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POLÍTICAS DE SALUD Y SUS IMPLICACIONES HACIA ÁFRICA.

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Trade Related Aspects of Intellectual Property Rights (TRIPs):

a barrier towards fighting HIV/AIDS in Africa

Since the negotiation of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement at WTO negotiations, rich countries and the pharmaceutical industry have delayed competition from generic medicines with disastrous consequences for millions of Africans with HIV/AIDS. This paper shall analyze:

- 1. How TRIPS Agreement safeguards to protect public health have been undermined by patent extensions, clinical trial data protection, obstruction on the import, export and transit of generic drugs thus favoring multinational pharmaceutical corporations,*
- 2. Other blocking strategies such as the "manufacture of consent" and establishment of linkages with Free Trade Agreements and the Anti-Counterfeit Trade Agreement,*
- 3. Intellectual Property (IP), and incentives to pharmaceutical Research and Development (R&D) in Africa,*
- 4. Drug Policy toward Africa by the major foreign actors USA, EU, China and India.*

TRIPS, HIV/AIDS, Pharmaceuticals.

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INTRODUCTION

Sub-Saharan Africa is the most heavily affected region in the world by HIV/AIDS, with an estimated 22 million people infected in the region, this corresponds to approximately two thirds of the global total. Globally 2.7 million people became newly infected with HIV in 2008; the good news is that this is a 17 percent decrease over the last eight years. In reality this means that for every two people accessing treatment, five people are becoming infected. Its impact will be most devastating in the next decade and have dire social and economic consequences in agriculture, industry and human security, especially on the African continent.¹

During the last decade three main reasons have led to a significant growth in the treatment of HIV/AIDS in developing countries, namely pressure exerted by civil society along with a more assertive behavior by emerging powers such as India, China, Brazil and South Africa relative to “Big Pharma”, and finally growing competition from generic manufacturers. The result has been a drastic reduction in the price of HIV/AIDS medicines known as antiretrovirals (ARVS). This “moderation” in prices has led to an estimated four million people, in low and middle income countries,² receiving treatment. However many of the newer more effective drugs, with higher prices are inaccessible to developing countries.

EVOLUTION IN TREATMENT

In 1996, when HAART (Highly Active AntiRetroviral Treatment) an effective combination therapy appeared on the market in the developed world,³ death rates fell 84 percent in four years.⁴ Unfortunately for developing world standards, the price range of between USD \$10 000 and \$15 000 per patient / year made the treatment inaccessible to the majority of the population in Africa and other developing countries.⁵ However in 2001, when the Indian manufacturer Cipla launched a generic triple-therapy ARV, costing \$350 per patient/year, prices suffered a remarkable reduction. The Indian generic manufacturer also innovated in producing a fixed dose combination

¹ UNAIDS. “2008 Report on the global AIDS epidemic”

http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp, accessed 15.08.2010.

² WHO/UNAIDS/UNICEF (2009), “Towards Universal Access: Scaling up priority HIV/AIDS Interventions in the Health Sector”.

³ David Brown. “With fanfare, Global AIDS Conference gets underway in Vancouver”, Washington Post 07.08.1996. <http://www.qrd.org/qrd/aids/cdc/daily.summaries/1996/july/07.08.96>, 15.08.2010.

⁴ The Lancet 2003. “Determinants of survival following HIV-1 seroconversion after the introduction of HAART”,. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(03\)14570-9/fulltext#cor1](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(03)14570-9/fulltext#cor1), 15.08.2010.

⁵ S Nolen. *28 Stories of AIDs in Africa*, Portobello Books, 2006.

(FDC) of three ARVs, making adherence by patients and therefore health workers job much easier, and reducing the incidence of drug resistance. The FDC was also heat resistant, which is of extreme importance in African countries, due to inexistent or malfunctioning refrigeration facilities and inefficient logistics. First-line ARV prices further declined between 30 and 68 percent, between 2004 and 2008, costing an average \$88 per person /year.⁶

Today India is still the largest supplier of ARV generics to developing countries, exporting two thirds of the drugs it manufactures.⁷ South Africa, Brazil, China and Thailand also produce important amounts of generic drugs, while African countries such as Ghana, Tanzania, Uganda, Zambia and Zimbabwe have developed a fragile local ARV manufacturing infrastructure.⁸

