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Analysis of Trips Agreement and implications on the fight against HIV/AIDS and poverty in Southern Africa

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Introduction

The Southern Africa region remains the epicentre of the global AIDS epidemic. About 14 million adults and children are currently infected with HIV in southern Africa, accounting for 51 percent of all infections in Africa. The following tables summarise HIV prevalence rates, numbers of people living with HIV/AIDS, people on treatment and the unmet need for treatment in selected southern Africa countries.

For countries to be able to trade with each other, goods and services have to be produced by labour. HIV/AIDS and poverty both influence negatively a person's ability to provide labour. As such, people are central to the production of both goods and services and therefore also to trade. However, the main focus of this paper is to highlight the link between trade in drugs for HIV/AIDS treatment and how trade laws and practices hinder access to treatment for people living with HIV and AIDS. The right to essential treatment for People living with HIV/AIDS (PLWHA) is a human right to life. Table 1 below indicates the number of people living with HIV/AIDS in southern Africa according to UNAIDS 2004.

Table 1: Overview of HIV and AIDS Epidemic in southern Africa

Country	Prevalence	Adults living with HIV	Women living with HIV
Angola	**3.9**	**240 000**	**130 000**
Botswana	**37.3**	**350 000**	**190 000**
DRC	**4.2**	**1.1 million**	**570 000**
Lesotho	**28.9**	**320 000**	**170 000**
Malawi	**14.2**	**900 000**	**460 000**
Mauritius	**-**	**-**	**-**
Mozambique	**12.2**	**1.3 million**	**670 000**
Namibia	**21.3**	**210 000**	**110 000**
South Africa	**21.5**	**5.3 million**	**2.9 million**
Swaziland	**38.8**	**220 000**	**110 000**
Tanzania	**8.8**	**1.6 million**	**840 000**
Zambia	**16.5**	**920 000**	**470 000**
Zimbabwe	**24.6**	**1.8 million**	**930 000**

The most severe development challenge facing the region (UNAIDS; WHO, 2004)

The need for antiretroviral therapy (ART) is urgent. As illustrated in Table 2 below, in most countries in southern Africa, less than 20% of the people who need treatment are currently accessing it (UNAIDS/WHO, 2005). This high level of unmet need for treatment can be reduced by the production and availability of cheap antiretroviral drugs that poor countries, communities and individuals can afford to buy.

Table 2: PLWHA on Treatment in southern Africa

Country	PLWHA on ART	%	Unmet Need
DRC	5000-6000	2-3	203 000
Lesotho	2500-3000	4-5	55 000
Malawi	18000-23000	11-14	150 000
Mozambique	11000-13000	5-6	204 000
South Africa	5500-9500	2-3	307 000
Tanzania	97000-138000	10-14	866 000
Zambia	26000-33000	14-18	153 000
Zimbabwe	9500-16000	3-5	308 000

(UNAIDS; WHO 2005)

UNAIDS (2005) noted that with the exception of Zimbabwe, the countries of southern Africa show little evidence of declining epidemics. While governments in the region have attempted to put in place infrastructure for the provision of HIV/AIDS treatment, universal access to treatment remains unattainable to many. This is clearly indicated by the number of people living with HIV/AIDS in need of treatment, but not accessing it, as discussed above. One may ask the question WHY treatment? While HIV/AIDS drugs are not a cure they will improve the health and well being of PLWHA leading to many years of healthy life and increased productivity; reduced numbers of orphans; and reduced burden of care on individuals, communities and governments.

In reality, the cost of providing ART to those who need it would more than exceed the health budgets of many countries. With the exception of Botswana, Namibia and Zambia where ARVs are for free, cost of treatment ranges from US$120.00 in Lesotho to as high as US$250.00 in Malawi (WHO, 2005). This is a clear indication of high pricing of life serving drugs in countries where 50% of their populations survive on less than US$1.00 per day. One of the reasons for this very high cost lies in the activities of the WTO and in particular, the provisions of the TRIPS agreement.

TRIPS Agreement on HIV/AIDS and POVERTY

It is imperative to highlight at the onset that the World Trade Organisation (WTO) Hong Kong meeting of December 2005 did not change anything on Trade Related Aspects of Intellectual Property Rights (TRIPS) of 1995. How then does TRIPS affect access to treatment?TRIPS covers trade in services and inventions, creations and designs (intellectual property).

- Creators are given the right to prevent others from copying or using their inventions, designs or creations as to an incentive to produce more new ideas.
- These might be in the form of medicines, films, music, and books, new technology, and branded clothing. It gives them the right to charge for the use of them. This is called patenting.
- TRIPS covers issues of copyrights, trademarks, industrial designs, patents, designs and trade secrets.

