*

**A combination:** Consultant to Médecin sans Frontières and editor of the French review *Prescrire*, Pierre Chirac says:

*“the best option would be Western countries implementing two-tiered pricing (but with no parallel imports from South to North) and/or accepting industries from the South competing locally (but without export to the North). In other words: compulsory licensing in India, accepting Indian exports to Burkina Faso and allowing Western companies to compete with Indian prices....”*

### 3.3.3 Access to drug information

Intellectual property protection in national legislation or through international trade agreements should not be used to unjustifiably maintain corporate control over drug information. Specifically, access to clinical trial data is necessary for the public and health care professionals to make rational decisions about drugs.

### 3.3.4 Alternatives to promote R&D locally

Patents are not the only means for promoting R&D nor do they ensure that needed drugs are brought to market. Trade agreements must be negotiated and interpreted in ways that will permit the adequate redress of that market failure.

### 3.3.5 Health registration data

Article 39 of TRIPS concerns health registration data. It is a little debated and little understood provision that requires WTO members to protect health registration data from disclosure or unfair commercial use. Some have argued that TRIPS requires countries to

provide some level of exclusivity for the use of scientific data to register a pharmaceutical product for sale, including restrictions on using the data to register a competing product. In bilateral trade actions, the US government argued that TRIPS obligates countries to prevent generic drug companies from even relying upon published scientific papers or foreign government regulatory approvals, without permission from the “owners” of the data on which the papers or approvals were based.

In the absence of data exclusivity, generic drugs or drugs produced under a compulsory license can be introduced into the market on the basis of simple bioequivalence tests, without having to replicate time consuming and expensive clinical trials used to establish the efficacy and safety of the products. But if the WTO requires countries to adopt excessive protection for data exclusivity, there will be problems providing marketing authorisation for generic products and drugs produced under a compulsory license using existing registration data. At present, several countries, including the US and the members of the EU, provide several years of data exclusivity, for purposes of regulatory approval of pharmaceuticals. Some public health groups propose that the current US and EU rules on data exclusivity be replaced with new rules that curb abuses such as the Taxol (Paclitaxel) case. Some proposals would include requirements that companies make public disclosures of the actual costs of clinical trials and other data they seek to protect from "unfair commercial use," and that protections be reasonably related to the actual investment costs.

The actual impact of Article 39 on competition and access to drugs is not clear, because the language in the Article is not precise regarding country obligations. The WTO interpretations of country obligations will be critical. The empirical evidence and economic analysis used to support various national policies regarding exclusive rights to health registration data, as well as the historical justification given for such policies needs to be examined. MSF argues that WHO should provide the WTO with a report on the least trade restrictive policies with regard to protection of such data and accept public comment on anti-competitive aspects of current national regimes. This would include the 10-year period used in the European Union that was initially introduced to compensate for the lack of patent protection in Spain and Portugal. By providing the WTO with a communication on the need to avoid excessive and anti-competitive levels of data exclusivity, countries can help set a pro-public health agenda on this issue.

### **3.4 TRANSPARENCY IN AND ENGAGEMENT WITH WTO**

The previous sections highlight the potentials and constraints to WTO agreements in relation to the public health interests of southern African countries. Clearly intervening to highlight the problems and direct WTO agreements towards a more comprehensive inclusion of the situation facing southern Africa, and indeed other developing countries, demands an open and transparent decision making process within the WTO. Several developing country WTO members states’ concerns about the lack of transparency (the practice of taking decisions “in the Green Room” of the director), are further highlighted by the protestors in Seattle in November 1999. Specifically in relation to TRIPS, within WTO, diverse groups of developing countries’ representatives are demanding flexibility on deadlines for TRIPS adherence, and more transparency, more of a share in decision making.

It is clearly an uneven playing field. The benefits Africa gained from the trade liberalisation decisions made in the course of the Uruguay Round have been questioned. If

there has been a global positive increase in trade estimated at \$212-510 billion, this has not been the case for Africa. Sub-Saharan Africa is set to lose US\$1.2 billion a year. (Koivusalo 1999). The UNDP (1999) reports that sub-Saharan African regional governments transferred to northern creditors for debt service four times what they spend on the health of their people.

*"The prospect of integrating our countries to the global economy is extremely dim," noted Benjamin Mkapa, President of Tanzania. "Meanwhile, such industries as we have will be affected by imported products that run our companies out of business."*

South Africa was among the first emerging country to join WTO. It had high expectations for export potential and capacity to attract foreign investors as a result of membership. But the country has seen economic growth rates decline from about 4% in 1994 to 0% in 1998 and a decline in key areas of social investment, such as health spending over the past five years. This signals the challenge that most SADC countries face in dealing with WTO. It would appear that under these conditions, with the added burden of HIV/ AIDS levels that exceed that experienced in any other region on the world, there is need to question the adherence to and clauses of TRIPS when they pose unfair choices between international trade and national health interests. This is not an issue for the region alone: It is an issue that relates to how institutions of international governance respond to the priorities of human development and health. This implies that in addition to the legal and policy responses noted in the previous section, SADC governments and civil society would need to explore the institutional options for ensuring that WTO policy discussions are better understood, include and responded to the realities and interests prevailing in southern Africa.