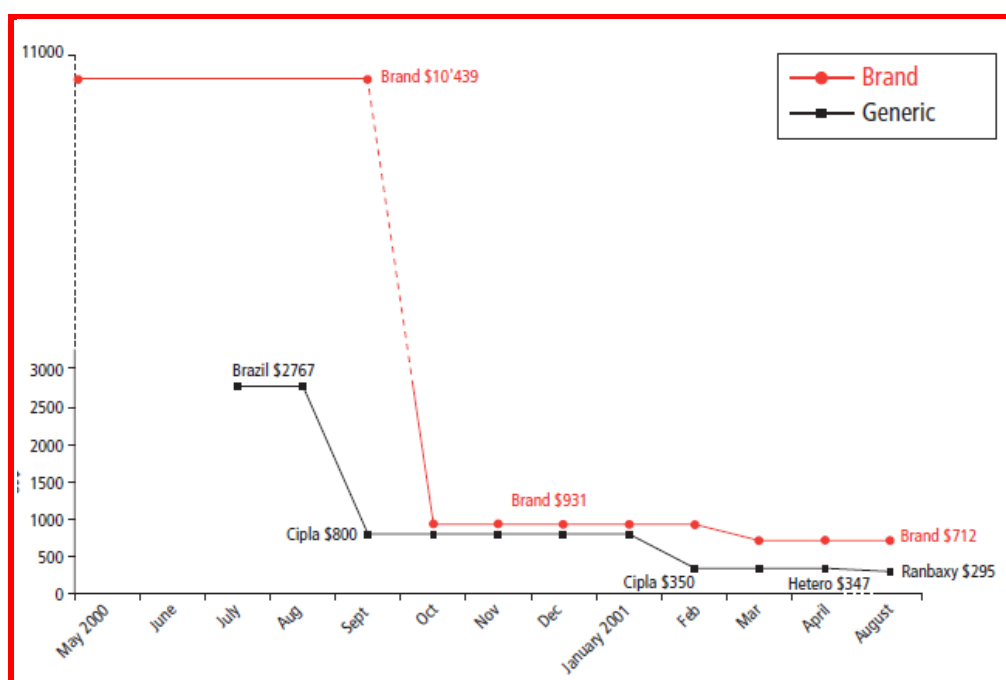


Figura 1: Effects of Generic Competition: AIDS Triple combination, stavudine(d4T), lamivudine (3TC) and nevirapine.

Source: http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf, accessed 15.08.2010.

Multiple organizations such as Doctors Without Frontiers, The Clinton Foundation, UNITAID, civil society groups and activists have had a fundamental effect on limiting prices, by exerting pressure on major pharmaceutical companies.

⁶ Médecins Sans Frontières (2001). "A Matter of Life and Death: The role of Patents in Access to Essential Medicines". http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf, accessed 15.08.2010.

⁷ UNAIDS. "2008 Report on the global AIDS epidemic" http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp, accessed 15.08.2010.

⁸ AVERT. "AIDS, drug prices and generic drugs", <http://www.avert.org/generic.htm>, accessed 15.08.2009.

TRIPS, a Regression in Treatment of HIV/AIDS?

Trade Related Aspects of Intellectual Property Rights (TRIPS) was introduced in 1995, and applicable to all World Trade Organization members. Different time limits were established for compliance to TRIPS: developed countries were given one year to comply, developing countries such as India 10 years, and finally least developed countries were given until 2016. Patents or exclusive rights to manufacture and sell a drug permit the proprietary drug maker to recoup the investment on research and development (R&D). Generic drug makers incur much lower costs since they do not undergo much of the R&D phases such as drug discovery or safety and efficacy trials. Thus, generic manufacturers use reverse-engineering techniques on known drug compounds with expired patents.

Exceptions to TRIPS established in the 2001 Doha agreement include **compulsory licensing**, which occurs when a government issues a license authorizing the copy of a patented pharmaceutical without fear of legal action. These licenses are issuable when the patent holder does not make the product available, or, asks for a price considered to be exceptionally high for a given market. Still even under this figure, the generic manufacturer has to negotiate the payment of royalties with the patent holder. The Doha agreement further acknowledges the issue of a compulsory license without the obligation to pay royalties, when a severe health emergency occurs in a country. Even though theoretically this option is possible, in practice, countries have huge difficulty in invoking these exceptions, and are highly constrained in doing so due to: retaliation by large pharmaceutical companies who refrain from introducing new products,⁹ besides issues relating to intellectual property being linked to economic and technical cooperation, and bilateral free trade agreements. Furthermore, invoking a compulsory license does not permit the parallel export to other emerging markets. The countries which do not have a domestic pharmaceutical manufacturing industry, have the possibility of adhering to a “paragraph 6 waiver” issued by the WTO allowing them to confront serious health crisis, by importing generics from other countries under compulsory license.¹⁰