A major area of TRIPS covers the regulations regarding the patenting of drugs. TRIPS protects companies from anyone copying their products including drugs for HIV/AIDS treatment. When countries sign on to the World Trade Organisation (WTO) they also sign up to protect the patent

rights of companies who sell products within their countries. TRIPS requires that a country provides patent protection on drugs for a period of 20 years, during which time, cheaper copies (generics) may not be produced or sold. Companies who have these patents on their products and drugs claim that this is an essential element in international trade, as it guarantees them income in return for the investment they have made in the development of the drugs. Patents are often a source of dispute between nations. One argument for strong protection of patents is that, if patents were ignored, there would be less incentive to be innovative in the pharmaceutical industry. However, it is known that the underlying argument for wide recognition of patents is that they provide financial incentives in the form of large profits, only part of which are used to support research and development. The patent system is designed to enable the patent holder to set prices higher than those that would be obtained in a competitive market.

This high cost of HIV/AIDS medicines is part of the grave problem that afflicts developing countries and least developed countries. Those against patent protection argue that the monopoly granted to patents allows the patent holder to charge high prices, depriving the poor of an essential product. Many people perceive this as putting profits first before human lives. The hundreds of people dying unnecessarily from HIV/AIDS in developing countries as well decisions by countries like South Africa to import generics in spite of the TRIPS regulations has led to pressure on pharmaceutical companies to lower the prices of drugs and for the relaxation of the patent laws to allow governments to save people.

Enforcing Intellectual Property Laws

TRIPS stipulates clear procedures to enforce intellectual property laws.
Governments have to ensure that intellectual property laws can be enforced in their countries using their own legal mechanisms
Penalties must be tough
Courts should have a right to destroy pirated products
Governments should make sure that IPR owners have the power prevent imports of counterfeit and pirated products through the assistance of customs authorities

However, at Doha, members agreed that the TRIPS agreement does not and should not prevent countries from taking measures to protect public health and that public health should take precedence. In theory this means poor countries can manufacture, buy and import cheap generic copies of the more expensive, patented drugs if there is a threat to public health. It was also agreed at this meeting, that exemptions on pharmaceutical patent protection for least developed countries be extended until 2016, and up to 2005 and others 2006 for developing countries.

This was catered for in what is generally known as the TRIPS Flexibilities, which include: compulsory licensing, parallel importation, and local production of patented products after declaring an emergency and using the compulsory licences.

How flexible are these flexibilities? What are the challenges that countries have encountered?

- *Interpretation of TRIPS on what constituted a public health emergency* was found a challenge by many developing countries. In the DOHA Declaration they recommended that it be made clear that in the event of a dispute between intellectual property rights (IPR) and public health, IPR should not override public health. These 'flexibilities' have been central to several analyses. However some governments remain unsure how these can be interpreted and how far their right to use them will be respected, without leading to censure from the WTO.
- *The process* by which a country can declare that it needs the patent for a drug to be suspended as a matter of emergency is wrapped in even more red tape and restrictions. The flexibilities are no more than cosmetic.

Compulsory license

Looking individually at three provisions encompassed as flexibilities, a compulsory license is a government license that enables people other than the patent holder to copy patented or copyrighted products and processes. Governments can issue them if a patent owner abuses their rights by, for example, failing to offer their product on the market, or offering it at price that is too high for potential buyers to afford. Competitors can then produce the product or use the process under government license without fear of prosecution.

Challenges with compulsory licenses are that Article 31 of TRIPS sets forth a number of conditions for the granting of compulsory licences (case by case determination) *A government must declare an emergency before it can use a compulsory licence,* and this requires prior negotiation with the patent owner and may also include some form of remuneration for the use of the patent. However, declaring a national emergency can allow a member to authorise the granting of compulsory licence in circumstances of extreme emergencies without the obligation to negotiate prior with the patent owner. In order for countries to fully take advantage of this flexibility and many others provided by the TRIPS agreement and confirmed by the DOHA Declaration, national laws must incorporate the appropriate rules in the form of Compulsory Licence and other relevant provisions.

A survey conducted by Thorpe in 2002 covering the patent laws of 70 developing countries indicates that only 13 have provided for national or health emergency as specific grounds for the granting of compulsory licences. This means very few countries are able to make use of this provision. Even then such flexibilities do not automatically translate into national laws and do not protect governments or private parties from legal actions based on national laws and regulations.

Like India, China made concessions in order to enter WTO that will directly impact its ability to produce generic ARVs. Despite the flexibilities contained within the TRIPS agreement, both countries now appear to be backing away from breaking patents and copying drugs such as tenofovir (viread) or lopinavir/ritonavir (better known as Kaletra), that are key ARVs in treatment scale-up. Why? Treatment advocates argue that pressure from both the United States and big pharmaceutical companies has seriously hampered the willingness of China, Brazil, and India to issue compulsory licenses for ARVs and break patents. Speaking at the Kobe meeting, China's vice-minister of health, Wang Longde, refused to endorse generic production of second-line ARVs. When asked by Chinese PLWHA how his government would handle the rapid growth of drug resistance that is being seen in China, Wang said only that "China made commitments when it joined WTO, and China will keep its word" not to break the patents.