Representatives from civil society have a role to play in informing parliamentarians about the repercussions of legislation. For instance, in Kenya, MSF works alongside local NGOs such as the Kenya Consumer Organisation to campaign for the repeal of a restrictive TRIPS bill. In India, the government signed a bill on Exclusive Marketing Rights (EMR) to become TRIPS compliant. In India, health NGOs are opposed to EMR because they are concerned it could lead to massive hikes in the price of medicines and jeopardise India's highly successful domestic generics industries. They are asking the Court to declare the EMR bill unconstitutional.

Health Action International (HAI) is calling for WHO's Action Programme on Essential Drugs and UNIDO to co-ordinate an international programme with generic manufacturers in developing and developed countries to produce a selection of essential drugs for the world market.

On a global level, such support from activists can help individual governments who are having difficulties asserting their rights under TRIPS. For instance, when South Africa came under attack by the U.S. government, AIDS activists such as ACT-UP were crucial in awakening popular sentiment, including in the U.S. They generated a lot of media coverage on the plight of AIDS victims and the terrible responsibility the government of South Africa faces. As a result, the government received support from international organisations like MSF and from Ralph Nader and Love's Consumer Project on Technology.

One critical institution of international governance that should be a focus of policy debate on these issues is the WHO. In May 1999, after more than a year of debate, the World Health Assembly (1999) unanimously called upon member states:

*(1) to reaffirm their commitment to developing, implementing and monitoring national drug policies and to taking all necessary concrete measures in order to ensure equitable access to essential drugs;*

*(2) to ensure that public health interests are paramount in pharmaceutical and health policies;*

*(3) to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs.*

The World Health Assembly resolution signals the beginning of a much-needed dialogue among governments, international organisations, NGOs and industry regarding trade agreements and health care technologies. The resolution gives WHO a new mandate to monitor the health implications of trade agreements and provide assistance to countries in implementing trade regulation while protecting public health. Indeed, there are signs that support for greater sensitivity to public health considerations in trade is gaining momentum. For example, over the past six months, high officials from the WHO, UNAIDS, the World Bank, and several national governments have expressed support for the use of compulsory licensing of patents to address the global HIV/AIDS crisis. There are several international discussions taking place regarding the WTO's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to determine if and how the TRIPS might be changed or interpreted to ensure that public considerations are indeed paramount in trade policy.

Such statements of principles and the priorities that guide the interaction between SADC countries and the WTO on health issues can usefully also be made at SADC level. National government and civil society health representatives can be usefully included in WTO consultations that have a direct bearing on health, such as TRIPS and GATS. SADC is also a useful vehicle for information and capacity development for national authorities and public representatives to better understand the health implications of WTO agreements and to prepare responses to them. Within a regional platform, SADC countries can usefully draw together their government and non-government organisations to develop a regional lobby towards the development of trade systems that are more responsive to the public health demands of the region.

## Abbreviations and Acronyms

ATN	African Trade Network
ARTs	Antiretroviral drugs
DAP	Action Programme on
DC	Developing Countries
DSB	Dispute Settlement Bo
DSU	Understanding on Rule
EMR	Exclusive Marketing R
EC	European Community
EU	European Union
FAO	Food and Agriculture O
GATS	General Agreement on
GATT	General Agreement on
GSP	Generalized System of
HAI	Health Action Internati
HIV	Human Immuno-defici
IBRD	International Bank for
IDRC	International Developm
IMF	International Monetary
IP	Intellectual Property
IPR	Intellectual Property R
ISO	International Standards
LDC	Least-developed Count
MAI	Multilateral Agreemen
MERCOSUR	Southern Common Ma
MFN	Most-favoured-nation
MSF	Médicins Sans Frontièr
MTCT	Mother-to-Child Trans
NGOs	Non Governmental Org
PhRMA	Pharmaceutical Resear
R&D	Research and Developm
SAA	Statement of Administr
SADC	Southern African Deve
TB	Tuberculosis
TBT	Agreement on Technic
TPRM	Trade Policy Review M
TRIMs	Trade-Related Investm
TRIPS	Agreement on Trade-R
UNCTAD	United Nations Confer
UNICEF	United Nations Childre
UPOV	International Union for
USTR	United States Trade Re
WHA	World Health Assembl
WHO	World Health Organiza
WIPO	World Intellectual Prop
WTO	World Trade Organiza

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