Free Trade Agreements (FTA) have often been used to extend patent protection way beyond that which is required under TRIPS, coining them the classification of TRIPS plus, reducing or eliminating outright public health safeguards. Some of these FTA go so far as to eliminate the possibility of a compulsory license during a health crisis. Other obstacles include the establishment of **data exclusivity**

⁹ This was the case of Thailand's compulsory licensing in 2006/07 of Merck's ARV Sustiva and Abbott's Kaletra. Abbott promptly announced it would not apply for licenses relative to at least 7 new products.

¹⁰ Oxfam. “Trading Away Access to Medicines: How the European Union's Trade agenda has taken a wrong turn”. Oxfam October 2009. <http://www.oxfam.org/sites/www.oxfam.org/files/bp-trading-away-access-to-medicines.pdf>, accessed 16.08.2010.

thus blocking the introduction of generic products. Data exclusivity means that where normally generic manufacturers simply proved bio-equivalence relatively to the original patented product, they actually relied on the original test data so as to prove safety and efficacy. Most FTA protects the data for five to ten years after it is initially submitted, forcing generic manufacturers to pay for the same trials as those already done by “Big Pharma”.

Patent extensions have also been added or frequently negotiated by the USA and the EU so as to protect its pharmaceutical industry. This patent extension beyond the standard 20 years stipulated by TRIPS, is supposedly meant to compensate for delays in regulatory approval. Some pharmaceutical companies use a further strategy, known as “evergreening”, which is an application for a new patent on a previously patented product, claiming “new use” of the drug.

A ground-breaking event occurred in 2001 when South Africa issued a law, allowing for easier production and importation of generic ARVS, and was immediately prosecuted by thirty-nine major pharmaceutical companies. Due to the enormous projection of South African government and international public outcry, the pharmaceutical industry caved in to negotiations. One of the major companies involved, GlaxoSmithKline (GSK), even issued a permission for a voluntary license for rights to its drugs AZT, 3TC and Combivir, to South African generics producer Aspen.¹¹

More recently partnerships between various NGOs and international institutions such as the William J. Clinton Foundation, UNITAID and Doctors Without Frontiers have continued to partner together and managed important reductions in prices of ARVS. The use of innovative methods, such as a system of “tiered pricing” has been developed, with the prices of drugs being calculated using a formula based on average income per head, originating lower prices in African countries.¹² Other initiatives aiming to achieve optimal pricing include The Global Price Reporting Mechanism (GPRM), developed by Aids Medicines and Diagnostic Services (AMDS) a team in the WHO HIV/AIDS division. This database provides information on transaction quantities and prices of ARVS in low and middle income countries¹³. Still these systems are considered to be over complicated and based on the goodwill of the pharma industry. Daniel Vasella former CEO of Novartis until recently, comments that the pharmaceutical industries view on Corporate Social Responsibility (CSR) by the

¹¹ Ben Hirschler. “Glaxo gives up rights to AIDS drugs in South Africa”, Reuters 06.10.2001. <http://www.aegis.com/news/re/2001/RE011009.html>, accessed 15.08.2010.

¹² UNAIDS. “2008 Report on the global AIDS epidemic” http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp, accessed 15.08.2010.

¹³ WHO (2009) “Global Price Reporting Mechanism 2009, Transaction prices for antiretroviral medicines and HIV diagnostics from 2008 to October 2009”, <http://www.who.int/hiv/amds/gprm/en/>, accessed 15.08.2010.

pharmaceutical industry has accompanied the attitude of NGOs and civil society in the direction of closer collaboration. Like companies, NGOs are not all the same: “They range from 180 degrees collaborative to 180 degree oppositional.” He argues that companies “need to keep open a dialogue with the ones we can, but so do they”.¹⁴

Counterfeits and Generics. Drugs and active pharmaceutical ingredients for ARVS and generics in general often originate from India, called by many African countries the “pharmacy of the world”. China has also seen a significant growth in its drugs manufacturing industry. For counterfeiters the absence of regulatory authorities, unreliable statistics and ignorant consumers makes the small African market tastier, than the much bigger and potentially more lucrative Western markets. However, any drug with an incorrect or absence of active ingredient may lead to serious health problems or create resistance to the specific drug. It is estimated that the prevalence of counterfeit drugs in Africa is between 16 and 35 percent.¹⁵ Even more dangerous is the fact that emerging markets located in Africa counterfeit not only lifestyle drugs, of which the best known examples are Viagra or Cialis, but also life saving drugs such as ARVs, antibiotics and treatments for malaria and tuberculosis.