Members can manufacture generic drugs

The second flexibility focuses on the manufacture of generic drugs by member states. Countries producing generics include Canada, Brazil, Zimbabwe, South Africa, China and Singapore. However, the biggest producer of generics is India, followed by Brazil. India has been the source of cheaper drugs for developing countries because they had no regulations on patenting for pharmaceutical products and they were able to produce generic drugs at a fraction of the price of the patented product. Not only do Indian companies make the finished tablet form of drugs, they also produce cheap generic versions of the raw ingredients and chemicals used in their manufacture, many of which are actually exported to major multi-national companies to produce their brand-named versions.

The main challenge for this flexibility is that most developing countries lack the capacity or have insufficient capacity to manufacture medicines on their own, or to produce active ingredients and formulations, and very few countries maintain significant research and development capabilities. On 1st January 2005 however, the 5-year transition period awarded to India to allow the country's laws time to conform to TRIPS, came to an end and new patent laws came into force. All drugs registered after 1995 will be affected. The ARV drug Combivir (zidovudine/lamivudine combination) commonly used in Africa, is one of the many that are

likely to be affected, as it was patented after 1995. Most of the producers of new HIV/AIDS drugs will already have filed for patents in India, which, if granted, will last for 20 years, preventing any generic copying during this time, as well as forcing all current production to stop. Countries that have no capacity to manufacture or import will be left with minimal choices and will be forced in some cases to purchase expensive, patented drugs.

Another problem is that TRIPS stipulates that a product made under the compulsory licence be supplied predominantly to the licencee's domestic market. In practical terms this means countries with large markets like India, the UK, and the USA could easily grant compulsory licences for the supply of patented medicines to meet public health needs. However, the member countries with small markets, like the African countries where the AIDS crisis is also most severe, will be unable to establish viable production if the manufactured product must be predominantly sold in the local market. Although TRIPS has provided for countries to import a drug that is patented in that country from a country where there is no patent on the same, the patent owner can block the supplies to the importing country.

In the same vein that country might not be allowed under its compulsory licensing, to export to another country, since the compulsory licensing demands that the producing country should predominantly supply the domestic market. The fear and uncertainty with regard to the legalities associated with parallel imports and the other flexibilities, is a discouraging factor and may effectively prevent the use of such a mechanism as a means to obtain medicines at lower prices than those domestically available. The only way around this problem would be for the government to grant compulsory licenses. Sadly these too, are not without their problems. They can be difficult and complicated to impose and require a great deal of government time and departmental cooperation to draw up. They also have political implications, as companies and countries that hold the original patents to drugs are unlikely to want to invest in a nation that is copying their products and will use this threat against them.

Parallel Imports

This principle allows the import of a patented product into a country without the authorisation of the title-holder or his licencees, to the extent that the product has been put on the market elsewhere in a legitimate manner. In the DOHA Declaration, the developing countries made sure they added that a member country is free to establish its own regime 'or' to adopt the international principle exhaustion of rights, to enable parallel imports without challenge, few countries have taken advantage of this.

In 2001 for example, thirty-nine major pharmaceutical companies tried to prosecute the South African government for passing a law (which they said was against TRIPS regulations) that allowed production and importation of generics. Following pressure from the South African government (which was itself under intense pressure from treatment activists), the European Parliament and 300,000 people from over 130 countries signed a petition against the action and the pharmaceutical companies were forced to back down. However the multinational pharmaceutical companies are now issuing compulsory licences, rather than allowing the cheapest generics to be widely available.

Despite all the flexibilities provided by TRIPS, access to treatment is still and will remain a dream for many people in developing and least developed countries, unless something changes.

Implications for the Fight Against HIV/AIDS and Poverty

Activists need to urgently mobilise and lobby for the following policy changes. Flexibilities need to move from being cosmetic to being applicable with minimal barriers. The barriers that hinder countries from taking advantage of the flexibilities provided by TRIPS need to removed as a matter of urgency. People are dying while the debate on patents and intellectual property rumbles on. This needs to stop and energies need to be directed at saving lives.

Countries like the USA must stop putting indirect pressure on governments on behalf of the big pharmaceutical companies, which prevents countries from utiliing the flexibilities. The 20-year patent periods are too long and serve the profits of the pharmaceutical manufacturers and not human life. Universal access to treatment is a human right and an obligation of governments and this can be realised through a reduction in the production costs of drugs.

The TRIPS agreement and its impact on the technological and development capacities of the region's countries, and the rights of governments to secure the production and provision of affordable medicines to deal with the HIV/AIDS epidemic and other diseases must be exposed. Other provisions under the GATS (General Agreement on Trade and Services) also impact on the delivery of human rights and health services especially for HIV/AIDS, and will hinder both social and economic development. The notion of NAMA (Non-Agricultural Market Access) favours the interests of transnational corporations (TNCs) and will have a serious impact on manufacturing and consequently on unemployment and poverty, compounding the effects of HIV/AIDS.

Civil Society Organisations Proposed Engagement

- Capacity development on the linkages between TRIPS, HIV/AIDS and Poverty
- Intensify research based advocacy to:
    - change trade laws and practices
    - secure debt relief
    - assist countries to utilise the flexibilities
- Strengthen government, NGO and private sector partnership to address the challenges

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