An important distinction needs to be made in that counterfeit are intentionally deficient products, while a substandard product may unintentionally have the incorrect ratio of ingredients or incorrect packaging. This substandard product may also derive from logistical insufficiencies such as, poor transit and storage conditions. Many pharmaceutical products, including ARVs, require strict storage temperatures, or, loss of efficacy becomes a reality as has occurred in Zambia in 1997 and in other developing countries¹⁶. Political and economic incentives and pressure may also originate deficiencies in technology transfer and premature local production, leading to situations such as the occurrence registered in Thailand in 2007, when the state owned Government Pharmaceutical Organization actually produced a sub-standard ARV known as GPO-Vir. When the factory was finally shut down, resistance among patients undergoing treatment had actually hit the 50 percent mark¹⁷

“The truth is polyedric” is an expression well applicable so as understand positions for and against anti-counterfeiting legislation. The EU and the USA, on the

¹⁴ Economist Intelligence Unit. “Doing good: Business and the sustainability challenge”, http://graphics.eiu.com/upload/Sustainability_allponsors.pdf, accessed 15.08.2010.

¹⁵ Bate. Roger. *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade*. The AEI Press, Publisher for the American Enterprise Institute Washington, D.C. 2008. http://www.aei.org/docLib/20080520_MakingaKillingnew.pdf. Page 15. Accessed 06.08.2010.

¹⁶ E. C. Consten, J. T. van der Meer, F. de Wolf, H. A. Heij, P. C. Henny, and J. J. van Lanschot, “Risk of Iatrogenic Human Immunodeficiency Virus Infection through Transfusion of Blood Tested by Inappropriately Stored or Expired Rapid Antibody Assays in a Zambian Hospital,” *Transfusion* 37:9 (1997), 930–34, doi:10.1046/j.1537-2995.1997.37997454020.x accessed 11.01. 2008.

¹⁷ Roger Bate, “Thai-ing Pharma Down,” *Wall Street Journal Asia*, February 9, 2007, available at http://www.aei.org/publications/pubID.25585/pub_detail.asp, accessed 27.07.2010.

one hand, have legitimately promoted initiatives against counterfeiting,¹⁸ but on the other have sought to confound the concept of counterfeiting generally a trademark issue, with quality and safety of generic medicines, thus ignoring more important measures such as fulfilling real public health interest or the strengthening of regulatory authorities in the developing countries.¹⁹ Thus these two northern blocks have endorsed negotiations on the Anti-Counterfeit Trade Agreement (ACTA), so as to justify anti-counterfeiting measures through FTAs and at multilateral organizations such as the WHO, WTO and World Intellectual Property Organization (WIPO). This has led to the capture, throughout the EU and other world ports, of numerous legal shipments of generic drugs. Amongst multiple episodes recently a core ARV, known as abacavir, intended for Nigeria was apprehended in Germany. The ARV was purchased by UNITAID from a legal Indian manufacturer. After much public outcry the EU countries involved, Holland and Germany, eventually liberated the cargo on to its final destination.²⁰ Thus we see on the same side of the barricade: a strong PR defense in the interest of Northern hemisphere countries, pharma industry and health advocates in favor of anti-counterfeit legislation so supposedly defending public health, on the other hand Southern hemisphere health advocates argue that this legislations real purpose is the defense of pharma industries interests.²¹ Even though major manufacturers of pharmaceuticals such as China and India have made efforts at cracking down on counterfeiting operations,²² they have not seen their efforts recognized, with the secretary general of the Indian Pharmaceutical Alliance (IPA) General DG Shah commenting on counterfeits that: "... The EU definition goes further than WHO's definition (of counterfeit), by saying that if a drug--being exported or passing through – does not hold a valid patent in the EU then it will be termed as counterfeit. It is proved beyond doubt that counterfeit is no longer just a public health issue but has become a

¹⁸ European Commission Directorate General for Trade adopted the *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, which sets the context for protecting IPR and measures such as the identification of priority countries, the dynamics of bilateral and multilateral agreements, technical cooperation, retaliatory measures, dispute settlement and the creation of public-private partnerships aimed at the enforcement of intellectual property rights.

¹⁹ Xavier Seuba. "Border Measures Concerning Goods allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit", International Center for Trade and Sustainable Development, June 2009. <http://ictsd.org/i/publications/53747/?view=document>, accessed 14.08.2010.

²⁰ Kaitlin Mara. "Drug Seizures in Frankfurt Spark Fears of EU-Wide Pattern", Intellectual Property Watch 05.06.2010, <http://www.ip-watch.org/weblog/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/>, accessed 14.08.2010.

²¹ Kaitlin Mara. "Coverage of Anti-Counterfeit Policy Debate Varies Widely across Global Media", Intellectual Property Watch 02.08.2010, <http://www.ip-watch.org/weblog/2010/08/02/coverage-of-anti-counterfeit-policy-debate-varies-widely-across-global-media/>, accessed 14.08.2010.

Marc Guéniat. "Les médicaments contrefaits tuent 200 000 personnes et rapportent 200 milliards de dollar", Tribune de Genève 28.07.2010, <http://www.tdg.ch/actu/economie/medicaments-contrefaits-combat-ambigu-2010-07-28>, accessed 14.08.2010.

CNBC. "Counterfeit Goods". <http://www.cnbc.com/id/37824347>, accessed 14.08.2010.

²² China Daily, "Wu defends crackdown on bogus drugs and underground radio", China Daily 16.04.2010. http://www.chinadaily.com.cn/hkedition/2010-04/16/content_9737275.htm, accessed 14.08.2010.

trade issue."²³ This has led to India and Brazil filing complaints before the WTO Dispute Settlement Body to declare EU anti-counterfeiting legislation illegal.²⁴

Proposed remedies ensuring public health and truly combating counterfeits have been developed in emerging markets such as SMS –based service mPedigree. MPedigree is a social organization using infrastructure provided by HP and established relationship with multinational pharmaceutical companies, allowing consumers to confirm if their medicine is safe and legitimate. How? The manufacturer puts a unique code with a scratch panel on the medicine, a SMS is sent with the information, and a message returned with “OK”, the name of the medicine, the batch and expiry date, and when the mobile unit permits it a picture of the box, or “NO”.²⁵ This use of information technology makes us understand why Jeffrey Sachs, the development guru at Columbia University’s Earth Institute and author of “*The End of Poverty*”, calls mobiles the single most transformative tool for human security and development.²⁶

Therapeutic Evolution – Second-line therapy

Since 2005 India, China, Brazil and Thailand were forced to issue patents as they were integrated in TRIPS, complicating the supply of ARVS. Basically patents on first-line AIDS drugs have expired but patents on second-line and new innovations are still standing. At the moment 10 to 15 percent of people taking ARVS will develop resistance within a four to five year time period. Thus, the necessity for the second line medicines which are generally less toxic, more effective and easier to take, leading to greater adherence and less growth in resistance.

TRIPS-plus provisions have led to reduced generic competition causing a huge disparity between first-line and second-line treatment prices. In 2008 the median cost of the most common second-line treatment was: \$1 105 for low income countries, \$ 2 192 in lower middle-income countries, and \$2 634 in upper middle-income countries. High prices in second-line treatments explain the high proportion of drug expenditure on these products, sometimes making up 80 percent of budget expenditure.

²³ Rupali Mukherjee. “Indian generic sales might be hit by counterfeit charge”, Times of India 27.01.2009, <http://timesofindia.indiatimes.com/articleshow/4034085.cms><http://timesofindia.indiatimes.com/articleshow/4034085.cms>, accessed 14.08.2010.

²⁴ CENTAD. “India, Brazil Challenge EU at WTO Over Drugs”, Centad Making Trade Work For Development 18.05.2010, http://www.centad.org/tradenews_1275.asp, accessed 14.08.2010.

²⁵ Simeon Bennett. “Scratch & Win War on Africa’s Counterfeit Malaria Medicines Gets Under Way”, Bloomberg 14.05.2010, <http://www.bloomberg.com/news/2010-05-13/scratch-win-war-on-africa-s-counterfeit-malaria-medicines-gets-under-way.html>, accessed 14.08.2010.

Mandy da Waal. “Fighting Africa’s fake-drugs monster”, The Daily Maverick 30.07.2010. <http://www.thedailymaverick.co.za/article/2010-07-30-fighting-africas-fake-drugs-monster>, 14.08.2010.

²⁶ Sachs, Jeffrey. *The End of Poverty*. The Penguin Press, 2005.

CONCLUSION

The great majority of patients doing ARV treatment in Africa and the developing world may take first-line treatment since they have a non-resistant variant of the disease. History however tends to repeat itself and the future growth in resistance will increase the need for second and third-line treatments, with its intrinsic costs. Countries such as South Africa and Brazil have carved out a place in the world stage, most other developing countries in Africa have greater difficulty in imposing themselves. Thus dynamics of defense undergone by NGOs and civil society are fundamental so as to make available second and third line treatments at an affordable price for all of Africa.

As many defend, the replacement of TRIPS by other R&D rewards and incentives should certainly be pondered. In 2009 one of the major pharmaceutical companies GSK and UNITAID proposed a “patent pool”²⁷; usable by the generic manufacturers for production aimed at least developed countries.²⁸ Participation by “big Pharma” though is almost completely subject to voluntarism and “...such hopeful thought should not disguise the fact that drug...companies ...remain self interested. GSK’s plans are laudable, but they are also a smart political move. The company gets good PR and, by starting the pool, it gets more say in how it is run, and which treatments should be included.”²⁹

The refusal of patents on secondary inventions should be the norm, such as “new formulations” or new combinations of known molecules.

Accountability of African leaders nonetheless is a fundamental axis towards treating HIV/AIDS, we should not forget that countries which took active steps in the beginning of the pandemic have a low prevalence of HIV/AIDS (example Senegal). Botswana with a high prevalence nonetheless took serious steps towards combating the disease, and today has over 80 percent of HIV and AIDS patients doing ARVS. South Africa is probably the last country out of the blocks and the most laid back in attitude. In 2006 the South African Health minister at the time, Manta Tshabalala-Mismang, even went on record in a international conference, attended by 24,000 delegates including former US President Bill Clinton and Microsoft founder Bill Gates,

²⁷ UNAIDS. “UNAIDS welcomes the efforts of UNITAID towards the creation of a patent pool entity”. UNAIDS 10.06.2010.

http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2010/20100610_UNITAID_PP.asp, accessed 15.08.2010.

²⁸ Jim Giles “It’s good to share”, Prospect Magazine April 2009,

<http://www.prospectmagazine.co.uk/2009/04/itsgoodtoSHARE/>, accessed 15.08.2010.

²⁹ Idem, Ibdem.

recommending AIDS be treated with lemon, beetroot and garlic!³⁰ This in the same year that the future president to be Jacob Zuma declared during a rape trial to have had a shower after unprotected sex with a HIV positive woman, so as to guard against possible infection.³¹ Still, President Jacob Zuma has recently committed his government to achieving a 80 percent coverage for antiretroviral therapy and to cutting new HIV infections by half.³² Swaziland has also had a recent episode showing how ruling figures seriously undermine the battle against HIV/AIDS, with a top aid to the ruler King Mswati III saying the country's HIV epidemic is being exaggerated for the benefit of pharmaceutical firms.³³ According to UNAIDS, Swaziland which is Africa's last absolute monarchy - has one of the highest levels of HIV infections in the world, with a prevalence rate of 26% in the adult population.

Thus TRIPS has certainly been a barrier towards treatment against HIV/AIDS but multilevel partnerships, Public Private Partnerships and political accountability should be a guiding light to find a way out.

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³⁰ Daily Mail. "South Africa's Health Minister advocates treating Aids with lemon, beetroot and garlic". <http://www.dailymail.co.uk/news/article-401485/South-Africas-health-minister-advocates-treating-AIDS-lemon-beetroot-garlic.html>, accessed 15.08.2010.

³¹ BBC. News. "Profile: South Africa's President Jacob Zuma", BBC 01.03.2010. <http://news.bbc.co.uk/2/hi/africa/4615019.stm>, accessed 15.08.2010.

³² UNAIDS Outlook 2010. http://data.unaids.org/pub/Report/2009/JC1796_Outlook_en.pdf, accessed 16.08.2010.

³³ BBC News. "Swazi anger at prince's HIV exaggeration claim", BBC News 20.08.2010, <http://www.bbc.co.uk/news/world-africa-11039276>, accessed 21.08.2010.

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